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

To Whom It May Concern:

The following comments, from Taylor Packing Co., Inc., Wyalusing, PA are in response to the proposed residue policy changes, Docket #00-026N, dated August 6, 2001. These comments are based on our experience with residues in beef and may not be applicable to other species.

Background

Taylor Packing Co., Inc. is a slaughter, fabrication and grinding plant that processes 1800 head of cattle per day. This includes both cows (75%) and fed cattle (25%). The USDA-FSIS staff at this facility has been exceptionally vigilant in surveillance of at-risk cattle for drug residues, averaging over 40,000 head per year tested. Likewise, plant management has aggressively pursued this issue as part of our comprehensive HACCP program since 1997. This combination of intensive surveillance and a pro-active management and prevention strategy has provided us with some unique insights into the issues associated with residue testing and prevention in beef.

Taylor Packing strongly supports the premise that all USDA and FDA food production policies and programs must be scientifically sound and consistently applied in all aspects of food production to assure consumers the safest possible food products.

Therefore, we welcome the opportunity to express the following concerns regarding the proposed policy change and how it may be applied to the National Residue Program.

Concerns Regarding Laboratory Capabilities

One of our major concerns is whether the USDA analytical laboratory for drug residues has sufficient testing capabilities and validated methods to accurately analyze specific compounds to the sensitivity levels specified in the FDA regulations.

One example that we see infrequently in beef is perlimycin. On past laboratory results, this compound has been listed as only a positive/negative result without quantification.

On the date we last received a positive perlimycin result, the USDA laboratory was unable to perform a quantitative analysis on this compound. What are the current capabilities? The previous policy, in our experience, was to condemn the muscle based on a positive in the organ tissues without quantification, even though FDA regulations allow a tolerance of 0.5ppm in the liver for cattle.

Another trend that we are seeing is a significant increase in the percentage of violations that are listed as lab code 201, "penicillin". This residue was the cause of 23% of our total residue violations in calendar year 1999 and has steadily risen to 53% of our violations for 2001. We are not aware of any major changes in veterinary treatment practices that could solely account for such a significant increase. Since we never see a lab report positive for any of the other beta-lactams, this raises the question of whether they are all reported as "penicillin". If this is the case, it should be noted that the different beta-lactams have different tolerances. However, our observations indicate that all dispositions are made using the penicillin tolerance of 0.05ppm for beef. How will the USDA assure that FDA tolerance guidelines are correctly applied to the various beta-lactams?

Can the USDA lab differentiate between spectinomycin and streptomycin residues? If not, how will the differences in allowed tolerances be handled?

Neomycin violations frequently elicit challenges from producers who claim they have never used this drug. Again, this raises the question of whether the lab method for this drug is specific enough to assure a high enough level of confidence in its accuracy.

Finally, we are very concerned about the huge increase in lab reports for UMI's, Unidentified Microbial Inhibitors. During calendar year 2000, we received 23 lab reports with UMI results. To date, we have received 74 lab results as UMI's for 2001. The disposition on UMI's has consistently been to pass the product. HACCP principles require that we verify product is safe before we allow its distribution for food use. However, in these cases we have a USDA Inspected and Passed product with an unidentified residue. We do not consider these UMI results acceptable. Why the sudden increase in Unidentified Microbial Inhibitors in the past few months? What changes need to be made in laboratory procedures to achieve a more definitive result? What is the basis for the USDA disposition in these cases? Will these dispositions change based on this policy proposal?

Concerns Regarding Policy Interpretation

Our major concern in this area is extra-label uses of drugs in species they were not originally intended for or approved for by FDA. This policy does not adequately clarify how dispositions will be handled in these cases.

For our operation, gentamicin sulfate is the primary concern. This product was not intended for use in cattle but USDA-FSIS surveillance at this plant has shown that this drug has been widely used in dairy cattle. Our records indicate confirmed cases of gentamicin positive test results in the kidneys of cattle up to 18 months after treatment.

This exceptionally long retention period has created residue violation problems repeatedly for producers and dealers who have purchased cattle with no way of knowing they were carrying gentamicin residues.

The USDA policy has been to test organ and muscle tissues for gentamicin and condemn based on presence in the specific tissues. We have received hundreds of laboratory reports with positive results for gentamicin in the kidneys but never one that was positive in the muscle tissue. This indicates to us that gentamicin, although a regulatory concern is not causing a food safety concern.

Our position has been to educate producers regarding the long retention period of gentamicin and to encourage them to seek alternative treatments to avoid regulatory issues. Despite the regulatory issues related to gentamicin use, there appear to be no significant food safety issues since, in case after case, residues are never found in the muscle tissue. **Yet under the proposed policy a large amount of unaffected meat could potentially be condemned causing significant financial loss to the packer with no significant improvement in food safety.** Additionally, the nature of how the affected cattle are marketed, often through auctions, and subject to prompt payment, provides no economic incentive for producers and their veterinarians to change treatment practices.

Unfortunately, the one drug that does present a known food safety concern, phenylbutazone, is not on the list of drugs (as we understand the charts provided to us) that are addressed in this policy proposal.

Policy should not be changed strictly for reasons of correlation between FDA and USDA practices. It should change based on scientifically established parameters that have been established for the specific purpose of assuring the safety of the food supply. From our perspective, the current drug tolerances serve more of a regulatory purpose without sufficient consideration for what tolerances are acceptable in terms of food safety.

Furthermore, since we export products worldwide, we believe that both USDA and FDA drug tolerance levels in meat should be consistent with the Codex Alimentarius recommendations.

Impact of Policy Change

The impact of this policy change is difficult to determine at this time because we have been unable to get clarification on the questions we have presented. Personnel, within the USDA-FSIS departments, responsible for making carcass dispositions, have been reluctant to cite specific examples of dispositions that would change as a result of this policy. This leaves us with many unanswered questions about how this policy will be interpreted if approved. These questions need to be resolved before any changes are approved.

Our company currently bears an estimated financial impact of approximately $750,000 annually in costs and product losses associated with the intensive level of residue testing in this plant. We accept that the USDA sampling and testing protocols in place in this plant are appropriate risk-based procedures that significantly enhance the safety of our products. **We are concerned that the USDA has been ineffective in raising surveillance to a similarly appropriate level in other USDA-inspected slaughter facilities.** Now USDA proposes to add to that financial burden with a policy that could potentially affect up to another 200 head of cattle per year in this plant (valued at approximately $100,000), depending on final interpretation. The USDA could do far more to assure food safety by consistently applying existing policies in all USDA-inspected slaughter plants. We routinely see increases in the frequency and levels of residues in livestock purchased outside of our normal purchasing and surveillance area. This is a clear indicator to us that more surveillance is needed, particularly in the upper Midwest and the Southeast.

Other Comments Related to the National Residue Program and its Implementation

USDA-FSIS personnel have frequently asserted, as in this policy memo that "Establishments should consider incorporating controls into their HACCP plans to avoid exceeding residue tolerance." **After five years of very aggressively addressing residues in a HACCP environment we have learned that our efforts alone will not resolve these problems.** The majority of the violations we address are first time violators. Almost all of the producers involved, during the current calendar year, have signed a certificate stating that the beef they are marketing contains no illegal levels of drug residues. All of those producers have been quite surprised to find out they didn't understand the complex issues of drug residues as well as they should have. Many of them marketed the cattle in question after consulting with their herd veterinarians who were also unable to provide them with adequate guidance to prevent drug residue issues. Others followed labeled instructions that advised insufficient withdrawal periods for the drug itself or did not take into consideration specific health complications.

In some cases, producers have sold previously medicated cattle for seed stock or dairy production with no intention of sending the animals to slaughter. However, when those animals fail to produce for the new owners, they are routinely sent to market by someone who has no knowledge that there is a past treatment history to be concerned about.

The majority of the violations are not intentional. They are from producers following commonly accepted management practices that have been in place for years. The single most important factor that can affect changes to these practices is consistent USDA surveillance followed by educational feedback to the producers.

Although we have petitioned the agency to improve surveillance nationwide, this concern has not been addressed effectively enough to assure that the National Residue Program is implemented in a consistent manner in all USDA inspected slaughter plants. We continue to support the intensive surveillance efforts in this plant. However, we remain adamant that the inconsistencies in program implementation must be more aggressively addressed before new policy, such as this

one, is introduced. Introducing this policy into the few plants that are experiencing adequate surveillance puts those plants at an even greater economic disadvantage while doing nothing to improve food safety or correct existing regulatory issues.

Summary

Implementation of this policy proposal will not be an effective step in improving food safety. It will, in fact, eliminate testing that is currently assuring that muscle tissues are not affected by certain drug residues. While this may ease the testing burden in the USDA laboratory, it will potentially result in significant quantities of safe meat products being condemned.

While we agree that the USDA and FDA regulations need to be correlated and consistently implemented, this policy proposal doesn't begin to address the many complex core issues with the National Residue Program. **Those issues need to be addressed in the context of assuring food safety, not in the context of assuring regulatory correlation.** Most importantly the issue of drug residue dispositions needs to be addressed in a way that assures our meat products are accepted as safe and wholesome in a worldwide marketplace. We feel the best way to achieve this is to work towards developing standards that are consistent with Codex Alimentarius guidelines.

Sincerely,

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