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FSIS Docket Clerk Food Safety and Inspection Service United States Department of Agriculture Room 102 Cotton Annex Building 300 12th Street SW Washington, DC 20250-3700 00-026N 00-026N-21 Mark D. Dopp

RE: FSIS Docket No. 00-026R Residue Policy

To Whom It May Concern:

As the Food Safety and Inspection Service (FSIS or the agency) has reopened the comment period for FSIS Docket No. 00-026R entitled "Residue Policy", the American Meat Institute (AMI) would like to take this opportunity to reiterate our objection to proposed policy change.

AMI is the nation's oldest and largest trade association representing packers and processors of beef, pork, lamb, veal, turkey, and processed meat products. Our member companies produce more than 90 percent of these products in the U.S., and these members are dedicated to providing safe products to consumers.

In achieving our goal to provide safe products for consumers, AMI supports efforts that enhance public health. On many occasions AMI has expressed to the agency that this notice will not enhance public heath. Rather it only serves to harm entities that are not responsible for the presence of drug residues in animals used for food. The notice would disregard long standing, successful processes for handling and disposing of carcasses following drug residue testing, leading to dramatic economic losses for packers and having little or no positive impact on public health. This change in policy is also likely to affect adversely the American meat industry's international trade capacity by creating inconsistencies with internationally established Codex Alimentarius (Codex) guidelines. The current internationally accepted residue policy practices and procedures have worked well, with no discernible adverse effects on the meat and poultry supply or public health;

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the proposed notice will neither improve nor ensure public health, but will assuredly harm the meat industry domestically and internationally. For these reasons AMI opposes the policy change.

The abandonment of long standing effective agency policy

AMI members are committed to providing the safest products possible and to supporting the agency by playing an active role in monitoring the meat and poultry supply where possible to ensure compliance with FDA regulations related to preventing violative residues. The primary and most effective way companies prevent violative residues in carcasses is by refusing to purchase animals suspected of having received illegal drugs or containing illegal levels of residue. AMI has worked with numerous agencies, including FSIS, FDA, and APHIS, to develop certification documentation that animals sold comply with drug use regulation. In addition, AMI has worked with these agencies to identify those marketers who repeatedly violate these regulations. Despite the agencies and industry's combined efforts, FSIS has issued this "Residue Policy" notice, which will have detrimental financial implications for meat packers without deterring animal producers from using drugs in an illegal manner.

For more than 25 years the agency has followed a policy of testing target tissues for violative residue levels. Organs with violative residue levels, which are considered adulterated, were condemned; then an additional laboratory analysis of the muscle tissue was executed to determine if the muscle portion of the carcass was safe for consumption. If the muscle tissue was not violative, there was no reason for it to be condemned, and the muscle was cleared for human consumption. This practice is consistent with the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (collectively the Acts), which as administered by FSIS exist to ensure a safe meat and poultry supply.

To implement this new policy would conflict with years of effective residue prevention as directed and administered by FSIS, and followed by meat and poultry processors to ensure a safe food supply. The new policy would only result in unnecessary punishment of packers with no benefit to public health. Rather than abandoning the testing program that has been followed for years the agency should continue testing muscle tissue for violative drug for the benefit of both processors and consumers, while devising new incentives for producers to use drugs responsibly.

Conflicts with the Codex Alimentarius

The change in residue policy could have serious export-import implications for the U.S. meat and poultry supply as it completely ignores Codex, which sets all international food standards and guidelines. Codex has established muscle residue

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tolerances and analytical methods for many drugs, many of which the FDA does not have established tolerances for. If the U.S. meat and poultry supply does not recognize international tolerances, then many imported products will no longer be acceptable in the U.S. market. However, the likelihood that all imported products will be tested for residues is unlikely and therefore puts American industry at a competitive disadvantage.

Codex is accepted and respected worldwide. The Codex standards system is accepted by U.S. world trading partners, utilizes FSIS analytical methods, is accepted by American consumers, and is chaired by the past FSIS Administrator; therefore, it seems inappropriate to exclude the Codex guidelines and recommendations from FSIS policies on residues. FSIS should either adhere to the generally accepted Codex established tolerances and analytical methods, or at a minimum include them for those residues for which FDA has not established acceptable muscle residue levels to ensure that American meat and poultry are acceptable for international consumption.

Adverse affect on the livestock and meat industries

The policy change will have severe adverse economic affects on the livestock and meat industries with no appreciable improvement in public health. This economic burden will be the result of the innumerable unadulterated carcasses that will be destroyed under the new policy that condemns a carcass before conducting muscle tissue testing for violative residue levels. Under the current FSIS residue testing policy, only 6.5% of carcasses with violative residue levels in an organ had any residual drug in the muscle tissue, thus resulting in condemnation. Under the new proposed FSIS notice, it is possible that a substantial portion of the remaining 93.5% of carcasses without violative residue levels in the muscle tissue will be condemned. If the average cost of an animal is \$500, the economic impact of the unadulterated carcasses is substantial. If the muscle is tested and shown to be clear of all drug residues, there is no legitimate reason for the agency to condemn the carcass; there is no harm to the consumer, and thus no public health benefit as a result of the condemnation policy.

The policy also places the economic burden of the presence of violative drugs on the packers, who are not responsible for the presence of the drug residue in the carcass. Packers essentially do not have the option of buying cattle or hogs that have been prescreened for drugs. By law a packer must pay for livestock before close of business the day following the sale. It is illegal to withhold payment until the animal has passed residue testing. Therefore, the policy gives little or no incentive for the animal producers to change their behavior in the use and administration of illegal drugs as they are not the ones experiencing the economic impact of the policy. Although packers can attempt to identify the original producer to let them know of the findings, there is no incentive or punishment passed back to the producer to discourage inappropriate drug use.

It can also be difficult for the packer to determine the original producer of the animal, especially in the hog industry. Essentially, this notice is misdirected in its attempt to eliminate illegal drug residues in meat and poultry. Rather than enacting a new policy to stop livestock producers from improperly or illegally administering drugs, this new policy only serves to further punish the packers for something beyond their control.

Cost Benefit Analysis

It is essential for regulations to have a higher benefit to society, than cost in order to justify issuance of a new regulation, or in this case a change in policy. Given the success of the current policy in its administration and implementation agency and industry wide, it is unclear what societal benefit would result by enacting the new policy. However, the cost to industry and potentially the consumer as a result of implementing the new policy could be severe.

For example, if, as stated above, the average beef animal costs \$500, and an establishment had an additional 200 animals condemned, animals that the 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. This \$100,000 worth of lost carcasses translates into larger sums of lost revenue. If the packer was to experience such economic losses, much of these costs either would have to be passed on to consumers or to livestock producers to sustain the industry. With avoidable costs like these, it is clear how detrimental the economic impact of this policy could be on meat packers individually, on the industry, and even the American consumer. With no higher benefit to society, and substantial cost ramifications for the industry, the change in policy is unjustified.

Summary

Changing the residue policy as proposed is illogical and unwarranted. The FDA's regulatory system of established tolerances and analytical methods are outdated and incomplete in comparison to the internationally accepted Codex Alimentarius. Implementing the proposed policy change could potentially result in dramatic economic losses to the packers, international trade, and eventually even the consumers as a result of increased costs as a result of the new policy implications.

If the agency's purpose is to protect public health, this policy is misdirected. To improve public health, policies must influence the industries responsible for the problem rather than harm those industries unwittingly associated. To ensure a safe food supply actual muscle tissue testing should be the basis for the decisions regarding the condemnation of a carcass rather than simply relying on a target

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tissue test. To ensure international congruency, we strongly encourage FSIS to consider adopting Codex tolerance standards and methods. Thank you for considering our comments. We continue to support policies that will provide the American consumer with a safe, wholesome, and healthy meat and poultry supply.

Sincerely,

Mark D. Dopp