

# Legislative and Regulatory Issues For the Feed Industry

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The legislative and regulatory arena is constantly changing. An overview of major issues and their status as of April 1, 2006 follows. Readers are encouraged to update the information as it is subject to change.

## **BSE (Bovine Spongiform Encephalopathy)**

The comment period for the Food and Drug Administration's (FDA) proposed rule for Specified Risk Materials (SRM) "lite" closed December 20. There were nearly 900 comments, most of which were *form* letters. Generally, FDA received support for the proposed rule. There were some significant comments regarding the underestimating of costs to the affected industries and a universal agreement that such a rule will result in significant disposal issues, which should be addressed. The American Feed Industry Association (AFIA) is leading a coalition to work with the federal government to address this disposal issue.

The acting FDA commissioner said the final rule would be published July 1. That's probably unrealistic, as the agency is still reviewing comments. However, it is realistic to say there will likely be a final rule this year. When it publishes, AFIA will be fighting for a minimum of 60-day implementation period, but hopefully, will receive more.

## **Dioxin**

FDA continues to sample food/feed for dioxin/polychlorinated biphenyls (PCBs). The focus this year is swine feed, products with potential soil contamination, and products made from wood product, with the usual assortment of clays, fats, and some minerals.

The Environmental Protection Agencies' (EPA's) draft risk assessment review by the National Research Council (NRC) is due out in early April. It will decide whether EPA is justified in saying some forms of dioxins are human carcinogens. The report is likely to generate considerable media excitement.

Generally, AFIA has been a staunch opponent of FDA establishing any dioxin tolerances, similar to those in the European Union (EU), but AFIA is supportive of FDA's sampling of feed and feed ingredients to build a baseline on dioxin. In nearly all areas, FDA sample results have been of low concern.

## **Salmonella**

FDA/Center of Veterinary Medicine (CVM) continues to sample for *Salmonella* and report results to firms, but not in regulatory letters, instead it uses *information* or *untitled* letters. FDA can determine that feed containing *Salmonella* to be adulterated under 21 CFR § 500.35, which is a long-standing regulation that has been rarely enforced.

One FDA district office began taking regulatory actions last year. Our efforts have been toward insuring that this does not occur again. CVM has provided that assurance. AFIA does not recommend sampling for *Salmonella* or dioxin unless firms have a clearly defined position for dealing with positive findings. Such positions should be developed in consultation with food and drug attorneys.

## **Animal Feed Safety System (AFSS)**

FDA announced two years ago that it is pursuing the development of a risk-based, comprehensive Animal Feed Safety System to be implemented by regulation in 2007. This would essentially provide a Hazard Analysis Critical Control Point (HACCP)-type approach to feed regulation and be applicable across the feed chain, including on-farm.

The agency has held two public meetings and invited and received comments from a wide variety of groups. Although this is a large plan, AFIA believes the lack of funding may slow the development of any rules, which may become a guidance document.

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. 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.

AFIA continues to focus on meetings with both AAFCO and FDA. The financial situation at FDA is such that pursuit of such rules is two or more years away.

### **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 over 120 facilities certified and more arriving daily.

### **Bioterrorism Act and Biosecurity**

The Public Health Security and Bioterrorism Response and Preparedness Act of 2002, commonly referred to as the "Bioterrorism Act," required FDA to promulgate four sets of regulations governing registration of facilities, notification of imports, administrative detention, and recordkeeping. These rules are published, and the one causing the most concern is the recordkeeping rule.

This rule requires records to be maintained by each feed facility and ingredient processor for a period of one year to trace forward and back one

level and quickly identify the supplier and recipient in the event of a serious contamination incident. Although this requires basic business records, there are some different requirements for records that are not typically kept by feed mills.

Among these is the requirement to retain the product lot code on each ingredient used, where available. Also, trucking information is required for in-bound and out-bound trucks that are not the firm's own trucks.

The most problematic requirement is to keep the suppliers and their information for products in bulk bins. FDA is interested in all potential suppliers in each bulk bin and such information must be supplied to the agency within 24 hours of its request.

More information on this law and its rules can be found at [www.fda.gov](http://www.fda.gov). The compliance dates for firms coming up are June 9 for those with 10 to <500 employees and December 9 for firms with less than 10 employees. AFIA held one webcast on the rule, which is available along with a compliance guide. We will hold a very basic, simple webcast (one hour) for use by dealers on compliance in April.

### **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 (generally regarded as safe) Notification proposed rule, which has never been finalized, although things are happening at FDA to finalize this rule. Basically, it says that if you submit a data pack to FDA on a self-affirmed GRAS product and the agency does not respond within 75 days, the market is yours, and the ingredient is essentially GRAS. CVM says it does not have the resources to review this onslaught and may resist approving this rule.

One option would be to push for legislation to get user fees for ingredient approvals. Another option would be to declare many of these novel materials as drugs and if no safety issues exist to declare them low regulatory priority (LRP) drugs. This has been done in the aquaculture market for nearly ten years.