What is Your Risk of Causing Meat or Milk Residues?

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The dairy industry is now under increased drug residue surveillance

Why?

Top sources of beef carcass drug residues

• Cull dairy cows

• Calves sold from dairies
  – Listed as “Bob Veal Calves” on USDA reports
  – Bob Veal are newborn calves < 21 days (150 lb)
  – Special Fed Veal are older raised calves fed nutritionally balanced milk formula

Carcass Residues by Animal Class & Year

Class # harvested adulterated rate
Fed Cattle 27,016,548 16 0.000059%
Beef Cows 3,575,807 52 0.001454%
Dairy Cows 2,606,240 788 0.030235%

Slaughter Violative Residue Comparison

• Dairy cows represent 20x the risk of Beef Cows
• 400x the risk of Fed Cattle

Reasons for the increased number of dairy carcass drug residue violations

• Increased testing
• More sensitive screening test

When you look harder with a more sensitive test you will find more
## FSIS residue violation information system

(Blazed Data) — 24 Feb 2009

<table>
<thead>
<tr>
<th>Product</th>
<th>Percent</th>
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<tr>
<td>Penicillin</td>
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<td>Flunixin</td>
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<td>Sulfadimethoxine</td>
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<td>Desfuroylceftiofur</td>
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<td>Gentamicin</td>
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<td>Oxytetracycline</td>
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<td>Phenoxymephenicol</td>
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>75%

### Antibiotic Violations 1999

- Gentamycin 39%
- Penicillin 25%
- Sulfadimethoxine 12%
- Streptomycin 9%
- Tetracylines 6%
- Neomycin 5%
- Tilmicosin 3%
- Sulfamethazine 2%

### What is it about Penicillin?

- **What are the “Label” indications and dose?**
  - Cattle and sheep - bacterial pneumonia (shipping fever) caused by Pasteurella multocida.
  - 1 ml per 100 lbs BW, IM, once a day for 3-4 days (4 d max)
  - No more than 10 ml per site, rotate sites
  - Milk withdrawal - 48 hrs after last treatment
  - Meat with holding - 10 days
    - Exceeding the recommended daily dosage of 3,000 units per pound of bodyweight; administering at the recommended level for more than four consecutive days and/or exceeding 10 ml per injection site, may result in antibiotic residues beyond the withdrawal time.
- **How much would you give a cow? 15 mls??**
- **ANYTHING** that is not listed above is considered **Extra Label Use**!

### Not all carcass residue testing is random

- **Targeted residue testing**
  - The following is a list of the pathologies and conditions that warrant retention and testing of carcasses:
    - Mastitis
    - Metritis
    - Peritonitis and surgery — carcasses with active peritoneal inflammation
    - Injection sites
    - Pneumonia

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**Intramuscular Flunixin Injection Site Lesions**

Dr. Ron Eustice, Univ MN Diagnostic Lab
FSIS violative residues – consequences

Everyone has access
Same Source Suppliers
Repeat Violators

FDA Warning Letters:
http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm

http://www.fda.gov/foi/warning_letters/

Milk is also now under consideration for increased drug residue surveillance by the FDA

The FDA’s basic assumption is that:
• We do a great job of testing for beta-lactam drugs
• There are other drugs that are used on dairy farms and there is no routine milk testing program for these drugs
• FDA has seen an increase in animal drug violations associated with tissue residues at slaughter plants
• Many of these tissue residue violations are associated with cows and calves sold from dairy farms
• FDA is concerned that this is indicative of a lack of control at dairy farms which could lead to these drugs being present in milk
PMO required drug testing on all tanker loads

- Penicillin G
- Ampicillin
- Amoxicillin
- Ceftioufur
- Cephapirin
- Cloxacillin

What drugs will the new test cover?

- Bacitracin
- Chlorotetracycline
- Doxycycline
- Erythromycin
- Enrofloxacin
- Flunixin
- Oxytetracycline
- Piroxicam
- Sarafloxacin
- Sulfachloropyridazine
- Sulfadiazine
- Sulfadimethoxine
- Sulfamerazine
- Sulfapyridine
- Sulfamethoxazole
- Sulfadiazine
- Tilmicosin
- Tylosin
- Virginiamycin
- Florfenicol
- Tylomycin

So what’s a producer and veterinarian to do?

We First Need to Understand Which Set of Label Directions to Follow

Three kinds of drugs on a dairy

- Over the Counter (OTC)
  - Purchased without a Veterinary Prescription
- Prescription
  - CAUTION: Federal Law restricts this drug to use by or on the order of a licensed veterinarian.
- Extra-label Drug Use (ELDU)
  - OTC or Prescription Drugs not used in accordance to label directions.

Extra-Label Drug Use (ELDU):

- Giving an animal a drug (OTC or prescription) in a manner different in any way from the manufacturer’s label.
- When OTC drugs are NOT used according to the manufacturer’s label directions they require a prescription
- Within the context of a valid Veterinary Client Patient Relationship (VCPR)
Valid Veterinary Client Patient Relationship (vVCPR)

- There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s).
- This means that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of an exam and/or medically appropriate and timely visits to the premises; and
- The practicing veterinarian must be readily available for follow-up in case of adverse reactions or failure of the regimen of therapy.

Conditions to satisfy

- Prior to Prescribing or Dispensing an FDA-approved animal or human drug for extra-label use in a food-producing animal the veterinarian must:
  - Take appropriate measures to assure that assigned timeframes for withdrawal are met and NO ILLEGAL DRUG RESIDUES or residues which may present a Risk to Human Health occur in any food-producing animal or food product subjected to extra-label treatment.

FDA’s Prohibited Drug List

- Drugs prohibited from use in food-producing animals:
  - DCP
  - DES
  - Chloramphenicol
  - Nitroimidazoles (including metronidazole)
  - Nitrofuranes (including topical use)
  - Quinolones
  - Oxytetracycline
  - Glycopeptides (example vancomycin)
  - Gentamicin
  - Eritromycin in adult dairy cattle
  - Antiviral compounds in poultry (including adamantane and neuraminidase inhibitors)
- Drugs prohibited from extra-label use in food-producing animals:
  - Sulfonamides in adult dairy cattle
  - Fluoroquinolones
  - Medicated feeds

- * Lactating (adult) dairy cattle are defined by FDA as dairy cattle 20 months of age or older regardless of whether they are milking or dry.
- ** Currently the only sulfonamide available for use in dairy cattle over 20 months of age is sulfadimethoxine (Albon bolus). In adult dairy cattle this drug may only be used on-label.

FDA is looking for certain Abx

- Any antibiotics found in cull dairy cows that are prohibited for use in female dairy cattle 20 months of age or older
  - A180 (danofloxaxin) {prohibited in any dairy animal}
  - Baytril (enrofloxacin)
  - Draxxin (tulathomycin)
  - Micotil (tilmicosin) and Tylan (tylosin)
  - Nuflor/Nuflor Gold/Resflor Gold (florfenicol)
- Extra label use requires a vVCPR
- To comply with ELUD, there MUST be no residues
- NO TOLERANCE in for these compounds!!!

Animal Residue Data

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Compare the tilmicosin tolerance for Cows-Beef and Cows-Dairy

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<tr>
<th>animal_type</th>
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The FDA is “convinced” that

All beef residues are the result of:
1. Extra-label drug use
2. OTC drug use without veterinary supervision

The FDA is concerned that many of the violative residues are from OTC antibiotic use

Hints that the FDA will consider making ALL antibiotics Prescription Only

Treatment record requirements:
• Uniquely identify all animals on the dairy
• Maintain all treatment records for a minimum of 2 years after animal leaves the operation
• Treatment records should contain the following information:
  – Identification of animal treated
  – Date treated
  – Product administered
  – Dosage used
  – Route and Location of administration
  – Earliest date animals will have cleared withdrawal time
  – Name of person administering product

Develop a proactive residue prevention plan
• Written set of treatment protocols
• Incorporate effective products which have a dairy-friendly residue risk profile
• Follow label directions
• Manufacturers label for OTC and prescription drugs
• Veterinarian’s label if ELDU
• Train employees
• Keep good records — daily!
• Verify the meat or milk withhold for every animal before it goes into the food supply
• Watch out for the exceptions
  • Dehydration, kidney failure, liver problems, poor rumen function, etc.

Summary
• Residue monitoring will certainly become more stringent — with a wider scope.
• Producers making their own Extra-label decisions may be in for an unexpected outcome.
• Protocols and prescriptions are a legal document between the veterinarian and the herd owner
  • Directions must be followed
  • Meat and Milk Withdrawals must adhered to.
  • Drug or protocol changes are not allowed without the authorization of the veterinarian

Remember, every dairy cow has two careers
• Currently society trusts dairy farmers to produce wholesome milk and beef.
• Never violate this trust!