

National Pork Producers Council

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FSIS Docket Clerk
Docket No. 00-026N
Room 102 Cotton Annex Building
300 12th Street, SW
Washington, DC 20250-3700

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Barbara Determan

Dear Docket Clerk:

The National Pork Producers Council (NPPC) appreciates the opportunity to present our comments on the notice, Docket No. 00-026N, on the Food Safety and Inspection Service (FSIS) proposed changes to the Residue Policy.

NPPC is a national organization that represents, through forty-four affiliated state associations, the nation's pork producers. NPPC membership accounts for most of America's commercial pork production. The U.S. pork industry is one of this country's most important agricultural sectors, accounting in a typical year for more than \$10 billion in annual farm sales. U.S. pork production generates overall economic activity of approximately \$64 billion annually and supports an estimated 600,000 American jobs.

The U.S. pork producers clearly play a key role in ensuring the food they produce is safe and it is one of the highest priorities in the industry. Effectively addressing food safety issues requires coordination throughout the food chain. The implementation of the Pathogen Reduction Hazard Analysis and Critical Control Points (HACCP) has allowed industry to take a proactive and systematic approach to food safety by identifying the hazards that could affect their products, institute controls to reduce or eliminate these hazards from occurring and monitor the performance of the controls. Pork producers realize that we are the first link in the food chain and stand ready to do our part to produce the highest quality and safest product and will continue to work with the entire food chain to provide consumer confidence in our products.

The pork industry has been very responsive to the issue of residues in the food supply and will continue to do so. The amount of residues currently in the pork industry is very low. This small percentage is due to aggressive producer education programs and the industry's concern for producing a safe product. We support FSIS in their intention to further protect public health. However, we believe that implementing the changes to the National Residue Program as


The Other
White Meat.

FSIS has proposed could have significant unintended consequences to the pork industry and the changes need to be evaluated before proceeding.

Pork Industry Activities

NPPC realizes that the use of antimicrobials is a vital tool in pork production and that producers have the responsibility to protect both animal and public health. That is why the industry has had an active and effective track record in creating and implementing educational programs for producers and veterinarians regarding the use of these products.

One program that demonstrates the pork industry priority of food safety is the implementation of the PORK QUALITY ASSURANCE™ (PQA) Program in 1989 to prevent drug residues and enhance herd health practices. Over 75,000 producers have completed this program. The PQA program emphasizes good management practices in the handling and use of animal health products to help all producers avoid drug residues and increase awareness of food safety concerns. Following the implementation of HACCP, most packers now require that producers be PQA certified. We continue to encourage producers to complete the PQA program to meet our goal of no violative residues.

The pork industry has also worked with American Association of Swine Veterinarians (AASV) to develop guidelines for producers and veterinarians on the judicious use of antimicrobials in pork production. Pork producers have used checkoff dollars to implement the One Is Too ManySM needle campaign to educate producers further in the proper administration of animal health products. Pork checkoff dollars have also been spent to conduct research projects that look for production practices or other alternatives to antimicrobials while maintaining the herd health needed to ensure a safe product.

The U.S. pork industry is committed to maintaining consumer confidence in our products. The industry was proactive to address the issue of drug residues with developing the PQA program. Violative residues in the pork industry continue to remain low, however the industry will continue to strive to eliminate all residues by carrying on with the research and educational programs that have been developed. FSIS in this notice has proposed changes to its approach to testing and disposition of carcasses for violative residues to be more consistent with the Food and Drug Administration's (FDA) residue policy. The goal is to ensure that meat containing unsafe levels of chemical residues is not released into commerce. NPPC supports FSIS in this goal to further protect public health, however, before these changes are adopted, we would like to offer comments on several items to decrease the possibility of unintended consequences upon implementation of the changes.

Areas of Concern

The Food and Drug Administration (FDA) has set different residue tolerance levels and marker or target tissues for the drugs approved for use in swine, based on data that was provided by the company for FDA to set the tolerance they were seeking. FSIS is proposing the changes to the residue program to be consistent with the determinations that underlie the FDA approach. FSIS has proposed in this notice that they will condemn carcasses based on the failure of a target tissue when no tolerance is also established for the muscle. FSIS has said that if a target tissue is identified and also a muscle tissue with an official analytical method for muscle residues, they will also test the muscle tissue for compliance with the established tolerance. NPPC does not object to a move to this method of testing for residues, however, we do have a concern with the "blanket" condemnation of carcasses simply because FDA has not established a muscle tissue tolerance or official analytical method when the meat may in fact be safe.

Of the drugs that are used in the pork industry, FDA has established a target tissue tolerance for ten drugs. Six of those 10 also have a tolerance for muscle tissue identified. We are concerned for those drugs that have target tissues identified, but not a tolerance for muscle, that there is a lack of strategy to establish those tolerances within FDA. FSIS must address this issue before moving to a new policy. Currently, FDA is able to evaluate previous data submitted by the sponsoring drug company only after request by the sponsor. If the company did not previously submit the proper data needed to develop the tolerance for muscle residues, they will need to supply it to FDA in order to establish the muscle tissue tolerance. This may require the company to conduct further research to gather the necessary data. We have concern that the company may not wish to spend the money to conduct this research. If this happens, the drug could essentially become unavailable to producers to treat their animals and this is something we cannot afford with the limited number of products available.

Codex Alimentarius, the respected international food safety standards setting body, has established muscle tissue tolerance levels for most drugs. FSIS should look at using the Codex established tolerances and analytical methods for drugs that FDA has not established muscle tissue tolerances.

Most U.S. pork packers already require the producer to certify that they have completed the PQA program before they can market swine. This gives a level of certainty to the packer that they are purchasing animals that will be safe and of high quality. The proposed residue program policy and notification changes will demand changes in the way establishments purchase market hogs, sows and boars. This could have a significant economic impact to the producer based on market access and timing of production schedules. This could unintentionally force suspect animals to move into different market channels

that have limited or less inspection oversight. Without question, should this notice be implemented as outlined, there will be significant economic impacts resulting from the dramatic change in marketing patterns.

If a violative residue is found, care must to be taken when identifying the violator, whether it is a producer, hauler, or auction market. There needs to be accurate identification of the source of the samples that have been taken. Has FSIS ever conducted a study for its inspectors correlating tissue collection with the actual source of samples? Having this information will assist the agency and protect the producers by ensuring the source of the sample is correctly identified. The potential for contamination of animals in markets or lairage holding facilities makes proper identification even more difficult.

When a violative residue is found and the violator can be directly identified, FSIS will open a case file and send a letter of notification to the violator. FSIS has also proposed they will post the list of violators on their website, with the violator listed for a year and eliminate the past "5/15" residue policy. NPPC has some concerns with this change and will address them in another letter to the agency. Pork producers sell their animals on a regular basis and prompt notification is necessary if a violation occurs to eliminate the problem. FSIS needs to continue the Memorandum of Understanding with FDA to continue the investigation of the violation in a prompt and impeccable manner to determine if the violator is indeed a repeat violator.

If FSIS were to adopt these changes outlined in this notice, a detailed directive to the field would be necessary. It should detail specifically to the inspectors, the different tolerances and target tissues that need to be tested. This directive needs to clearly detail the drug, the marker or target tissue, the official analytical method, the tolerance level and the guidance to correctly identify the source of the sample.

Conclusion

NPPC supports FSIS in their goal of further protecting public health. NPPC would suggest that FSIS clearly look the issues we have identified before they pursue these changes in order to eliminate the difficulties and unintended consequences of the policy as stated. NPPC and the pork industry would like to work with FSIS to address these concerns and continue to assure a safe and high quality pork product and avoid the unintended consequences that would occur if this notice were implemented in its current form.

Sincerely,



Barb Determan
President