THE FOOD SAFETY AND MODERNIZATION ACT AND ITS IMPACT ON THE FEED INDUSTRY

J. Goodson
Evonik Corporation
Kennesaw, GA

The Food Safety and Modernization Act (FSMA) is a law that was signed by President Obama on January 4, 2011. This law brings significant changes to governmental approaches to food safety. The bill was introduced and passed by Congress due to the fact that in the United States there are about 48,000,000 people, that is 1 in 6 Americans who suffer from food poisoning annually. This results in large numbers of people being hospitalized and around 3,000 deaths every year. Many of these cases can be prevented with a new approach to food safety. The bill will result in important changes in how the Food and Drug Administration (FDA) approaches food and feed safety.

The feed in industry as you no doubt know is regulated by FDA. Their regulatory oversight is based on a simple clause in the original Food Drug and Cosmetic Act of 1938. 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 regulations and rules that determine how the feed industry can operate.

FSMA brings sweeping changes to food and feed regulation, which has not been updated for over 70 years. If you are interested in the full text of the law, it can be found here: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247548.htm

Depending on the style it is in, the law is about 80 pages of fine print, which takes a while to go through. The law 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 not produced many of the regulations demanded in the law. As of late August, 2013, FDA has released the Rules for Human Foods. These regulations are about 680 pages long. FDA has indicated that the Animal Food Rules will be very similar, with a major exception being that food contact surfaces will not need to be sanitized. Several feed industry associations are responsible for convincing FDA to separate out the Animal Feed Rules from the Human Rules. Obviously, sterilizing grain legs, augers, mixers, trucks etc. in a commercial feed production plant makes no sense, and most likely would be impossible to accomplish. At this time, late August 2013, the Animal Feed Rules are at the Office of Management and Budget for their review. We have been told that OMB is in the process of calculating some of the costs to industry that are related to the Animal Feed Rules. These calculations will be completed prior to releasing the proposed rules. When the proposed

rules are released, there will be a period during which FDA will accept public comments. After this period, FDA will review the comments and determine if the rules need amending. When this process is finished, FDA will release the Final Rules, which will then take effect. Currently the Human Food Rules are in the Public Comment period, which will last for several months. FDA is having a series of public meetings around the US to solicit public comment on the proposed rules that were released earlier this year.

Now we will discuss the teeth of the FSMA. This huge change in food safety regulation will take this area from a reactive process to a preventative process. In the past, for the most part, FDA could only react to cases of adulterated feed or food. Now they are on a firm legal footing to issue rules which put prevention out front.

A major portion of this process will be based on hazard identification and preventative controls. The law does not use the term HACCP, (Hazard Analysis and Critical Control Point) however the details seem to indicate that this is what FDA expects. HACCP is not new to FDA, they have had mandated HACCP plans for seafood and other human foods in place for some time. The law does not mandate a HACCP plan however. We have been told that there are consultants out in the market place telling feed manufacturers that they will need a HACCP plan, and this is not true.
For those not familiar with HACCP look at this:
https://en.wikipedia.org/wiki/Hazard_analysis_and_critical_control_points

What feed manufacturers will have to do is this:

(B) HAZARD ANALYSIS

The owner, operator, or agent in charge of a facility shall—

(1) identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility, including—
  (A) biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives; and
  (B) hazards that occur naturally, or may be unintentionally introduced; and

(2) identify and evaluate hazards that may be intentionally introduced, including by acts of terrorism; and develop a written analysis of the hazards.

These few sentences cover a lot of territory!

First of all, the feed mill will have to be studied from the front gate all the way through to the back gate. The owner, operator etc. will be expected to identify all potential hazards associated with the feed manufacturing and delivering process. This person, more likely a group, will be expected be aware of all potential hazards in that plant. Section A in the above statement lists the hazards. As you can see, this list is very general and covers many areas. FDA has not indicated what they see as falling in each of these areas. The law itself is not prescriptive, in other words these decisions are

left up to the people doing the hazard analysis. Hopefully, the FDA will agree with that analysis.

Biological hazards may include such things as rodents and 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 be needed, identifying how often the bait stations are checked, what kind of activity was noted, what specific chemical was used. This report will most likely need to be completed monthly. It will need to be signed by the persons doing the work. The owner/operator will be required to be able to produce such records when an FDA inspector shows up. A similar program will have to be in place in regard to insect control. FDA will probably expect windows and doors to be screened to prevent insect and rodent entry. They will expect the perimeter of the building to be clean and weed free. This process greatly reduces the chance of rodent entry. Holes in siding must be patched etc. etc. In general most of these areas are covered by cGMPs. The facility will be expected to be able to document that they are following cGMPs.

cGMPs include a vast range of issues. One of the largest relates to employee training. An example of this is personal hygiene. Are employees provided with a clean sink to wash their hands prior to entering the feed plant? Have they been trained on the appropriate method to wash their hands? This may sound silly, but many poultry integrators are bringing in Public Health nurses to do training on hand washing. When training is give, a record of that training, the date, who attended must be kept. Each person receiving that training, or any other for that matter, must sign the roster, indicating that they have received specific trainings. The owner/operator will be expected to be able to produce these records during an FDA inspection. This is just one example of cGMPs, but the record keeping requirements are the same for all of them. Some of the other things to consider in regard to personal hygiene relate to clothing. Do you have a policy on clothing cleanliness and shoes? Many feed mill employees are also part time farmers. You do not want an employee coming to work with manure on his shoes. Some companies have written policies on footwear. Many require their employees to have a dedicated pair of shoes that they put on when arriving to work, and take off and leave in the shower room when leaving. Do you have a written policy on illness and infections? Have you trained your employees on what you expect of them in this regard? Have you documented it? If a person seems to have the flu, do you allow them to work? Again, these calls are up the owner/operator to make and document. Keep in mind, FDA has said and continues to say, “If it is not documented, it did not happen.”

Each plant will no doubt be required to have a written housekeeping plan. Who cleans what and when? What tools are they provided with? The days of using an air hose to blow away dust are going to end. This process simply moves microbial contamination from one are to another. Many pet food plants are installing central vacuum systems. So far I have not seen this in poultry feed mills, but some integrators are talking about it. Each time an area is cleaned, the cleaning must be documented. The person doing the work must initial or sign that the cleaning was done on a certain

date. Has each person with cleaning responsibility been trained on how to do it? Is the training documented? The owner/operator will be expected to be able to produce these documents when inspected.

The last point up there is a bit of a red herring:

(2) identify and evaluate hazards that may be intentionally introduced, including by acts of terrorism; and develop a written analysis of the hazards

This point suggests we will need a Food Defense Plan. At this moment, it looks like this may not be included in the Animal Rules. If it does become part of the Animal Feed Rules, it will require more analysis and more documentation. Since it is not clear if this will be needed or not, I will not go into it here.

If you are interested and if it comes to pass, I suggest the following reference:

The AIB Guide to Food Defense, for Food Processing, Packaging and Distributing Facilities.
AIB International, 1213 Bakers Way, PO Box 3999, Manhattan, KS, 66505
800-633-5137
www.aibonline.org
ISBN: 1-880877-22-8

This is a very short overview of hazard analysis. Companies will be expected to have written Standard Operational Procedures (SOP) in place. Training on the SOPs will be necessary and must be documented. Many companies place a copy of the SOP in each employee's personnel file after they have been trained, along with a document signed by the employee testifying to the fact that they have been trained on a certain area, i.e. SOP. Having a complete and current set of SOP's as well as cGMPs will make the hazard analysis much easier.

(C) PREVENTIVE CONTROLS

The owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances that—

(1) hazards identified in the hazard analysis conducted under subsection (b)(1) will be significantly minimized or prevented;
(2) any hazards identified in the hazard analysis conducted under subsection (b)(2) will be significantly minimized or prevented and addressed, consistent with section 350i of this title, as applicable; and
(3) the food manufactured, processed, packed, or held by such facility will not be adulterated under section 342 of this title or misbranded under section 343(w) of this title.

This section asks the question, how are you going to mitigate the hazards that you have identified? If a facility had indicated that Salmonella is a hazard, what are you going to do to reduce it? Maybe you have a kill step, for example you decided that your pellet

conditioner temperature must always reach 180F for >1 minute. Or maybe the unloading pit is a point of hazard. What will you do to mitigate this hazard to prevent feed adulteration? Perhaps the unloading pit is always kept covered when not in use. Perhaps it is in a shed that has doors that can be closed when not in use, and the overhead is closed off to prevent birds from roosting. Again, recall, this law is not prescriptive, the owner/operator makes the call on what is hazardous and what is not. However, FDA may not agree with you. They may think something is hazardous that you do not. In this case you will be expected to have documentation showing why this point is not a hazard.

(D) MONITORING OF EFFECTIVENESS

The owner, operator, or agent in charge of a facility shall monitor the effectiveness of the preventive controls implemented under subsection (c) to provide assurances that the outcomes described in subsection (c) shall be achieved.

(E) CORRECTIVE ACTIONS

The owner, operator, or agent in charge of a facility shall establish procedures to ensure that, if the preventive controls implemented under subsection (c) are not properly implemented or are found to be ineffective—

(1) appropriate action is taken to reduce the likelihood of recurrence of the implementation failure;
(2) all affected food is evaluated for safety; and
(3) all affected food is prevented from entering into commerce if the owner, operator or agent in charge of such facility cannot ensure that the affected food is not adulterated under section 342 of this title or misbranded under section 343(w) of this title.

Monitoring means: Is what I think is happening really happening? Someone goes out on a schedule to check that the unloading pit is covered when not being used. Then a document with a date and signature is created to attest to the fact that this control point is being monitored.

In regard to corrective actions, the question becomes, what do we do it the monitored process is not happening the way we think it is? If the pit is not covered, how did it happen that the cover was left off (root cause analysis)? If the doors to the unloading area are not closed when no truck is present, why not? Who left them open? Has this person been trained on the SOP for controlling the unloading area? If they have been trained, they clearly need to be retrained. A document must be created which has the date of when this happened, and what corrective actions were taken. The person was retrained and they signed off on the retraining. A copy of these documents goes in that persons file. Perhaps you have a documented policy, which you have trained your employees on that says if a person commits the same infraction 3 times, they can be terminated. Again, if it is documented, you can make it stick. Without documentation, it will be tough.

(F) VERIFICATION

The owner, operator, or agent in charge of a facility shall verify that—

(1) the preventive controls implemented under subsection (c) are adequate to control the hazards identified under subsection (b);

(2) the owner, operator, or agent is conducting monitoring in accordance with subsection (d);

(3) the owner, operator, or agent is making appropriate decisions about corrective actions taken under subsection (e);

(4) the preventive controls implemented under subsection (c) are effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means; and

(5) there is documented, periodic reanalysis of the plan under subsection (i) to ensure that the plan is still relevant to the raw materials, conditions and processes in the facility, and new and emerging threats.

Verification simply means that the process has been tested on a scheduled basis, with documentation. To do this, the system must be challenged to see if it is preventing what we hope to prevent. An example might be the case of Salmonella. The monitoring process requires that we check at scheduled times to see that the pellet conditioner is hitting 180F. The verification step, would be to collect a sample of processed feed and have it tested for Salmonella. It is Salmonella negative, the process is working. It if is positive, this would show that 180F is not enough to kill this organism. Whatever the control point is, the owner/operator must devise a way to test the system on a scheduled basis to prove that it is working. Of course, all this must be documented. .

(G) RECORDKEEPING

The owner, operator, or agent in charge of a facility shall maintain, for not less than 2 years, records documenting the monitoring of the preventive controls implemented under subsection (c), instances of nonconformance material to food safety, the results of testing and other appropriate means of verification under subsection (f)(4), instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions.

This section is very clear. You must keep records for 2 years. These records must show how and when the process is monitored and how it performed, i.e. did you have any nonconformance's? What means are being used to verify the process? How often it is being verified and what corrective actions were needed if any?

(H) WRITTEN PLAN AND DOCUMENTATION

The owner, operator, or agent in charge of a facility shall prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of this section, including analyzing the hazards under subsection (b) and

identifying the preventive controls adopted under subsection (c) to address those hazards. Such written plan, together with the documentation described in subsection (g), shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request.

The plan that is created must be written. All the procedures used to meet the requirements of the law must be recorded. The record keeping requirements are stringent. Note the last sentence, the records must be made available to an FDA inspector promptly. It is generally thought that this means a maximum of 24 hours. However, if an inspector is on the plant site and asks for records that cannot be produced fairly rapidly, I suggest that things may not go well. In this regard, make sure all records are organized and known by more than one person. If an FDA inspector shows up while that feed plant manager is on vacation fishing in Canada and no one else knows how to find the appropriate records, there are going to be some problems. Make sure at least several people on the site know where the records are kept and how they are organized, so that they may be accessed rapidly.

(l) REQUIREMENT TO REANALYZE

The owner, operator, or agent in charge of a facility shall conduct a reanalysis under subsection (b) whenever a significant change is made in the activities conducted at a facility operated by such owner, operator, or agent if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard or not less frequently than once every 3 years, whichever is earlier. Such reanalysis shall be completed and additional preventive controls needed to address the hazard identified, if any, shall be implemented before the change in activities at the facility is operative. Such owner, operator, or agent shall revise the written plan required under subsection (h) if such a significant change is made or document the basis for the conclusion that no additional or revised preventive controls are needed. The Secretary may require a reanalysis under this section to respond to new hazards and developments in scientific understanding, including, as appropriate, results from the Department of Homeland Security biological, chemical, radiological, or other terrorism risk assessment.

This requirement is typical of a HACCP plan. Reanalyzing the plan must occur when ever changes are made in any process covered by the plan. If no changes are made in the manufacturing process, the plan must be re-evaluated every 3 years. It is hard to imagine that nothing will change in a feed mill over 3 years. Be certain that when new equipment is added or modified, that these changes are reflected in the hazard analysis and that all changes are documented. For example if a mixer ribbon is replaced, be certain that a mixer profile is run following the repair to be certain that the mixer is still capable of performing its function in an accurate fashion. Records of the mixer profile must be signed and retained. If a software change is made in the panel, the processes that are affected by this change must be documented.

Hazard analysis and preventative controls are going to be the major impact on the feed industry. There are other points in the law that will affect us too. FDA is in the process of accrediting laboratories, which is something they have never done before. In the future if there are any disputes about adulteration of a feed, the analysis will have to be conducted at an FDA accredited laboratory. Laboratories owned and operated by feed manufacturers will be eligible to be accredited.

FDA now has the authority to issue a mandatory recall notice. In the past they could only suggest a recall.

In general, while this law is going to require substantially more record keeping, for the most part plants that are already operating under cGMPs and have detailed SOP's in place, the biggest challenge will conducting and documenting the hazard analysis and preventative controls. Many poultry integrator plants already have full blown, third party audited HACCP plans in place. These facilities will have no problem meeting the new regulations. Again, recall that FSMA does not require a HACCP plan as such; it does require hazard analysis and preventative control. This plan must be written and documented, but does not have to be audited by a third party auditor.

Finally, the critical issue is going to be the requirement for extensive, well organized records. I suggest that every feed mill, not having a HACCP plan in place purchase this document from National Grain and Feed Association:

The HACCP Approach to Feed Quality Assurance…What It Entails…
National Grain and Feed Association
1250 Eye Street., N.W., Suite 1003, Washington, D.C. 20005-3922
Phone: (202) 289-0873, Fax: (202) 289-5388 Web Site: www.ngfa.org

This document walks through a lot of the hazard analysis and critical controls that are required under FSMA. It will provide a lot of the back ground information that will assist feed manufacturers to meet the new regulations. Be aware that the Animal Feed Rules may be released at any time, and they are expected to be about 500 pages long! FDA is in the process of training their inspectors and their state contractors. In many cases FDA inspections will be conducted by state feed control officials. However, even in states that have contracts with FDA, FDA still has the right to send in their own employees to conduct inspections. This is a sea change for FDA and perhaps we in the industry will be able to gently train inspectors when they show up to do their first FSMA inspection. This will require that we have all the documents in place and readily available. Finally, be certain that any trash, junk, old pallets etc. are removed from the feed mill property. These are the things that an inspector sees first up arrival, and first impressions are important. Housekeeping and pest control will probably be front and center.