World Pork Expo
AASV Members-Only Session

Antibiotic Use Update

ELDU Restrictions and Duration of Use

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ELDU Restrictions

- AMDUCA revisited
- Guidelines permitting ELDU
- Special restrictions

AMDUCA Revisited

- Animal Medicinal Drug Use Clarification Act
- Implemented by FDA in 1996
- Governs extra-label use of animal and human drugs
- Previously, ELDU was considered “unsafe”

AMDUCA Revisited

- ELDU is defined as the use of any drug other than as approved and described on the label
  - Indications
  - Route of administration
  - Species
  - Dosage
  - Duration of use

AMDUCA Allows ELDU:

- To treat disease
  - When there is no approved food animal drug containing the needed ingredient, in the proper dosage form and labeled for the condition being treated or
  - The veterinarian determines the approved drug is clinically ineffective.
  - For prevention of diseases if the vet can substantiate that the health of the animals is threatened.

ELDU requirements:

- A valid VCPR
  - Vet assumes responsibility for clinical judgements about the health of the animal(s) and need for treatment and the client agrees to follow recommendations
  - Vet has sufficient knowledge of the animals to make a diagnosis
  - Vet is available for follow-up

ELDU requirements:

- Use only as prescribed by a vet
- Only FDA-approved animal and human drugs may be used
- Injectable and water meds
- Prolonged withdrawal
- ELDU of some drugs or drug classes may be prohibited or further restricted

ELDU requirements:

- Only allows for treatment not production uses
- Records must be maintained for 2 years
- Extra-label drugs must be individually labeled

ELDU is prohibited:

- For production purposes
  - FDA has said reproductive use is usually not considered therapeutic
- For feed-grade antibiotics
- If there is an approved effective food-animal drug
- By lay persons
- For cost-savings
- If the drug is unapproved or on the FDA prohibited/restricted list

FDA Prohibited List:

- Chloramphenicol
- Clenbuterol
- Diethylstilbestrol (DES)
- Dimetridazole
- Ipronidazole
- Other Nitroimidazoles
- Furazolidone, Nitrofurazone, Other Nitrofurans
- Sulfonamide drugs in lactating dairy cows (except approved use of sulfadimethoxine, sulfabromomethazine, and sulfaethoxypyridazine)
- **Fluoroquinolones**
- Glycopeptides (example: vancomycin)
- Phenybutazone in female dairy cattle 20 months of age or older
- Adamantane and neuraminidase inhibitor classes of drugs that are approved for treating or preventing influenza A are prohibited therapy in chickens, turkeys, and ducks (Effective: June 20, 2006)
- **Cephalosporin** (excluding cephapirin) in cattle, swine, chickens, or turkeys
  - Using cephalosporin drugs at unapproved dose levels, frequencies, durations or routes of administration is prohibited;
  - Using cephalosporin drugs in cattle, swine, chickens or turkeys that are not approved for use in that species (e.g., cephalosporin drugs intended for humans or companion animals);
  - Using cephalosporin drugs for disease prevention.

AMERICAN ASSOCIATION SWINE VETERINARIANS

Fluoroquinolones
Approved use

Administer, either by intramuscular or subcutaneous (behind the ear) injection, a single dose of 7.5 mg/kg of body weight (3.4 mL/100 lb). For the control of colibacillosis, administration should be initiated within the first 60 days post-weaning when clinical signs are present in at least 2% of the animals in the group. If no improvement is noted within 48 hours, the diagnosis should be reevaluated.

Indication:

For the control of colibacillosis in groups or pens of weaned pigs where colibacillosis associated with Escherichia coli has been diagnosed

Administer, either by intramuscular or subcutaneous (behind the ear) injection, a single dose of 7.5 mg/kg of body weight (3.4 mL/100 lb).

Indication:

For the treatment and control of swine respiratory disease (SRD) associated with Actinobacillus pleuropneumoniae, Pasteurella multocida, Haemophilus parasuis, Streptococcus suis, Bordetella bronchiseptica and Mycoplasma hyopneumoniae.

Fluoroquinolones
Extra-label use

All extra-label use is prohibited

Cephalosporins

Approved use

3 to 5 mg per kilogram (/kg) body weight by intramuscular injection for 3 consecutive days.

Indication:

For treatment and control of swine bacterial respiratory disease (swine bacterial pneumonia) associated with Actinobacillus (Haemophilus) pleuropneumoniae, Pasteurella multocida, Salmonella choleraesuis, and Streptococcus suis.

Cephalosporins
Extra-label use

Extra-label use is prohibited if used:

- At unapproved doses, frequencies, durations, or routes – can only be used for different indications
- In an unapproved species
- For disease prevention

EXTRALABEL DRUG USE IN SWINE

When using antibiotics in an extralabel manner, always ensure the use is judicious and complies with all state and federal regulations.

Remember that the extralabel use of cephalosporins and fluoroquinolones is restricted.**

Cephalosporins (e.g., ceftiofur)

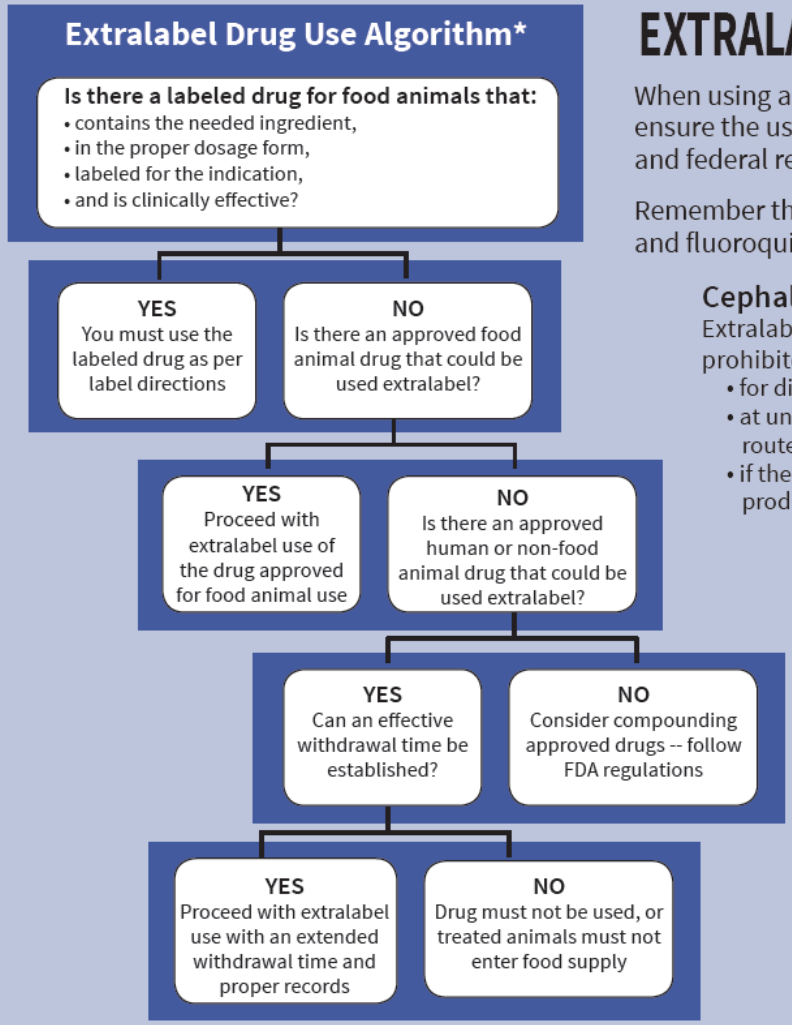
Extralabel use in food-producing animals is prohibited:

- for disease prevention purposes;
- at unapproved doses, frequencies, durations, or routes of administration; or
- if the drug is not approved for that species and production class.

Fluoroquinolones (e.g., Baytril®)

All extralabel use in food-producing animals is prohibited.

**Refer to FDA's AMDUCA regulations for a complete list of drugs prohibited for extralabel use in food-producing animals.



* Adapted from the AVMA AMDUCA webpage (https://www.avma.org/KB/Resources/Reference/Pages/AMDUCA2.aspx)

Duration of Use

- Some currently approved drugs lack a defined duration of use
  - "Feed continuously" and
  - "Feed continuously as the sole ration"
- FDA is considering establishing durations of use for medically important drugs for feed and water meds

TABLE 2—ANTIMICROBIALS WITH APPROVED THERAPEUTIC (TREATMENT/CONTROL/PREVENTION) INDICATIONS WITH UNDEFINED DURATIONS OF USE IN SWINE

Indication/disease	Ingredient(s)
Atrophic rhinitis	Tylosin. Tylosin With Sulfamethazine. Chlortetracycline. Sulfamethazine.
Pneumonia	Tylosin With Sulfamethazine. Oxytetracycline.
GI-Parasites [1]	Hygromycin B.
GI-Bacterial [2]	Tylosin With Sulfamethazine. Lincomycin. Chlortetracycline With Sulfamethazine. Chlortetracycline. Oxytetracycline.
Jowl abscesses	Chlortetracycline.

[1] An example of Gastrointestinal (GI)-Parasite indication is "Control of infestations of large roundworms (*Ascaris suis*), nodular worms (*Oesophagostomum dentatum*), and whipworms (*Trichuris suis*)."

[2] Examples of Gastrointestinal (GI)-Bacterial indications are: "For treatment of swine dysentery"; "To help prevent bacterial swine enteritis"; and "Treatment of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis* and vibrionic dysentery)."

AASV Comments

- FDA should not apply arbitrary durations of use – should be based on scientific justification
- Vets should be allowed flexibility of use
  - Due to training
  - Oversight
  - Experience
  - Familiarity with the animals and disease challenges
- Cited 2 examples from PI committee
  - Lincomycin for GI disease
  - Chlortetracycline for jowl abcesses

Questions?