



## AMERICAN FEED INDUSTRY ASSOCIATION

### **Legislative and Regulatory Issues For the Feed Industry**

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#### New Administration Impact

With the inauguration of President Barak Obama, as with any new President, a executive order has been issued to stop all rulemaking in progress, which includes final rules that have not been implemented. This would impact the BSE rule due to be implemented on April 27<sup>th</sup> and the SPCC rule. The implementation dates are to be extended for 60 days while the issuing agency is required to review the rule with new guidelines.

As for appointments and changes in departments and agencies, nearly all cabinet officers have been confirmed, but an FDA commissioner appointment has not occurred and may be some months. It appears that priorities for this Administration do not include food/feed safety legislation at this time, due to the overwhelming economic problems, demand for health care and importance of environmental issues.

#### BSE(Bovine Spongiform Encephalopathy)

The final rule amendments published April 25<sup>th</sup> and require that the brains and spinal cords (B/CS) of all cattle 30 months of age and old be removed, or those cattle may not be used in any animal food. Beef tallow that comes from cattle for which the B/CS have not been removed may not be used in cattle feed, and beef tallow must be 0.15% or less insoluble impurities to be used in cattle feed. This rule is effective April 27, 2009, but as indicated earlier, a new date will be established or the rule may be withdrawn.

Cattle material from which the B/CS have not been removed must be dyed and cannot be used in animal food. Furthermore, AFIA is concerned about the tallow limitations on firms that use only one liquid fat tank. This rule poses some concerns and may lead to the reduction in use of tallow in plants that make both ruminant and non-ruminant feed.

This rule may cause considerable disruption in the deadhaul industry, as cattle that cannot be picked up before 12 hours post mortem will likely not be picked up. This may cause these haulers to cease doing business if the bulk of their regional business is cattle deads. AFIA has spent considerable time on the issue of animal disposal and led a coalition to address this at the federal level by budget and policy.

Canada has a more restrictive rule that went into effect July 2007, and the Canadian cattlemen are spearheading a movement to harmonize the rules toward the US rule. The National Renderers Association is developing a compliance guide for its members.

## Federal Food/Feed Safety Legislation and Regulations

There were over 30 bills in Congress last session that proposed to deal with food/feed safety issues, as a result of melamine, spinach and peanut butter contamination and export concerns. Although this is a new congressional term, it's clear some of these major bills will be reintroduced. The most likely vehicle is a bill by Senator Richard Durbin (D-IL), the deputy majority leader of the Senate, and Obama's mentor.

It's clear the Senate will likely pass Durbin's bill, but the House committee with oversight does not have this issue as a priority. Instead, health care, cap/trade (environment) and fuel efficiency are the posted priorities.

The Durbin bill is similar to most of the others and involves a risk-based approach to processing controls in food/feed facilities. It also covers produce safety, creates fees for inspection and attempts to control foreign imports of food feed. It has a mandatory recall procedure for which the sponsors have added several adequate controls suggested by AFIA, including a facility's allowance to voluntarily recall product before FDA mandates a recall.

Of principal concern in the Durbin bill is the treatment of food and feed in a similar manner. The term "food" is defined as "...feed for man or animals." in federal Food, Drug and Cosmetic Act. Senator Durbin's bill is littered with the "food" term, and hence means feed without the qualifier of "human food" or allowances for the FDA to separate the two. AFIA has been lobbying hard for this distinction. Otherwise, feed and ingredient facilities will need to deal with allergen prevention, sanitizing services and looking at unrealistic microbial hazards. The bills would require a number of rulemaking procedures to ensue, which would take considerable time and resources for FDA. Currently, AFIA is working between FDA and the Senate to reach a reasonable agreement.

On a similar vein, FDA announced more than seven years ago that it is pursuing the development of a risk-based, comprehensive Animal Feed Safety System (AFSS) to be implemented soon. This would essentially provide a HACCP-type approach to feed and be applicable across the feed, pet food and ingredient chain, including on-farm.

The agency has held four public meetings, and one other may be held this year. Although this is a large plan, AFIA believes the agency has received renewed funding to finalize this and prepare and publish mandatory process control rules. Also, Congress has mandated processing control regulations for the pet food industry. FDA is rolling this pet food effort into all animal feed. However, agency officials have said the cost is very high to the industry, and the Administration must decide what to do. FDA may only decide to publish pet food rules only due to the high costs, as these are mandated by the new law and must be published by September 27<sup>th</sup>.

Similarly, the Association of American Feed Control Officials (AAFCO) is pursuing a similar program by developing a set of model feed safety regulations that are based on the medicated feed good manufacturing regulations (CGMPs) developed in 1971. However, these are not a risk-based approach. They are more like a proscriptive approach. AAFCO is doing this to offer each state the option of adopting such rules, should FDA's AFSS not be finalized. Each state would be required to adopt the AAFCO model rules in order for them to be enforced. AAFCO expects these would apply to on-farm operations as well. However, that change would necessitate a change to each state feed law, which is unlikely.

AAFCO bogged down at its last two meetings addressing the format of the draft rules. However, many expect them to move and be adopted by the AAFCO membership at its August Centennial meeting in Washington, D.C. States would then be able to adopt the rules one by one. All indications are that Texas will be the first, but 10 states have indicated to AFIA that they would seriously consider such adoption.

A "model bill" may be passed by AAFCO that will offer the option for controlling "non-commercial feed." However, this would necessitate enacting this bill in every state. Should that occur, such a state that then adopts the model GMP regulations would have control over integrated operation feed mills.

#### FDA's Food Protection Plan

In November 2007, FDA published this plan in response to spinach, melamine and other contamination episodes. It plans to strengthen its Prevention, Intervention and Response areas. It will do this with a number of different approaches, including asking Congress to give the agency the authority to recognize true, third-party certification programs and mandatory recall. It also wishes to adopt the best of the industry quality programs and recognize those as risk reduction factors, as well.

AFIA is supportive of this approach and is supportive of efforts to give FDA sufficient funding to carry out this new mandate. The Administration has received 25% more funding and is hiring 700 new employees to staff this program.

The third-party recognition program is an important component of FDA's Plan. AFIA is discussing with CVM what approach it will take before Congress gives it the authority to recognize third-party programs (and it may not). CVM officials have told AFIA that it can use informal recognition of such programs by considering what the program offers, who is involved and determining whether the program offers significant risk mitigation factors to be considered. If the answers are positive, FDA can instruct its inspection staff to reduce or eliminate inspections to participation third-party certified facilities or reduce the time spent inspecting those plants.

This month FDA published a final guidance for industry on voluntary third-party certification programs. It is quite complex, and FDA has no timeline for implementing it, but it's clear FDA plans some recognition of these types of program. This will be come

extremely important, as FDA moves to adopt a mandatory AFSS program with inspections. AFIA is meeting with CVM in the near future to discuss this recent document.

### Safe Feed/Safe Food Certification Program

AFIA has developed a facility-based certification program that has guidelines for operation of all feed, ingredient and pet food manufacturing facilities. It provides for outside, third-party certification and authorizes use of a certification seal on products.

There are 320+ facilities certified and more arriving daily. This basic feed safety system is being adopted by facilities as “the right thing to do.” There is an “Ambassador” program for firms to educate, promote and mentor suppliers and dealers about SF/SF. For more information, contact AFIA’s Keith Epperson ([kepperson@afia.org](mailto:kepperson@afia.org)). This program is in its fourth year of operation, and FDA’s efforts have given it a boost.

### Ingredient Approvals

AFIA has been wrestling with CVM on several levels on this issue. The 2-3 years it’s taking to get novel ingredients approved must change. One area that could shorten this timeframe would be the GRAS Notification proposed rule, which has never finalized, although things are happening at FDA to finalize this rule. Basically, it says that if a firm submit a data packet to FDA on a self-affirmed GRAS product, and the agency does not respond within 75 days, the market is available for this ingredient, and it is essentially GRAS. CVM says it does not have the resources to review this onslaught and may resist approving this rule.

This issue of lagging ingredient approvals is a major priority for AFIA and this new director set up a webinar on the issue with FDA. It was quite successful, but more importantly, it catalyzed a discussion by AFIA and FDA and cause the agency to make some pending decisions. There are also serious discussions regarding claims on these types of products. The “claims” issue has also lagged considerably behind the food side of the industry. FDA has agreed to continue discussing these issues in hopes of reaching resolution(s) mutually satisfactory to both sides.

### Voluntary Self-Inspection Program (VSIP)

After over nine years, FDA has published a notice and draft Compliance Policy Guidance (CPG) manual for comment. Basically, this program would allow licensed facilities to likely not be inspected by FDA, if the firm has a good inspection record, files notice to participate in this program and provides Facility Annual Inspection Reports (FAIRs) on FDA forms.

AFIA has been told by FDA that this program will be held for a while, as it’s not in line with its current approach to inspection as detailed in the *Food Protection Plan*.