National Pork Board

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August 30, 2001

Dr. Daniel L. Lazenby
Acting Director, Technical Analysis Staff
Office of Policy, Program Development, and Evaluation
FSIS, USDA
Room 409, Cotton Annex
300 12th Street, SW
Washington, DC 20250

00-051N 00-051N-3 Beth Lautner

RE: Docket No. 00-051N, Residue Testing Procedures

Dear Dr. Lazenby:

These comments are submitted on behalf of the National Pork Board. 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 reviewing the notice announcing the discontinuance of the "5/15" policy and its replacement with a website posting by the FSIS of the names and addresses of the sellers of livestock and poultry with repeat residue violations, the National Pork Board has identified several areas needing further clarification. It should be noted that the pork industry was not one of the parties involved in the series of past discussions with FSIS on sales of market cattle with violative levels of animal drug residues and also was not involved in the request for changes in how the Agency responded to residue violations made by several associations. Therefore, the pork industry has several procedural questions on this concept that were not addressed in the notice. Since there was not a proposed rule process for this change in approach to residue violations, there-was not a prior opportunity to have these questions addressed. The National Pork Board would appreciate a response to our questions to allow us to

accurately and clearly communicate the impact of this procedural change to pork producers.

The PQA Program is currently undergoing revision and this change in FSIS procedures including clarification of its impact on producers needs to be included in Program materials. The Program communicates to producers the consequences of improperly using these types of products.

The National Pork Board understands that a directive or notice to the FSIS field personnel to explain these changes and their potential impact on activities has not yet been distributed. In recent discussions with pork plant personnel, there is concern that this may result in some confusion on expectations of Agency personnel, plant personnel, and producers. With the new procedures being effective on September 5, 2001, it is important that everyone involved understands the implications of these changes and that these are clearly communicated to any plants or producers that are impacted by these changes. Delays in being able to ship animals while clarification is being sought is disruptive and causes economic hardship to producers and should be avoided.

The National Pork Board has three main questions. They are related to procedures to ensure accurate identification of the source of the violation with the producer actually responsible, how the "seller" will be identified between FSIS and the Food and Drug Administration (FDA) records on the website, and website management.

With the potential increased consequences to a producer identified as responsible for a violative residue under this new policy, correct identification of the tissue sample source is critical. Pork producers have had experience in the past with misidentified slaughter samples resulting in misdirected on-farm investigations. Pork plants have expressed concern that samples taken may not always be properly identified to the source farm. With the very serious potential consequences to producers of being listed on a publicly available website, it is imperative that the correct producers are held accountable.

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 traceback of animals with a violative residue to the wrong producer and a producer being inaccurately placed on the website list with potentially serious economic ramifications. Has FSIS conducted

studies to ascertain the correlation between target tissue collection and correct carcass identification?

A second question is in regard to how the "seller" of the livestock and poultry is defined. There are many livestock producers with multiple distinct farm sites that may sell under one name; i.e. the payment for the animals may be made to one individual or company. However, the management on these sites including the types of animal health products used, feed sources, health status, etc. may be different. While the "seller" may be one designation based on who payments are made to, the actual site which was responsible for the residue violation may be distinct. In an effort to identify a repeat violator the most applicable identification would be at the site level of production. This identification of site may or may not be the identification of the producer that is used by FDA at this time for investigative purposes to assign responsibility for a violative residue. We feel that it is essential for FSIS, as well as FDA, to identify violators on a production site basis to accurately identify and correct the actions of the repeat violator.

The third question relates to management of the website. How often will the website information be updated with regard to the addition of names and the deletion of names after the 12 months have elapsed? What group within FSIS has been assigned this responsibility?

The National Pork Board would appreciate clarification of these questions. We are supportive of the goals of continuing to reduce the already small number of residue violations and would like to have this information to clearly communicate with producers how this change will be implemented. If you have questions or need further clarification on our comments, please contact me at 515-223-2623.

Sincerely,

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

Beth Lautrer

Vice President, Science and Technology

cc:

Mr. Tom Billy, FSIS Administrator

Dr. Steven Sundlof, Director, Center for Veterinary Medicine