

PUBLIC HEALTHWORKER SAFETY

Title: A study to correlate procaine penicillin G in tissues, plasma and oral fluids of sows and determine environmental transfer of penicillin to untreated sows - **NPB #13-236**

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Scientific Abstract:

Procaine penicillin G (PPG) residues are the most common violative residues detected in swine at slaughter. The United State Department of Agriculture Food Safety Inspection Service (FSIS) has replaced their Fast Antimicrobial Test (FAST) with the Kidney Inhibition Swab (KIS) test, which is in part responsible for widespread reports of PPG residue detection in cull sows. Direct measurement of the concentrations in tissue that result from typical administration routes and extra-label doses are needed to establish safe withdrawal periods.

Forty-seven (47) sows were divided into three different treatment groups. Fifteen (15) sows were allocated to Treatment Group 1 (TG1), and sixteen (16) sows were allocated to each of the remaining treatment groups. TG1 was administered 3,000 IU/lb PPG IM according to the labeled dose, Treatment Group 2 (TG2) was administered a dose of sterile saline IM once a day for three days and a volume equivalent to the average volume of PPG given to the PPG-treated groups, and Treatment Group 3 (TG3) was administered an extra-label dose of 15,000 IU/lb PPG IM once daily for three consecutive days. Sows were housed in pens of three with one sow from each treatment in a pen and assigned to one of four necropsy time points, which corresponded to 1, 6, 14, and 28 days following the last administration of PPG. Blood samples and environmental samples were taken on all sows immediately before first administration PPG, on Day 3 post-administration of PPG, and immediately before euthanasia on sows to be necropsied. Urine and tissue samples (liver, kidney, injection site, semimembranosus/semitendinosus muscle) were collected at necropsy.

This study demonstrated that at extra-label dosing regiments tissue residues of PPG in the kidney can be detected in the kidney up to 6 days after final administration of PPG. Residues in the skeletal muscle were depleted more slowly than the kidney and detected out to at least 14 days. Injection site residues were the most marked and depleted the most slowly with PPG detected at high levels up to the conclusion of the trial at 28 days. Statistical modeling is needed to extrapolate the depletion profile of these tissues. From the raw data presented, the proposed 15 day withdrawal would not be sufficient for full tissue depletion. Further analysis of data will clarify whether the proposed 51 day withdrawal would be sufficient for full tissue residue depletion due to persistence at the injection site. Plasma concentrations very closely correlate with tissue residue depletion of PPG in kidney and skeletal muscle. For extra-label doses and on-label doses, plasma concentrations of PPG were consistently higher than those found in kidney and skeletal muscle. With this information, plasma appears to be a good antemortem sample for PPG residue detection. However, the only method used for plasma residue detection was LCMS analysis. Because of the complexity of LCMS analysis, use of plasma as a practical, quick antemortem PPG residue sample is limited. Therefore, urine and environmental samples were also assessed for use in antemortem residue detection. Urine residues of PPG were found as consistently as plasma and tissue

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residues. TG1 sows had urine residues at Day 6 post-administration of PPG and TG3 sows had urine residues at Day 14 post-administration of PPG when analyzed by LCMS. Rapid testing methodology using both Charm MRL™ and SNAP™ tests demonstrated consistent results when detecting urine residues compared to the LCMS analysis. With this evidence, antemortem urine testing using these tests would provide accurate information about PPG residues in the sow of interest. However, PPG residues in environmental samples were not correlated to tissue residues. There was no consistency between the Charm MRL™ and SNAP™ tests to any of the other sample types. Residues were consistently detected in the environment with the SNAP™ test, which indicates presence of PPG residues in the environment surrounding sows treated with PPG within at least 28 days. The LCMS testing methodology was consistent with the KIS testing of kidneys used by the FSIS and is a reliable analytical tool to assess PPG residues.