AMERICAN MEAT INSTITUTE

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00-026N-11
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September 5, 2001

FSIS Docket Clerk
Food Safety and Inspection Service
United States Department of Agriculture
Room 102 Cotton Annex Building
300 12th Street SW
Washington D.C. 20250-3700

RE: FSIS Docket No. 00-026N *Residue Policy*

To Whom It May Concern:

The American Meat Institute (AMI) is the national organization representing the interests of meat and poultry slaughterers and processors and their suppliers throughout North America. AMI's members produce the majority of meat and poultry products manufactured in the United States. We appreciate the opportunity to comment on the above captioned notice.

AMI has reviewed the notice and discussed with Food Safety and Inspection Service (FSIS or the agency) officials on numerous occasions the issues it raises. AMI members are dedicated to providing safe products to consumers. This notice, however, will not enhance the public health; it only serves to harm entities that are not responsible for the presence of inappropriate drug residue levels in animals used for food. Specifically, the notice would abandon longstanding agency practices regarding the handling and disposition of carcasses after testing for residues – practices and procedures that worked well, with no discernible adverse effect on the meat and poultry supply, nor any adverse public health ramifications. A true public health based approach would concentrate resources on prevention, not punishing packers economically. Finally, the notice will conflict with international practices and standards established by the Codex Alimentarius (Codex), a conflict that could adversely affect the American meat industry's international trade capacity. For these reasons AMI opposes the notice.

The notice would abandon longstanding and effective agency practices, harming packers without benefiting the safety of the food supply.

AMI members are committed to providing the safest meat and poultry products possible, including the preclusion and exclusion of illegal drug residues. Companies accomplish this goal in part by refusing to purchase animals that are even suspected of having received illegal drugs or not having been subjected to proper drug withdrawal times, which may result in illegal drug residue levels.[1]

In that regard, AMI has worked with numerous federal agencies, including FSIS and the Animal and Plant Health Inspection Service (APHIS), and FDA, to develop systems that identify marketers of animals who knowingly and repeatedly sell animals containing violative residues to slaughter establishments. AMI, along with other trade groups also developed and disseminated model language that has livestock producers and sellers certifying that the animals they sell comply with federal regulatory requirements regarding veterinary drug use. Notwithstanding these efforts, the agency has published a notice regarding animal drug residues that will not benefit the public health but instead punishes meatpackers. To that end, the FSIS notice titled, "Residue Policy," is unwarranted.

AMI favors a consistent approach across agencies in policy development and implementation. However, it is equally important that FSIS not impose theoretical barriers or extend regulatory restrictions that do not affect or benefit the public health. The above-referenced notice is just such a barrier.

The notice confirms that for more than 25 years "FSIS has condemned only the organ with a violative residue level and has conducted a laboratory analysis of the muscle tissue to determine whether the muscle portion of the carcass is safe for consumption. This has been the practice even for residues of those new animal drugs for which FDA has not established a tolerance or testing methodology for in the muscle tissue." 66 *Fed. Reg.* 40965. If the agency was unable to detect the residue in the muscle tissue, the carcass was released for human consumption. That is, the agency has, consistent with its obligations under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) (collectively the Acts), been finding that muscle tissue taken from carcasses is "not adulterated" under the Acts after testing that tissue and finding either no residue in the tissue or levels that were within acceptable levels determined by the agency.

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[1] However, live animals that appear perfectly healthy to even a trained observer may violate Food and Drug Administration (FDA) established tolerance levels for drug residues.

FSIS is charged with administering the Acts to ensure that consumers receive safe meat and poultry products. Testing muscle tissue for residues when the target tissue exceeds the established limit accomplishes that goal, and enables safe and wholesome food to enter into commerce. Significantly, application of the notice as published means that FSIS has, for approximately 25 years, been allowing products to enter commerce that, under the very theoretical concepts underlying the notice, it should have precluded. The agency's own testing regime over that time period, however, demonstrates that the theoretical concepts underlying the notice are flawed and that the products produced by industry and approved by FSIS were safe and wholesome. Rather than abandon the testing program that has been followed for many years FSIS should continue testing muscle tissue as it has to find violative drug residues in the muscle tissue.[2]

The notice conflicts with the standards established by Codex Alimentarius.

The notice ignores entirely the position of the Codex Alimentarius, the international food standards and guidelines setting body. Codex has established tolerances and analytical methods for many drugs, including some for which FDA has not established muscle residue tolerances. For example, FDA has not set a muscle tissue tolerance for tilmicosin, occasionally found in cattle. Under the agency's new policy, if tilmicosin is found at levels greater than 1.2 parts per million (PPM) in the liver of an animal, FSIS would condemn both the liver and the muscle tissue, *i.e.* the entire carcass. However, for international trade purposes, Codex has set a limit of 100 µg/kg for tilmicosin in beef muscle tissue. FSIS acknowledgement of the Codex standard, even if the liver exceeded 1.2 PPM, would allow the agency to test the muscle tissue and assert that the muscle was safe for consumption, so long as it did not exceed the Codex limit of 100 µg/kg. The same could be demonstrated for numerous other drugs, including fenbendazole in cattle and carbadox in swine.

Taking into consideration that Codex is respected world wide, has been agreed upon by the United States' world trading partners, utilizes many of the same analytical methods as FSIS, and has credibility with American consumers, in addition to being chaired by the FSIS Administrator, it seems inappropriate to exclude Codex-established tolerances and analytical methods from FSIS policies on residues. FSIS should include Codex-established tolerances and approved analytical methods for drugs for which FDA has not established muscular residue tolerances.

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[2] The FSIS decision to test muscle tissue for an animal drug, even absent FDA having established a muscle tolerance, does not conflict with FDA policy in that FDA's policy does not prohibit further testing of the animal carcass for residues when the target tissue exceeds the level of drug tolerance.

The notice will adversely affect the livestock and meat industries with no appreciable public benefit.

The agency's proposed policy change also will have significant cost implications for the meatpacking and livestock industry. Under the currently applied FSIS policy, only 6.5% of carcasses with violative residue levels in an organ had any residual drug in the muscle tissue, and in those cases resulted in carcass condemnation. Under the proposed FSIS policy, it is possible that a substantial portion of the remaining 93.5% of carcasses without violative residue levels in muscle tissue will be condemned. If, for example, each animal costs, on average, $500, the cumulative effect of this new policy will be substantial, with no appreciable or identifiable benefit to the public health. Thus, an establishment that has an additional 200 animals condemned, animals that FSIS has for the past 25 years allowed to go into the food chain after testing the muscle tissue, the cost to that packer under the new policy would be an additional $100,000 annually. If muscle tissue is tested and shown to be clear of any drug residues, there is no legitimate reason for FSIS to condemn the carcass. Simply put, zero is zero.

In conclusion, packers essentially do not have the option of buying cattle that have been prescreened for drugs. By law, unless buying "subject to," which commercially is often not feasible, a packer must pay for livestock before the close of business the day following the sale. 9 CFR § 201.43(a). Accordingly, withholding payment for an animal until it has passed residue testing is illegal. Therefore, the policy change gives little to no incentive to animal producers to change their behavior of inappropriately administering veterinary drugs to food animals. Rather, the policy change further punishes the packer for something beyond its control.

Changing the residue policy as proposed is unwarranted. FSIS should consider the potential impact that this policy change will have on the industry, international trade, and consumers, and ask how the public and the industry will benefit from a change in policy? FSIS should utilize Codex tolerances and methodologies to test for drug residues in tissues where FDA has not established tolerances. Changing policy to mirror FDA's outdated or incomplete regulatory system is inappropriate in this case.

Sincerely,

Mark D. Dopp