National Pork Board

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August 30, 2001

FSIS Docket Clerk Docket # 00-026N Room 102, Cotton Annex Building 300 12th Street, SW Washington, DC 20250-3700



00-026N 00-026N-3 Beth Lautner

RE: Docket No. 00-026N, Residue Policy

These comments are submitted on behalf of the National Pork Board in response to your request for comments. The National Pork Board was established by an act of Congress in 1985 and is responsible for the collection, distribution, and program accountability for the money generated by the pork checkoff. A Board led by 15 pork producers creates programs in the areas of promotion, research, and consumer information. These programs support producers by providing them with information on many areas including swine health and pork safety. The information contained in this communication is intended to share scientific information and experiences generated by producer checkoff investments and the application of that information to pork production.

The National Pork Board has been pleased to work with the Food Safety and Inspection Service (FSIS) in the past to address our mutual goals of ensuring the production of safe, wholesome products. The National Pork Board has invested several million dollars of checkoff funds in the development and implementation of food safety educational programs for producers. The PORK QUALITY ASSURANCE™ (PQA) Program provides the opportunity to ensure the more than 75,000 participants are aware of their responsibilities to properly use animal health products including avoidance of violative residues.

In this notice, FSIS is announcing its intent to harmonize its procedures with those of the Food and Drug Administration (FDA) with respect to target tissue/marker residue policy in testing animal tissues for residues of new animal drugs and requesting comments prior to implementation of this procedural change. The National Pork Board has some points needing clarification and information to provide on the potential impact of this procedural change on producers.

While the number of residue violations in all classes of swine is extremely low and this change would address a very small number of carcasses, providing a detailed list of the compounds affected by this proposed policy would be useful in understanding the potential consequences of this change and being able to accurately communicate its impact to producers.

After conducting our own review of FDA publications, the National Pork Board has preliminarily identified four compounds approved for use in swine that have established a target tissue and do not have a muscle residue tolerance level: carbadox,

doramectin, apramycin, and tiamulin. Other livestock groups may identify other specific compounds. Prior to implementation of this policy, we would appreciate having sufficient time to discuss the feasibility of muscle tolerances for these compounds with the appropriate pharmaceutical company and the FDA. We would also like to discuss with FDA the availability of resources to review any muscle tolerance levels that may be submitted to that agency and the expected timeframe for its review.

Due to the increased economic losses when an entire carcass is destroyed if the target tissue is found to be violative, correct identification of the sample becomes even more critical. We urge FSIS to cooperate with the plants to ascertain the correct identity of every carcass from which samples are obtained.

Will there be a directive issued and/or additional training provided to all inspectors to standardize sample collection procedures for both monitoring and enforcement residue testing? Important components would include:

- A standardized protocol for what tissue samples are collected from each carcass to be tested
- Correct identification of carcasses tested
- Correlation of target tissue collection with carcass identification
- Observation by plant officials of sample collection
- Communication with the plant on carcasses tested

Having plant personnel observe sampling and concurring on the correct identification would minimize challenges at a later date. There have been reports of residue violations being attributed to a producer who had documentation of no usage of the product responsible for the residue. Standardization of procedures, along with communication with the plant, will minimize or eliminate condemnations not related to the correct carcass. Has FSIS conducted studies to ascertain the correlation between target tissue collection and correct carcass identification?

The National Pork Board appreciates the opportunity to provide these comments and looks forward to continuing to work with FSIS to further reduce the already low number of violative residues in swine.

Sincerely,

Beth Lautner, D.V.M., M.S.

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Vice President, Science and Technology