



UPDATE ON IMPLEMENTATION OF NEW MARYLAND LAW SB471

USE OF ANTIMICROBIAL DRUGS – LIMITATIONS AND REPORTING REQUIREMENTS

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NEUSAHA DISTRICT MEETING

OCTOBER 29, 2019



WILL REVIEW....

- SB471 Summary & Deadlines
- Medically Important Antibiotic Use Reporting Requirements - Progress Report
- Blanket vs. Select Dry Cow Treatment Restrictions - Progress Report on BMPs

MD SENATE BILL 471 – MIAD LAW

- Prohibits use of medically important antimicrobial drugs (MIAD) “in a regular pattern” by feed or water in large cattle, swine and poultry operations and requires vet eval for RX or VFD by **January 1, 2018**.
- Requires submission by veterinarians of copy of VFD or RX for MIAD in feed or water for large cattle, swine & poultry operations beginning **January 1, 2020**



ELEVATED RISK REQUIRED FOR PROPHYLACTIC USE

- “Elevated risk” means
 - a risk that is significantly higher than that present under normal or standard operating conditions, and
 - does not include a risk typically or frequently present under normal or standard operating conditions

VFD SUBMISSION & REPORTING

This fillable form is published by the American Veterinary Medical Association, 1931 North Meacham Rd, Schaumburg, Illinois 60173. The form is provided for your convenience, and is consistent with the common format published in the Food and Drug Administration's draft Guidance for Industry #233, "Veterinary Feed Directive Common Format Questions and Answers." This form is not intended to provide legal advice or opinion and should not be construed as such. This form should be completed with all information required by applicable federal statutes and regulations related to the Veterinary Feed Directive.

Veterinary Feed Directive

Veterinarian: _____ Client: _____
Address: _____ Address: _____

Phone: _____ Phone: _____
Fax or email (optional): _____ Fax or email (optional): _____

Drug(s): _____ Drug Level: _____ g/ton Duration of Use: _____
No substitutions allowed

Species and production class: _____ **No refills/reorders authorized**
Indications for use: _____
Caution (if any): _____

USE OF FEED CONTAINING THIS VETERINARY FEED DIRECTIVE (VFD) DRUG IN A MANNER OTHER THAN AS DIRECTED ON THE LABELING (EXTRALABEL USE) IS NOT PERMITTED

Approximate number of animals: _____
Premises: _____
Other identification (e.g., age, weight) (optional): _____

Special instructions (if any): _____

Affirmation of intent (for combination VFD drugs) (mark one statement)*

(*For VFD drugs for which there are no approved VFD combinations, only the first affirmation statement should be marked)

This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drugs.

This VFD authorizes the use of the VFD drug(s) cited in this order in the following FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component:

Drug(s)	Drug Level(s) and Any Special Instructions

This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component.

◀ Withdrawal time (if any): This VFD must be withdrawn _____ days prior to slaughter ▶

VFD date of issuance (month/day/year): _____ VFD expiration date (month/day/year): _____
(As specified in the approval; cannot exceed 6 months after issuance)

Veterinarian's signature: _____
All parties must retain a copy of this VFD for 2 years after the date of issuance



Veterinary Feed Directive for Chickens ChlorMax® (chlortetracycline)

Veterinarian: _____ Client: _____
Address: _____ Business or Home Address: _____
Phone #: _____ Phone #: _____
FAX or email: (optional) _____ FAX or email: (optional) _____

Indications, Drug Level, and Duration of Use: (select one and specify additional required information)

- 1) Chickens: Control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.
Drug level: _____ g/ton (100 to 200 g/ton)
Duration of use: _____ days (7 to 14 days)
- 2) Chickens: Control of chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli* susceptible to chlortetracycline.
Drug level: _____ g/ton (200 to 400 g/ton)
Duration of use: _____ days (7 to 14 days)
- 3) Chickens: Reduction of mortality due to *Escherichia coli* infections susceptible to chlortetracycline.
Drug level: 500 g/ton
Duration of use: 5 days

USE OF FEED CONTAINING THIS VETERINARY FEED DIRECTIVE (VFD) DRUG IN A MANNER OTHER THAN AS DIRECTED ON THE LABELING (EXTRA-LABEL USE) IS NOT PERMITTED.

Approximate number of **Chickens** to be treated: _____
Premise or Location of animals: _____

Special Instructions and/or other animal identifications:

Affirmation of Intent (for combination VFD drugs): check the appropriate box:

- This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drugs.
- This VFD authorizes the use of the VFD drug(s) cited in this order in the following FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component. _____ (List the specific approved combination)
- This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component.

▶ **Warning:** Do not feed to chickens producing eggs for human consumption.
Indication 1, 2: No withdrawal period required.
Indication 3: Withdraw 24 hours prior to slaughter. ▶

Date of VFD Issuance: _____ (dd/mm/yyyy) Date of VFD Expiration: _____ (dd/mm/yyyy)
(Cannot exceed 6 months after issuance)

Veterinarian's signature: _____

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DRY COW LAW

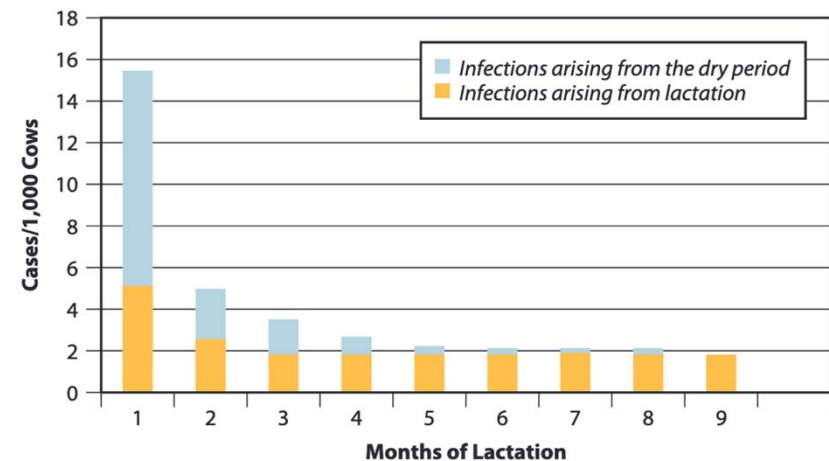
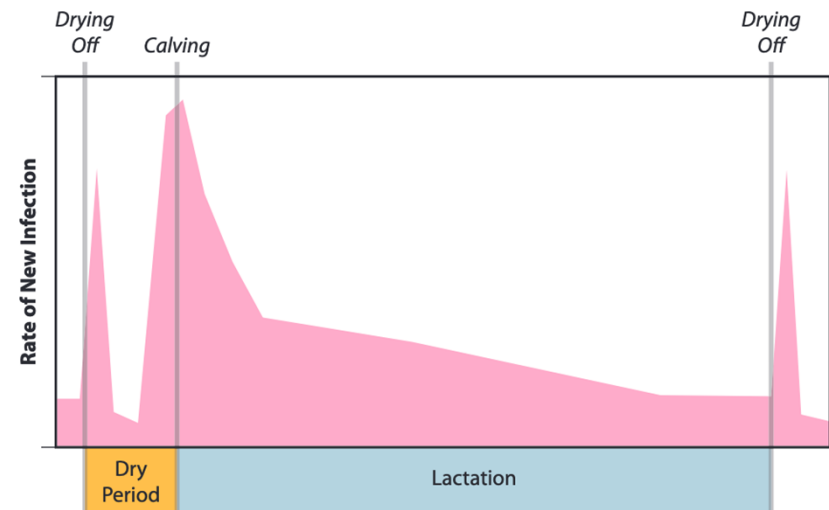


- Prohibits blanket treatment of dairy cows at dry-off using medically important antimicrobial drugs by **January 1, 2021**
 - Must have **assessment of the presence** of an intra-mammary infection to treat with MIADs (does not specify by veterinarian)
 - MIAD may be administered if veterinarian judges the MIAD is “necessary for prophylaxis to address an elevated risk of contraction of a particular disease or infection”....
 - unclear in law if blanket treatment is allowed under this stipulation
 - Farms with fewer than 300 cattle are exempt
- **WORKING GROUP SET UP WITH GOAL:**
REACH CONSENSUS ON REGULATIONS TO IMPLEMENT SELECTIVE DRY COW TREATMENT REQUIREMENT UNDER SB471

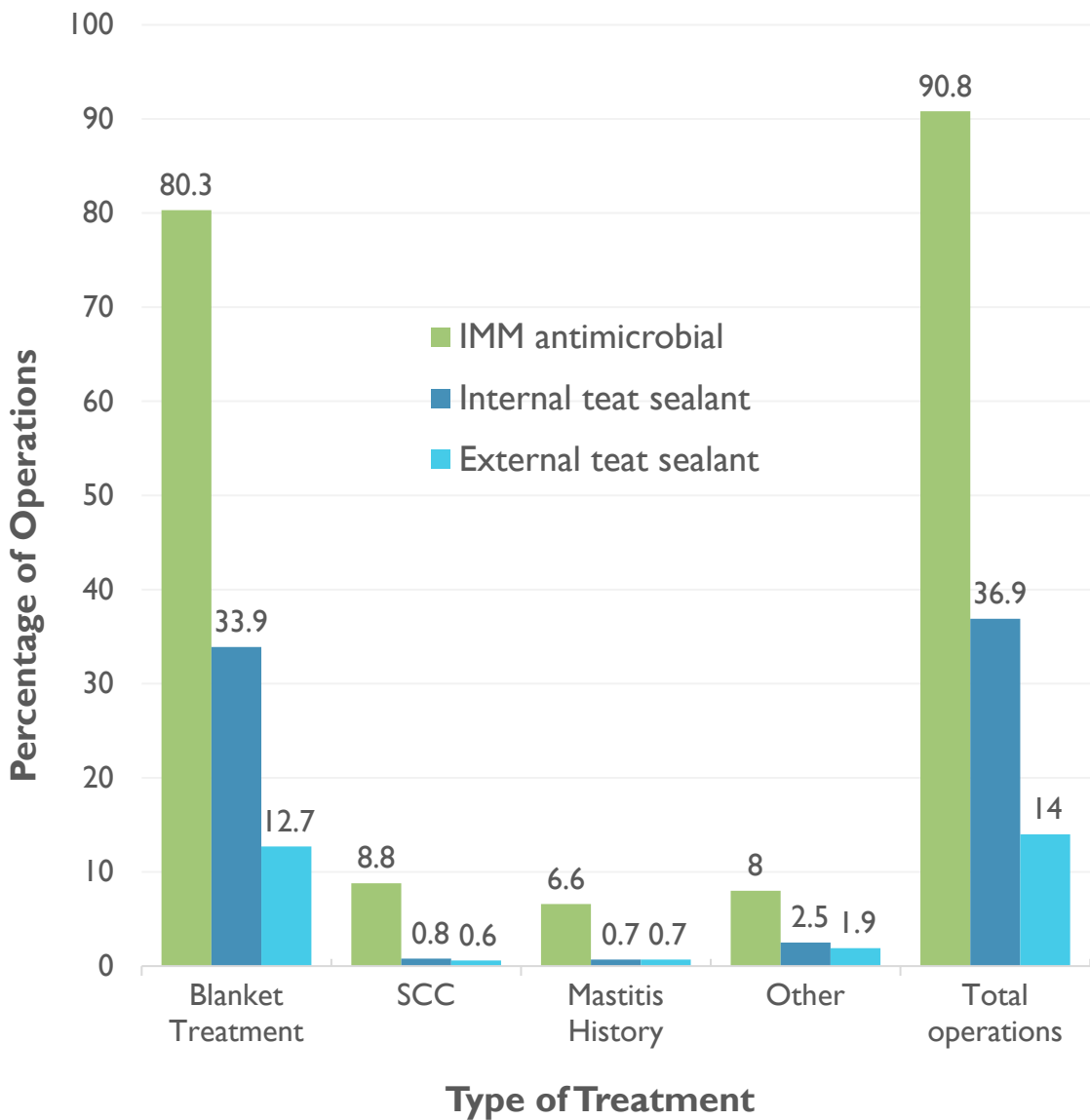


DRY COW THERAPY

- Dry cows are at ↑ risk of mastitis
 - Fewer management techniques
 - Immune suppression
- Subclinical mastitis in dry cows leads to
 - ↑ clinical mastitis
 - ↑ SCC in next lactation



CURRENT DRY COW ANTIBIOTIC USAGE



DESIGN THAT FAILED

97 Dutch herds; 1,657 low SCC cows
(L1 < 150,000 SCC, L2+ < 250,000 SCC)
- Split udder design: Randomly assign quarters

BDCT Group
All quarters treated

“SDCT” Group
Quarters not treated

Tracked from calving to 100 days in milk (DIM)





Results	BDCT	SDCT	P value
Prevalence of IMI at calving	38%	49%	< 0.01
Clinical mastitis (cases/qtr day at risk)	0.24×10^{-3}	0.41×10^{-3}	< 0.0001
SCC at 14 DIM (median)	30,000	40,000	< 0.01
Drug use at dry off (dose/animal)	3,314	0	
All antibiotic drug use by 100 DIM	3,692	542	

Why?

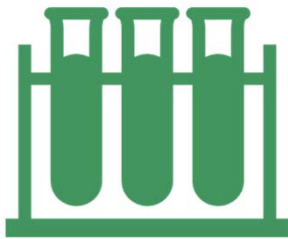
WHY DID SELECT TREATMENT FAIL?

Conclusion: SDCT reduced drug use but resulted in more clinical mastitis and ↑SCC

- **Why did this SDCT program fail?**
 - 1) **Insensitive diagnostic test (SCC) (did not identify subclinical cases)**
 - 2) **No teat sealant (did not protect from new infections)**
 - 3) **No modification of environment to protect from mastitis**

- Scherpenzeel , et al., 2014. JDSci 97

DESIGNS THAT SUCCEEDED



Sensitive
Diagnostic Test



Treat Current
Mastitis Cases



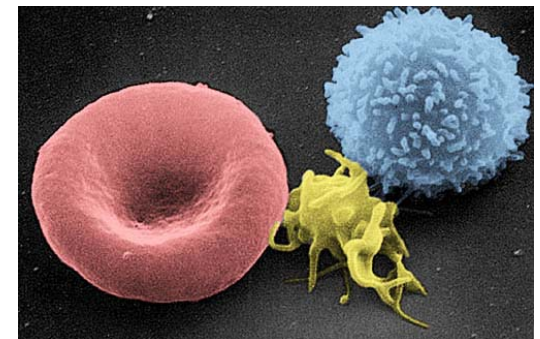
Protect from New
Infections

RECOMMENDATIONS

- Reduce risk of dry period infections
 - Clean, dry, even bedding in dry-cow yards
 - Gradual dry-off over 1-2 weeks to <10kg per day
 - Gradually decrease concentrate fed
 - Decrease number of milkings per day
 - Dry-cow rations by nutritionist
 - Individual calving pens
 - Milk cows within 24h of calving
 - **Proper infusion technique of teat sealant**

RECOMMENDATIONS

- Herds with bulk tank SCC <250,000
- No contagious mastitis organisms on farm
 - *Strep. agalactiae*, *Staph. aureus*, and *Mycoplasma* primary contagious pathogens
- No introduction of new cows to dry herd
- Gram-negative core antigen vaccination
- Monitoring outcomes
 - Dairy Herd Improvement Association

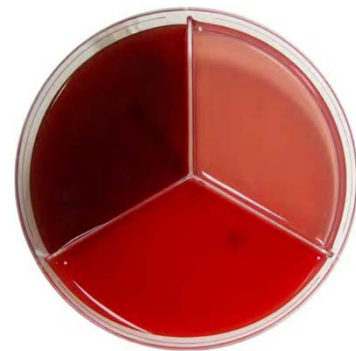


RECOMMENDATIONS

- UK's AHDB Dairy Mastitis Control Plan
 - Formulated for each farm by trained veterinarians
 - Cow housing, including dry cows and heifers
 - Milking parlour function and milking routine
 - Management of the dry period
 - Treatment of mastitis
 - Other areas such as biosecurity and youngstock management
 - <https://dairy.ahdb.org.uk/technical-services/mastitis-control-plan/#.WgIrrWi0OUk>

MORE RECOMMENDATIONS!

- Cow-level criteria
 - In last three months, individual SCC:
 - <150,000 for cows
 - <100,000 for heifers
 - Maximum of one episode of clinical mastitis during current lactation
 - No mastitis in last three months
 - Negative CMT test at dry-off
 - Negative milk culture



MASTITIS TESTS

Test	Sensitivity	Specificity	Speed	Reference
Cow level				
CMT (\geq trace)	70%	48%	Rapid (cowside)	Sanford et al., 2006
SCC ($>$ 200,000)	70%	51%	Rapid (if use DHIA)	Torres et al., 2008
On-farm culture	85%	73%	1-2 day turnaround	Cameron et al., 2013 (Petrifilm system, 3M)
Quarter level				
CMT (\geq trace)	61%	80%	Rapid (cowside)	Middleton et al., 2004
SCC ($>$ 200,000)	57-64%	66-86%	0.5-1 day turnaround	Pantoja et al., 2009; Middleton et al., 2004
On-farm culture	92%	52%	1-2 day turnaround	Royster et al, 2016 (MN Easy™ 4Cast™, UMN)

From Godden, Royster, Timmerman, and Patel, College of Veterinary Medicine, University of Minnesota

ASSESSMENTS PROPOSED ACCEPTABLE TO INDICATE THE PRESENCE OF AN INTRA-MAMMARY INFECTION

Test	Speed	Cost
Cow or Quarter Level		
Clinical Signs of Mastitis (visibly abnormal milk including the presence of clots, heat, pain, or swelling of a gland)	Rapid (cowside)	None
Clinical Signs of Mastitis at any point in immediate prior lactation	Rapid (cowside)	None
California Mastitis Test = "Paddle Test" (≥ trace)	Rapid (cowside)	\$2-\$7
SCC "high" (> 200,000) 2 or more x in immediate prior lactation (alternatives: 250K, or >100K Heifers, >150K cows)	Rapid (if use DHIA)	
	Or 0.5-1 day turnaround	\$2/test ?
On-farm culture	1-2 day turnaround	\$3/test, \$100 startup
Referral Lab Aerobic culture (MDA)	24-48+ hr turnaround	\$2.50 subsidized \$15+ actual Courier needed

OR.....VETERINARIAN DIAGNOSIS

- In ~~California~~ **Maryland**, the potential use of medically important antimicrobial drugs (hereafter referred to as antibiotics) in livestock must be deemed necessary under the professional judgment of a ~~California~~ **Maryland** licensed veterinarian, within the context of a valid veterinarian-client-patient relationship (VCPR) and in accordance with current veterinary medical practice and legal parameters.
- **To use antibiotics effectively and responsibly, a veterinarian must first develop a preliminary or general diagnosis, or have an indication of elevated risk of disease or infection.**
- **The diagnostic process includes consideration of the history, clinical judgment, and epidemiological knowledge of the veterinarian.**

<https://www.cdfa.ca.gov/AHFSS/aus/>

HERD ASSESSMENT TO SUPPORT BLANKET DRY COW TREATMENT

Test	Speed	Cost
Bulk Tank or Herd Representative Sample		
SCC "high" (> 400,000) 2 or more x in immediate prior lactation	Rapid (if use DHIA)	
	Or 0.5-1 day turnaround	\$2/test ?
Herd Culture (50 samples/herd)	48 hr+ turnaround	\$125/herd

THE ROAD AHEAD.....

LESSONS LEARNED

- Increase Outreach to Vets, Stakeholders on ABX Use
- Consider Requiring Veterinary CEU on ABX Use
- Establish an Advisory Group Sooner than Later
- Explore Funding Sources to expand support to state Dairy Industry, including promotion of Judicious Use of Antibiotics

- **COMMENTS/IDEAS/QUESTIONS:**

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