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National Milk Producers Federation

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September 5, 2001

00-026N
00-026N-4
John B. Adams

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

RE: Residue Policy, Notice, Request for Comment, Docket Number 00-026N

Dear Sir/Madame:

The National Milk Producers Federation (NMPF) is submitting the following comments to the United States Department of Agriculture (USDA), Food Safety and Inspection Service's (FSIS) Notice regarding their Residue Policy Procedures (Docket Number 00-026N). The National Milk Producers Federation, headquartered in Arlington, VA, develops and carries out policies that advance the well-being of U.S. dairy producers and the cooperatives they collectively own. The members of NMPF's 30 cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of 60,000 dairy producers on Capitol Hill and with government agencies.

NMPF completely supports the need to assure the public that all meat and meat products derived from the slaughter of dairy market animals are safe. Food safety is the ultimate objective which guides the development of all on-farm herd health programs supported by NMPF. A significant portion of dairy farm income for producers and their families is derived from the sale of market slaughter animals. Therefore, NMPF is interested in assuring that the fair market value for carcasses from such animals is preserved, provided food safety is not compromised.

NMPF does not support the changes to the Residue Policy outlined in the notice and believes that the contemplated action by FSIS may have a significant economic impact upon dairy producers. Smaller farm families may be particularly impacted because a substantial portion of their net farm income has been traditionally derived from the sale of market slaughter animals. If this Policy Change is enacted and slaughter plants are required to condemn carcasses without FSIS actually conducting laboratory analysis of the muscle tissue, as is current FSIS policy, then a significant number of nonviolative carcasses may be condemned based on an imputed analytical relationship utilized by the Food and Drug Administration (FDA) in approving new animal drug applications.

FSIS proposes to modify present slaughter surveillance procedures for determining that carcass meat tissue is safe. Under the proposed residue policy change, FSIS will no longer test edible muscle tissue if FDA has established a marker residue tolerance in a specified target tissue without establishing a tolerance for a residue in muscle tissue and no official analytical method exists for muscle residue. This new policy is deemed to be more consistent with those analytical determinations that underlie FDA's approach to establishing tolerances in muscle tissue based on the New Animal Drug Approval Process. Therefore, FSIS proposes to condemn the entire carcass if animal drug residues found in target tissues (i.e., liver, kidney or fat) exceed the FDA established tolerance for animal drug residues in the target tissues, provided that no marker residue tolerance or analytical method has been established for the same marker residue in muscle tissue.

If FDA has established a tolerance for a residue in muscle and an analytical method for the muscle residue, FSIS will test the muscle using the official methodology to determine whether the concentration of residues in the muscle is at or below the muscle tolerance. If acceptable, FSIS will permit the release of the muscle. For those new animal drugs for which a marker residue tolerance in a specified target tissue has not been identified, FSIS will continue to collect and monitor multiple edible tissues.

NMPF believes that FSIS should determine if the analytical relationship for measuring the depletion of animal drug residues in target tissues utilized by FDA in approving new animal drugs corresponds to the actual level of the residual animal drug residue found in the carcasses of cattle at slaughter. FSIS should validate, under market conditions, that when FSIS employs the same analytical procedures embodied in the FDA New Animal Drug Approval process, violative levels of animal drugs will be found in the carcass when the target tissues are determined to be violative.

Under conditions required for FDA-approved use for new animal drugs, drug manufacturers conduct residue depletion studies in animals under very controlled conditions. These studies are designed to determine the depletion profile of a particular marker residue in the target tissues by employing a methodology selected by the drug manufacturer. Therefore, under such controlled conditions, FDA can be expected to know the relationship between the concentration of the marker residue in the target tissue and the concentration of the total residues (parent and metabolites) in the edible tissues.

Contrary to the FDA drug approval process, FSIS is testing the kidneys and livers in slaughter plants with a broad-spectrum residue detection plate test. This is not a determinant method utilized by FDA to determine the residue depletion profile of a new animal drug. It is also not a methodology specific for any given drug marker residue or its metabolites. NMPF is concerned that FSIS will not be using the same methodology that underlies the new animal drug approval process employed by FDA. If the exact same methodology is not conducted by FSIS, the residual levels of animal drugs in target tissues may not accurately reflect the actual residue profile in the carcass tissue of the same animal at slaughter. This situation may be compounded by the fact that drug residues generally deplete more slowly from target tissues which FSIS is selecting (e.g., kidney and livers) than from muscle tissues. FSIS should evaluate the use of a

broad-spectrum test compared to the determinant methodologies used in the drug approval process. For the above reasons, it is important for FSIS to determine the number of nonviolative carcasses that would be condemned based on the testing of livers and kidneys with a nondeterminant method.

The notice of change in residue policy is likely to result in an increased number of condemned carcasses. NMPF is concerned that many of these may be nonviolative for drug residues in muscle tissue. The result may be reflected in lower overall market prices for market slaughter animals from dairy farms. Therefore, NMPF believes it is important to verify the science behind this policy change to assure the protection of public health and food safety, but to also prevent the potential for the unnecessary destruction of safe meat. We urge FSIS to conduct the necessary scientific justification to assure that the change will not inadeverantly result in an adverse market impact upon an important segment of dairy farmer income.

Thank you for the opportunity to submit these comments. If you have any questions or would like to discuss this further, please contact me.

Sincerely,

John B. Adams
Director Animal Health and Farm Services