



South Dakota Department of Agriculture

523 East Capitol Avenue, Pierre, SD 57501-3182
(605) 773-3375 (605) 773-5926 FAX

OFFICE OF THE SECRETARY NOV 18 P1:33

November 13, 2003

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket Number 2003N-0312

The South Dakota Department of Agriculture is pleased to learn that the Food and Drug Administration is considering the development of a comprehensive, risk based animal feed safety system (AFSS). My staff has attended the meeting you sponsored and has worked to develop responses to the six questions you asked in the Federal Register that was published. These six questions seek to address key elements of what should be considered in an AFSS. The questions and our responses are as follows.

1. What are the strengths of the current Federal and State regulatory programs for feed safety?

The current Federal and State Regulatory programs have done a good job of monitoring the use of drugs in medicated feed. They have also done an excellent job of monitoring labeling and guaranteed analysis of medicated and non-medicated feeds. Many states have a feed program that reviews labels for completeness and nutritional claims to see that they are appropriate for the species to which they are to be fed. They also review the labels for micro-nutrients that can cause problems because of high natural levels in other feed stuffs in certain areas. The FDA and cooperating states have done a reasonably good job of enforcing the BSE – Ruminant feed rule (there are some glaring deficiencies, see the answer to question 2) and in monitoring feed ingredients for pesticides, mycotoxins and other contaminants to prevent the unsafe adulteration of commercial feeds.

2003N-0312

C6

2. What are the weaknesses of the current Federal and State Regulatory programs for feed safety?

A primary weakness is that some states don't have programs and/or choose not to enforce certain provisions.

Another weakness of the current system is that in some cases the system is reactive instead of proactive in preventing problems. A glaring example of this is the lack of enforcement of the feeding of poultry litter to ruminants, primarily cattle. It is inevitable that chickens will spill a certain amount of their feed. If poultry are being fed ruminant by-products and the litter is being fed to cattle, then there is a significant risk for the spread of BSE in our cattle. The FDA and States need to enforce this provision of the rule, which we don't feel is currently happening. For example, the just released FDA Compliance Program Guidance Manual for BSE/Ruminant Feed Ban Inspections makes no reference to the feeding of litter. In addition, FDA needs to be more vigilant in protecting the long-term viability of the cattle industry by considering the ban of feeding any animal by-products to cattle. This should be FDA's approach to requirements as they pertain to all livestock industries.

3. What are the strengths and weaknesses of current industry feed safety programs?

The strength is that most of the major feed manufacturers already have some type of HACCP type program in place. They are using ingredient suppliers that are guaranteeing the suitability of their products to produce safe feed products free of contaminants. They are monitoring the feed they produce on a regular basis for consistency, conformity to guarantees, and contaminants. They are also monitoring their transportation systems whether it be trucks delivering ingredients to them or their delivery to the consumer or farm consuming the feed. Some have instituted ISO Certification and are training their employees and also management and documenting that training. Most are using some type of self or third party audit to verify their systems.

The weakness probably is the fact that not all firms are doing this as there is no requirement in regulations that they do so, other than following the CGMP's. It might be beneficial if FDA provided an example program for producers and agri-business to follow on a voluntary basis.

4. What are the potential benefits of a comprehensive, risk-based Federal feed safety program?

The benefits of a program would be to answer consumer concerns and hopefully remove the relationship of animal feed to human foodborne illnesses. It may help control some pathogens that cause foodborne illnesses and protect the long-term viability of the livestock industry.

5. What components should be included in an AFSS?

Components should address all possible contaminants. Possible components would be: 1. Standards. 2. Surveillance. 3. Management practices. 4. Evaluation 5. Revisions.

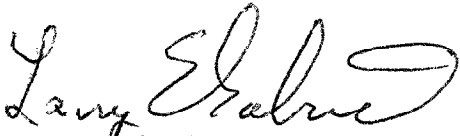
6. What is the potential burden (increased cost and manpower) of a comprehensive, risk-based Federal feed safety program, and what options are available to minimize the burden?

Components of an Animal Feed Safety System would have to be flexible to fit all sizes of operations including Federal Licensed Feed Mills, Unlicensed Feed Mills, Rendering Plants, Protein Blenders, Ingredient Suppliers, Transportation Companies, On The Farm Mixers, and Feeders. It would require the involvement of Federal Agencies (EPA, FDA, USDA, DOT, CDC), State Governments, Industry, and Producer Associations (Beef Quality Assurance, Pork Quality Assurance, Egg Quality Assurance, Etc.). The HACCP program would have to be based on a science based risk assessment and be enforceable.

A Farm to Fork System would probably require some type of licensing system to identify all stake holders in the system. There would have to be changes in laws and regulations to facilitate on-farm inspections. The cost of implementing the system may be a limiting factor during this time of deficit budgets for most state governments. The federal government would have to take the lead in providing funds for the system. It may be possible for producer associations to help with training their producers to understand known and emerging health risks associated with animal feeds and to do self-inspections. Some Industry sources estimate they are now incurring costs of .25 to .35 cents per ton to ensure safety of their products.

Thank you for the opportunity to participate and comment on this important endeavor.

Sincerely,



Larry E. Gabriel
South Dakota Secretary of Agriculture