



Milken Institute School
of Public Health
THE GEORGE WASHINGTON UNIVERSITY

ANTIBIOTIC
RESISTANCE
ACTION CENTER



WOMAN'S DEMOCRATIC CLUB
OF MONTGOMERY COUNTY, MARYLAND

September 4, 2018

Lawrence Hogan Jr.
Governor of Maryland
100 State Circle
Annapolis, Maryland
21401-1925

Michael W. Radebaugh, VMD
State Veterinarian
Maryland Department of Agriculture
50 Harry S. Truman Parkway
Annapolis, Maryland 21401

Re: Please Strengthen Proposed Regulations Implementing Keeping Antibiotics Effective Act [COMAR 15.01.15 Use of Antimicrobial Drugs]

Dear Governor Hogan and Dr. Radebaugh,

We face an urgent global antibiotic resistance crisis, driven in part by widespread overuse of antibiotics in animal agriculture. Maryland Senate Bill 422 (Keeping Antibiotics Effective Act) set forth pioneering restrictions to curb this overuse. We urge you to revise and strengthen the Department of Agriculture's proposed livestock antibiotic regulations to prohibit routine use of antibiotics in healthy livestock.

Specifically, there are two aspects of the regulations that need revision.

First, the extremely narrow definition of "regular pattern" would allow many routine uses of medically important antibiotics to continue, contrary to the purpose of SB 422. The statute prohibits use of medically important antibiotics "in a regular pattern." This prohibition means that livestock operations cannot routinely administer antibiotics for disease prevention.

The draft regulation defines "regular pattern" as "repeating the dosage of medically important antimicrobial drug known as pulse dosing to the same animal or group of animals that is inconsistent with its approved duration and indication of uses." Under this definition, the regulation appears to prohibit only uses that are already illegal—only uses inconsistent with approved durations and indications.¹ It does not eliminate routine uses that are permitted under federal law. In addition, this definition narrows the applicability of the law further to "pulse dosing" – a novel and uncommon use of antibiotics. SB 422 intended to cover **all** routine uses of antibiotics. This "regular pattern" definition is not a defensible clarification of the statute necessary to "carry out" the law (3-1006); rather, it is a substantive change to the law that undercuts the main purpose of SB 422.

➤ Recommendation

- Clarify that medically important antibiotics must not be administered repeatedly, i.e. twice or more in the same animal or group of animals for the same purpose, or as standard operating procedure, for prophylaxis.
- Identify specific prohibited uses, including, but not limited to, repeated use in correspondence with a life stage, as an ongoing management strategy or tool, when moving animals from one location to another, and when a dairy cow enters a dry cycle.

Second, the definition of "prophylaxis" could be construed as allowing the use of antibiotics to address risks that stem from unhealthy conditions normally present at concentrated animal feeding operations. To avoid an exception that swallows the rule, the regulations should draw a distinction between general "prophylaxis" (prevention of illness) and prophylaxis to address an "elevated risk."

¹ See Iowa State University, Extension and Outreach, Iowa Beef Center, "Feeding CTC to Feedlot Cattle," available at <https://vetmed.iastate.edu/sites/default/files/VDPAM/Extension/Beef/2017%20CTC%20feedlot%20cattle.pdf> (explaining that repeated pulse dosing of certain drugs is prohibited by federal law).

➤ Recommendation

- Remove “elevated risk” from the definition of “prophylaxis.”
- Add a separate definition of “elevated risk” that clarifies risks are only elevated if they are not present under normal operating conditions.

Attached is revised regulatory language that carries out these recommendations. We strongly urge for these changes to be included in the final regulation or propose revised regulations for further public comment. We also request that you schedule a public hearing.

Respectfully,

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Attachment: Proposed revisions

Revisions to Proposed Regulation Clarifying SB 422 Prohibited Regular Patterns of Use

.01 Purpose.

The purpose of this chapter is to describe the restrictions on the use of medically important antimicrobial drugs in the production of cattle, swine and poultry.

.02 Definitions.

- A. In this chapter, the following terms have the meanings indicated.
- B. Terms defined:
 - 1) "Animal" means cattle, swine or poultry.
 - 2) "Elevated risk" means an unusual and heightened likelihood of contracting a specific, identified disease or infection. A risk typically or frequently present under standard operating conditions is not an "elevated risk."
 - 3) "Medically important antimicrobial drug" means any drug from a class of drug or derivative of a class of drug that is:
 - a) Made from a mold or bacterium that kills or slows the growth of other microbes, specifically bacteria; and
 - b) Used in human beings or intended for use in human beings to treat or prevent disease or infection; or
 - c) Listed in Appendix A of the federal Food and Drug Administration's Guidance for Industry #152, including critically important, highly important, or important antimicrobial drugs.
 - 4) "Prophylaxis" means the prevention of illness.

.03 When Permitted.

- A. Except as provided in this regulation, a person may administer a medically important antimicrobial drug to cattle, swine, or poultry if, in the professional judgment of a licensed veterinarian, the medically important antimicrobial drug is necessary:
 - 1) To treat a disease or infection;
 - 2) To control the spread of a disease or infection; or
 - 3) For a surgery or medical procedure.
- B. A person may administer a medically important antimicrobial drug to cattle, swine, or poultry if, in the professional judgment of a licensed veterinarian, the medically important antimicrobial drug is necessary for prophylaxis to address an elevated risk, provided that it is not used repeatedly, i.e. twice or more in the same animal or group of animals for the same purpose, or as standard operating procedure.
- C. Unless administration of a medically important antimicrobial drug is consistent with subsection (A) of this regulation, a person may not administer a medically important antimicrobial drug repeatedly, i.e. twice or more in the same animal or group of animals for the same purpose, or as standard operating procedure, for prophylaxis. Prohibited uses include, but are not limited to, repeated use in the following circumstances:
 - 1) In correspondence with a life stage (e.g., in-ovo, at birth or hatch, at weaning);
 - 2) As an ongoing management strategy or tool (e.g., in correspondence with: age or weight of animals; time of week, month, or year; or season);
 - 3) When moving animals from one location to another;
 - 4) When a dairy cow enters a dry cycle.
- D. A person may not administer a medically important antimicrobial drug to cattle, swine, or poultry solely for the purpose of:
 - 1) Promoting weight gain; or
 - 2) Improving feed efficiency.