Department of Legislative Services

Maryland General Assembly
2012 Session

FISCAL AND POLICY NOTE
Revised

House Bill 167 (Delegate Hucker, *et al.*)
Environmental Matters Education, Health, and Environmental Affairs

Agriculture - Commercial Feed - Arsenic Prohibition

This bill prohibits a person from using, selling, or distributing within the State any commercial feed intended for use as poultry feed that contains roxarsone or any other additive that contains arsenic. The prohibition, however, does not apply to commercial feed intended for use as poultry feed that contains histostat. The bill terminates with respect to an arsenical additive that receives approval by the U.S. Food and Drug Administration (FDA) if FDA, on review of new information under specified FDA regulations, issues a finding that approves the use of the arsenical additive and includes in its approval an evaluation of (1) human food safety; (2) impact on the environment; (3) safety to animals; (4) effectiveness of the drug for its intended use; and (5) chemistry and manufacturing procedures. The Maryland Department of Agriculture (MDA) must notify the Department of Legislative Services (DLS) within five days after such a finding is issued.

The bill takes effect January 1, 2013.

Fiscal Summary

State Effect: Assuming the bill's prohibition remains in force with respect to any additive, enforcement of the prohibition is expected to be able to be handled with existing resources, at least initially. If existing feed sampling and analysis does not provide sufficient enforcement, additional personnel and expenditures may be required in future years. Imposition of existing criminal penalties for violations of the bill's prohibition is not expected to materially affect State finances.

Local Effect: Assuming the bill's prohibition remains in force with respect to any additive, imposition of existing criminal penalties for violations of the bill's prohibition is not expected to materially affect local government finances.

Small Business Effect: Potential meaningful.

Analysis

Current Law: Under the Maryland Commercial Feed Law, the Secretary of Agriculture must sample, inspect, test, and make analyses of commercial feed distributed in the State at any time and place and to the extent considered necessary to ensure compliance with the law. A distributor generally must register each brand name or product name of commercial feed before distributing it in the State, unless it has been registered by another person and the product label has not been altered or changed.

A person may not adulterate or misbrand a commercial feed, distribute adulterated or misbranded feed, or distribute a commercial feed that is not registered. The Secretary may issue and enforce a written stop-sale order to the owner, custodian, or distributor of any commercial feed found to be in violation of the Maryland Commercial Feed Law or its implementing regulations, or that has been found by federal or State authorities to cause unreasonable adverse effects to humans, animals, or the environment. A person may not remove or dispose of a commercial feed in violation of such a stop-sale order. Finally, a person may not alter or destroy any required label on commercial feed products.

Generally, any person who violates any provision of the Agriculture Article is guilty of a misdemeanor, and unless another penalty is specifically provided, is subject to a fine of up to $500 and/or imprisonment for up to three months. Any person found guilty of a second or subsequent violation is subject to a fine of up to $1,000 and/or imprisonment for up to one year.

Background:

Roxarsone and Other Arsenic-based Poultry Feed Additives

MDA indicates that roxarsone is used to control parasites that cause coccidiosis (a common avian disease affecting poultry). FDA regulations defining the approved uses of roxarsone in chicken feed indicate it can also be used for "increased rate of weight gain, improved feed efficiency, and improved pigmentation." However, concern has been raised about the health and environmental effects of roxarsone and other arsenic-containing additives in poultry feed. MDA indicates that approximately nine poultry feed products (out of 55) registered in Maryland contain roxarsone. Registrations are issued on an annual basis from May 1 to April 30 of the following year.

Sales of roxarsone (or 3-Nitro) were recently voluntarily suspended by Alpharma, a subsidiary of Pfizer Inc., in response to an FDA study that detected inorganic arsenic, a known carcinogen, at higher levels in the livers of chickens treated with roxarsone than in untreated chickens. FDA indicated that the levels of inorganic arsenic detected, however, were very low, and that continuing to eat chicken as sales of roxarsone were suspended did not pose a health risk. Pfizer announced in June 2011 that the suspension would go into effect in July 2011, allowing poultry producers a month to adjust to the suspension. Pfizer advises that the company limited the amount of roxarsone that could be purchased by companies to normal amounts over the month between the announcement and the suspension.

Prior to the suspension of the sale of roxarsone, it was the most commonly used arsenic-based animal drug. According to FDA, other arsenic-based drugs approved for use in food-producing animals (poultry and swine) include nitarsone, arsanilic acid, and carbarsone. Organic arsenic is the active ingredient in these drugs, as well as in roxarsone, which, according to FDA, is less toxic than inorganic arsenic and is not known to be carcinogenic. FDA's study of roxarsone was conducted in response to scientific reports that organic arsenic could transform into inorganic arsenic.

According to FDA and Pfizer, with sales of roxarsone suspended, nitarsone is the only remaining arsenic-based poultry feed additive being marketed (also by Alpharma/Pfizer), in a feed additive called Histostat. Based on FDA regulations and information provided by Pfizer, Histostat appears to be primarily used for the prevention of blackhead disease (or histomoniasis) in turkeys, although it is also approved for the same use in chickens.

FDA New Animal Drug Approval Process

The FDA new animal drug approval process is initiated by the drug sponsor. A drug sponsor can be any organization or person but typically is a pharmaceutical company. The drug sponsor is responsible for collecting information about the safety and effectiveness of the animal drug, or conducting studies to get the information, and FDA's Center for Veterinary Medicine reviews the information to determine whether the drug is safe and effective and whether the approval requirements have been met. The approval process consists of five major technical sections (similar to those referred to in the bill): (1) target animal safety; (2) effectiveness; (3) human food safety; (4) chemistry, manufacturing, and controls; and (5) environmental impact (pursuant to the National Environmental Policy Act).

State Chemist

MDA's State Chemist Section regulates the sale and distribution of animal feed products, and FDA regulates the manufacturing and distribution of food additives and drugs given

to animals. In addition to animal feed, the State Chemist Section also regulates the sale and distribution of pesticides, pet foods, fertilizers, compost, soil conditioners, and agricultural liming materials.

State Fiscal Effect: DLS advises that it is unclear to what extent the bill's termination provision impacts the bill's prohibition. It is unknown to what extent FDA will issue findings as described in the bill with respect to arsenical additives. To the extent that poultry feed containing an arsenical additive subject to the bill's prohibition remains available, MDA must enforce that prohibition.

MDA advises that its existing staff in the State Chemist Section are already fully engaged in administrative, field, and lab activities for current regulatory programs and could not handle the extra workload of enforcing the bill's prohibition. MDA indicates that it would need to hire an additional inspector and a chemist to inspect records at feed mills, sample feed for analysis, and handle the increase in sample analysis work. Additional expenditures for those positions, including associated operating expenses, total just over $70,000 in fiscal 2013, accounting for the bill's January 1, 2013 effective date and over $130,000 annually thereafter.

DLS advises, however, that enforcement of the bill's prohibition can likely be handled with existing resources, at least initially. State Chemist Section inspectors currently routinely sample randomly selected products at retail outlets, distribution centers, warehouses, and formulating facilities. Feed, and/or ingredients that are used in the production of feed, are sampled and analyzed to help ensure the safe and effective use of drugs in livestock feed, ensure compliance with State law requiring use of phytase or similar phosphorus-reducing enzymes or additives in contract poultry feed, and screen for pesticides and heavy metals. Because the State Chemist Section is currently undertaking feed sampling and analysis, it appears that testing for arsenic-based additives could be incorporated, on a limited basis, in the existing feed sampling and analysis process without a significant increase in workload. The fact that roxarsone is currently off the market also raises uncertainty as to the need for a more comprehensive sampling and analysis program.

Roxarsone, however, could possibly be put back on the market in the future, which could affect the level of resources needed to enforce the bill if the bill's prohibition remains in effect with respect to roxarsone. If the current feed sampling and analysis conducted by the State Chemist Section proves to be insufficient to adequately enforce the bill's prohibition at any point, at least a portion of the time of an additional inspector and/or chemist could be required to implement more comprehensive sampling and analysis of poultry feed for arsenic-based additives.

Small Business Effect: Prior to the suspension of the sale of roxarsone, based on information provided by Delmarva Poultry Industry, Inc. (DPI) in early 2011, roxarsone was being used by certain meat-chicken companies operating on Maryland's Eastern Shore. According to DPI, however, by the end of 2011, following the suspension of the sale of roxarsone, all the Maryland chicken companies were no longer using the product.

DPI indicates that the meat-chicken companies contract with family farms to raise the companies' birds. The family farm growers are paid based on the amount of meat provided and the extent to which the grower can minimize company input costs (the companies provide the feed, bird health programs, bedding material, propane gas to heat the houses, and technical advice). DPI indicates that, if roxarsone is put back on the market, prohibiting the use of roxarsone in Maryland could put Maryland growers at a competitive disadvantage to growers contracting with the same company in other states with respect to their level of operating (feed) costs and meat production. MDA similarly indicates that poultry producers may be adversely impacted due to loss of production.

With roxarsone currently off the market, however, small business poultry producers should not be affected in the immediate future. If roxarsone is put back on the market and the bill's prohibition remains in effect with respect to that additive, DLS advises that the extent of any future impact on growers is not clear. With respect to the current suspension of the sale of roxarsone, FDA indicates that it may cause producers to rely more heavily on existing anticoccidial drugs or seek alternatives for controlling the disease through vaccines, better management practices, or other technologies.

Additional Information

Prior Introductions: SB 417 of 2011 received a hearing in the Senate Education, Health, and Environmental Affairs Committee, but no further action was taken. Its cross file, HB 754, received an unfavorable report from the House Environmental Matters Committee. SB 859/HB 953 of 2010 received hearings in the Senate Education, Health, and Environmental Affairs Committee and the House Environmental Matters Committee, respectively, but no further action was taken on either bill.

Cross File: SB 207 (Senator Pinsky, *et al.*) - Education, Health, and Environmental Affairs.

Information Source(s): Maryland Department of Agriculture; U.S. Food and Drug Administration; Pfizer Inc.; Delmarva Poultry Industry, Inc.; U.S. Department of Agriculture; Department of Legislative Services

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