How does FSMA affect your plant?

Insight on compliance and antibiotics from Industry Consultant Bob Miller

As part of my activities as a consultant I have had the opportunity to visit many ethanol production facilities. During these visits the Food Safety Management Act (FSMA) often comes up as a topic for discussion. In these conversations I frequently hear the same questions, which have ranged from the basic "Is my plant subject to new regulation under the FSMA?" to the more difficult "What do I need to do to be fully compliant with the applicable provisions of the FSMA?"

While the majority of plants have moved beyond just hearing and thinking about FSMA to at least beginning to construct a program for compliance, most have yet to fully develop a program. This is understandable as the final rules are not yet published. Even though there have been many articles written on this topic and there is certainly abundant information available via the Internet and other resources a great deal of uncertainty remains. What is clear is that much remains to be done and waiting for absolute clarity is not an option. As they put their programs together plants will confront a myriad of issues, one of which is whether or not the use of antibiotics will be included in the production of ethanol in their facilities. Assuming, as currently appears likely, that the FDA does not outright ban the continued use of antibiotics there are still numerous additional questions that need to be addressed by plant management personnel if the use of antibiotics is contemplated. Examining what information and guidance is available can provide the information required to at least begin building a program.

The General Requirements portion of Section 103 of the FSMA addresses Hazard Analysis and Preventive Controls and adds a new Section 418 to the FD&C Act (21 U.S.C. § 350g) requiring registered facilities to perform a hazard analysis and implement a preventive controls plan. Section 103 (a) states:

> The owner, operator, or agent in charge of each registered facility is required to conduct a hazard analysis and develop and implement a written preventive controls plan to ensure that food is not adulterated under FD&C Act Section 402 or misbranded under FD&C Act Section 403(w) (allergen labeling). The written plan must include the following elements: hazard analysis, preventive controls (including preventive controls at critical control points, if any), monitoring, verification, corrective actions, and recordkeeping.

Hazard Analysis is addressed in Section 103 (b) of the FSMA, which states:

> The owner, operator, or agent in charge of a registered facility is required to identify and evaluate all known or reasonably foreseeable hazards that may be associated with the facility (including biological, chemical, physical, and radiological hazards as well as natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives) and prepare a written hazard analysis. 21 U.S.C. § 350g(b).

This means the ethanol plant is required to conduct a hazard analysis and develop and implement a written preventive controls plan to ensure that food is not adulterated under FD&C Act Section 402 or misbranded under FD&C Act Section 403(w) (allergen labeling). The written plan must include the following elements: hazard analysis, preventive controls (including preventive controls at critical control points, if any), monitoring, verification, corrective actions, and recordkeeping.

If the ethanol plant is going to continue to use antibiotics the plan must address the possibility of drug residues occurring in distillers grains or any other co-product, such as corn oil, that is sold or could be sold as an animal feed. Since there is no allowable limit for drug residues in any ethanol co-product to be sold as animal feed the program needs to be air tight and fool proof. This is necessary to eliminate the potential impact of having a product recall or worse having to deal with the liabilities of adulterated feed getting into the market place. Plants constructing a FSMA program should also keep in mind provisions such as under 21 U.S.C. § 350k that requires laboratory tests to be used for regulatory purposes must be performed by either a Federal laboratory or an accredited non-Federal laboratory, and lab test results must be sent directly to FDA. The practical effects of such restrictions may result in having to wait for lab test results before shipping DDG's or corn oil. What this means to production schedules etc. must be considered if plant operations are not to be impacted. Costs related to implementation and continued maintenance of the program also needs to be considered.

Among many other considerations that should also be contemplated as the FSMA compliance program is developed are:

- What do your customers want and are customers downstream of your immediate clients demanding more or something different?
- Are there cost effective alternatives to what the plant is currently doing?
- What is reasonably expected to happen with future changes in FSMA? Will regulations probably become more restrictive? Or will they be eased?
- Is the continued use of antibiotics in ethanol production contributing to the development of antibiotic resistant bacteria?

Remember:

- FSMA is current law and it applies to ethanol plants.
- FDA has the authority to order a mandatory recall of food.
- FDA has the authority to administratively detain food based only on a "reason to believe" the food is adulterated or misbranded.
- FDA has the power to suspend the registration, and thereby suspend the operations, of any food facility if FDA determines that food manufactured, processed, packed, or held by the facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals.
- You will eventually be audited.

If an ethanol producer is committed to using antibiotics, becoming a licensed medicated feed supplier may be an alternative to including antibiotic use in a FSMA compliance program.

Plant management teams are encouraged to consult with subject matter experts and legal counsel to ensure their facilities are ready to deal with an FDA audit.

A recognized industry expert, Bob Miller brings over 25 years of experience in the production of alcohol and alcohol related products, including beverage alcohol, wine, cooking wine and vinegar as well as fuel and industrial ethanol. His experience includes four years as plant manager of an ICM designed, Fagenbuilt ethanol plant. His consulting business, Bob Miller Limited, is utilized by many companies serving the fuel ethanol business, including BetaTec Hop Products.
