# The Regulatory Future of On-Farm Mixing—Assuring Safe Food Richard Sellers American Feed Industry Association Arlington, VA 22201 USA

### Introduction

On-farm feed mixers are bound by the same laws and regulations that govern commercial and integrated feed millers with one major exception. However, there is very little enforcement, except after the fact, meaning as a follow-up to meat residues or dead or dying animals. Obviously there are no feed tag requirements for on-farm mixers unless the product is being shipped from one location to another. Then, any medications in the feed must meet federal labeling regulations.

There's a good and bad side to on-farm mixers in terms of safety. The good side is the costs are usually reduced, as there's no middleman to pay. The bad side is that there is a limited amount of quality assurance testing and assessment that can or will be done. That sums up the situation in terms of costs and differences. The legal requirements are a bit more complex.

Under the federal Food, Drug and Cosmetic Act and applicable state feed laws, it is illegal to add anything to feed for animals that has not been prior sanctioned or is generally recognized as safe (GRAS). In the case of most state feed laws, this doesn't apply to feed that is not in commerce. However, federal law is a bit more far-reaching.

Several court cases have provided FDA with the authority to regulate on-farm practices if the animals are intended for food. The courts clearly ruled in FDA's favor and said Congress intended to allow FDA to regulate food, including animals intended for food or as one court opined "Hogs are food." This means all the provisions of the federal act with respect to food animals must be followed.

It's clear FDA cannot visit and cover over 1,000,000 farms with livestock in the US. FDA rarely visits farms except as a matter of following up on illegal residues reported by the USDA. These residues can be either unapproved substances (e.g. pesticides, industrial contaminants) or illegal drug residues in meat, milk, eggs or fish. If the farm or producer is culpable, then FDA typically issues a "Warning Letter" detailing the violation and requesting the producer respond to what is or will be done about the violation.

More serious and repeated violations can and will result in further legal action the most common of which is a consent decree in which FDA asks a court to enjoin the producer from further violations. These are quite costly and involve high legal costs, monitoring by FDA and considerable follow-up. Further violations are dealt with the court as contempt violations, which can mean serious penalties, such as jail time or stiff fines. These are more commonly seen against dairy producers with repeated drug tissue violations for mastitis treatments, where the animal eventually is sent to a livestock auction.

## Feed Safety Legislation

The future for the feed industry, including on-farm looks bleaker in terms of regulation. This session of Congress, which ends in December of this year has seen an unprecedented number of food/feed safety bills, as a direct result of peanut butter, spinach and melamine contamination episodes from both domestic and foreign sources. It is unclear what final impact these bills will have on-farm, but Congress can clearly provide FDA more authority to regulate on-farm practices, if it chooses to do so.

Currently, these bills are using the Bioterrorism Act as the starting point for facilities registered under that act. These facilities will likely have more regulation, including required hazard analysis and risk management, mandatory recalls, fees for regulation, and increased penalties. The Bioterrorism Act exempts animal producers feeding their own animals on their own land, the so-called "farm" exemption. However, companies feeding animals on contract on a producers' land are fully covered by this act and will likely fall under any of these new provisions that are expected to be enacted. This type of feed operation is generally quite large and common in the poultry and pork industry. As with any legislation, the game isn't over until the President signs the bill into law, and any rules are published and final.

## Assuring Feed Safety on the Farm

The goal of every animal producer should be to produce the safest product for the lowest cost and best quality. However, increasing input costs are causing many to look at alternative and questionable ingredients. There are a number of mineral ingredients being offered in the marketplace that do not meet "traditional" standards of nutrients. As long as the product is properly identified, then the buyer should beware.

How does an on-farm producer deal with quality aspects of suspect ingredients? There are several programs designed for producer use in these scenarios. The National Pork Board is creating one based on the American Feed Industry Association's Safe Feed/Safe Food Certification Program. This group already has its Pork Quality Assurance (PQA) Program that deals with most of these issues. There are similar programs in the various commodity groups, such as the Beef Quality Assurance Program, Milk Quality Assurance Program, and others.

These programs are developed by professionals and based on sound quality and feed safety management systems. But, will producers follow them? In the pork industry, in particular, the PQA Level III program is required by most packers to market hogs. It has a requirement for each producer to be recertified each year by a veterinarian or other outside expert. The Pork Board's on-farm feed mixing program is being computerized for distance teaching and learning.

Producers and their consulting nutritionists should pay particular attention to "good deals." The rising costs of feed ingredients gives rise for the potential of increasing these good deals with little oversight by regulators. These types of ingredients fall into one of three categories: new, unheard of ingredients; existing ingredients with enhanced nutrients; and existing ingredients with health claims.

There has been an increasing volume of imports from China and other nations of minerals and vitamins. While most are of feed quality, without some criteria with which to judge a supplier's quality program, there is the potential for fraud and food safety breaches. AFIA recommends that several concerns with foreign firms be addressed early in the procurement process. These include such things as, visiting the foreign firm's operations, which is not always possible; procuring specimen samples of the firm's products; reviewing the firm's quality programs; taking samples of the firms' products when they arrive at a producer's operations and from time-to-time analyzing the samples for nutrients and common hazards. Although costly, these are the tasks feed companies perform to assure that the seller is abiding by purchasing agreements.

Purchasing agreements and contracts are excellent tools in the development of quality programs. In most cases these are legally binding agreements that are useful for maintaining stability in the marketplace. But, they are only as good as the enforceability of the agreement. For foreign firms, this becomes very difficult. It may be necessary for a foreign supplier to use a surety bond to guarantee products.

AFIA has long recommended development of "preferred supplier lists" as an excellent method of assuring quality. The development of such lists follows many of the things previously mentioned. Preferred suppliers are facility specific and are maintained on that list until they warrant removal. Development of a "delisting" process is as important as developing a supplier list. Similarly, a procedure needs to be developed that looks at how to procure ingredients outside of a supplier list, when transportation, weather, and other factors impede receipt of ingredients from preferred suppliers.

## Near and Far-Term Outlook for On-Farm Feed Manufacturing

As the regulatory requirements for commercial feed operations become more rigorous and the costs of feed increases, more operations move to the farm to save costs. It's clear the FDA will not likely do much, if any on-farm pre-inspections. However, recent produce contaminations have convinced many in Congress to more closely control on-farm produce growing and processing.

In the European Union, the requirements for on-farm mixing are the same as for commercial operations, as they are in Canada. The EU changes were brought about by outbreaks of bovine spongiform encephalopathy (BSE) and dioxin contamination in Belgium. However, it should be noted that little on-farm inspection is performed in these countries, but the resulting enforcement actions from a contamination breach can be significant, as they can be in the U.S.

With increasing feed costs, it is inevitable that more feed mixing will move onfarm. However, FDA is aware that the risk mitigation procedures for controlling hazards are lessened and of concern.

More regulation of on-farm mixing depends on several factors that include the following: relative number of violations and feed safety breaches; increasing outcry from the commercial industry; lack of producer knowledge of feed safety issues by the producer; recognition of third-party certification programs by FDA, thereby freeing resources for on-farm inspections; and risk ranking of hazards and facilities by FDA and where those resources are placed by the agency.

Congress is also prepared to provide FDA with more far-reaching authority onfarm; however, the funding authorizers do not seem as inclined to fund this authority, which will require millions of dollars.