

AMENDED IN SENATE MARCH 26, 2014

SENATE BILL

No. 835

Introduced by Senator Hill

January 6, 2014

An act to amend Section 14288 of, and to add Article 4.5 (commencing with Section 18770) to Chapter 4 of Part 3 of Division 9 of, the Food and Agricultural Code, relating to food and agriculture.

LEGISLATIVE COUNSEL'S DIGEST

SB 835, as amended, Hill. ~~Food-producing~~ *Food* animals: medically important antimicrobial drugs.

Under existing law, the Secretary of Food and Agriculture has the responsibility of ensuring that food products are not adulterated and that they are capable for use as human food. A violation of the laws and regulations relating to the adulteration of livestock or poultry products is a crime, punishable as specified. Existing law regulates the sale of livestock drugs by the secretary, and requires livestock drugs to be registered.

This bill would prohibit the secretary from registering a medically important antimicrobial drug, as defined, ~~for use on a food-producing animal~~, *which is administered to food animals, as defined, through feed or drinking water*, unless prescribed requirements are met. The bill would, *except as specified*, provide that a medically important antimicrobial drug currently registered with the department that does not meet the prescribed requirements has until January 1, 2017, to meet the prescribed requirements and reregister with the secretary. The bill would require a veterinarian-client-patient relationship, as described, to exist prior to the use of a medically important antimicrobial drug.

Because a violation of the bill's provisions would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 14288 of the Food and Agricultural Code
2 is amended to read:

3 14288. The secretary shall refuse to register a livestock drug
4 if he or she finds any of the following is true of the drug:

5 (a) It is of little or no value for the purpose for which it is
6 intended to be used.

7 (b) It is dangerous to the health of livestock if used in accordance
8 with the instructions.

9 (c) The instructions for use do not contain adequate warnings
10 against use in those conditions, whether pathological or normal,
11 under which its use may be dangerous to the health of livestock
12 or humans who consume products from the livestock, or against
13 unsafe dosage, unsafe duration of use, or unsafe methods of
14 administration.

15 (d) If the application and the accompanying material, data, and
16 information do not comply with the requirements of this chapter
17 or are insufficient to permit the secretary to make the
18 determinations that are required by this section.

19 (e) It is a medically important antimicrobial drug, as defined in
20 Section 18770, ~~for use in food-producing animals, which is~~
21 *administered to food animals, as defined in Section 4825.1 of the*
22 *Business and Professions Code, through feed or drinking water,*
23 unless the drug complies with Section 18771.

24 SEC. 2. Article 4.5 (commencing with Section 18770) is added
25 to Chapter 4 of Part 3 of Division 9 of the Food and Agricultural
26 Code, to read:

1 Article 4.5. Medically Important Antimicrobial Drugs

2
3 18770. For purposes of this article, the following definitions
4 apply:

5 (a) “FDA” means the federal Food and Drug Administration.

6 (b) “*Food animal*” has the same meaning as defined in
7 subdivision (c) of Section 4825.1 of the Business and Professions
8 Code.

9 ~~(b)~~

10 (c) “Medically important antimicrobial drug” means an
11 antimicrobial drug listed in Appendix A of the FDA Guidance for
12 Industry #152, including a critically important, highly important,
13 and important antimicrobial drug. The secretary ~~may determine~~
14 ~~that shall have the discretion to consider any updates changes to~~
15 this list by the FDA ~~are also to determine whether a substance is~~
16 a medically important antimicrobial ~~drugs drug~~.

17 (d) “*Veterinary feed directive*” is the directive described in
18 Section 354 of Title 21 of the United States Code.

19 18771. To comply with FDA Guidance for Industry #213,
20 dated December 2013, a medically important antimicrobial drug,
21 including a combination drug incorporating a medically important
22 ~~anti microbial~~ antimicrobial drug, shall meet all of the requirements
23 in the guidance document, including, but not limited to, the
24 following:

25 (a) To reflect the need for professional oversight by a licensed
26 veterinarian, the manufacturer shall remove from the approved
27 production uses on the label of the medically important
28 antimicrobial drug or combination drug the production indications,
29 including, but not limited to, “increased rate of weight gain” or
30 “improved feed efficiency.”

31 (b) The manufacturer shall revise the condition of the use of the
32 medically important antimicrobial drug or combination drug from
33 over the counter availability to a marketing status requiring
34 veterinary prescription, including, but not limited to, the following:

35 (1) For medicated feed products, a change from over the counter
36 to veterinary feed directive.

37 (2) For medicated drinking water products, a change from over
38 the counter to veterinary prescription.

39 (c) ~~The~~ When administered through feed or drinking water the
40 medically important antimicrobial drug may only be used to treat,

1 prevent, or control disease under the supervision of, or by
2 prescription from, a licensed veterinarian.

3 18772. There shall be a veterinarian-client-patient relationship
4 to ensure that a medically important antimicrobial drug is used in
5 a manner that is consistent with professionally accepted best
6 practices. For the purposes of this section, a
7 “veterinarian-client-patient relationship” is a relationship meeting
8 the requirements of Section 2032.1 of Title 16 of the California
9 Code of Regulations.

10 18773. (a) (1) If a medically important antimicrobial drug,
11 or combination drug, for use in ~~food-producing~~ *food* animals is
12 registered with the department as of January 1, 2015, and the drug
13 does not comply with Section 18771, the manufacturer of the
14 medically important antimicrobial drug, or combination drug, shall
15 have until January 1, 2017, to reregister the drug with the secretary.
16 The secretary shall refuse to reregister the drug unless it complies
17 with Section 18771.

18 (2) *Notwithstanding paragraph (1), if a drug label reviewed by*
19 *the FDA under the Guidance for Industry #213 is delayed beyond*
20 *January 1, 2017, the secretary shall have the authority to continue*
21 *registering the drug during the FDA’s review period.*

22 (3) *If revision to the veterinary feed directive causes the FDA*
23 *to delay implementation of the Guidance for Industry #213, the*
24 *secretary shall have the authority to extend the time period by*
25 *which a manufacturer is required to reregister the drug pursuant*
26 *to paragraph (1) to be consistent with the delay in the*
27 *implementation of the guideline. If the secretary extends the time*
28 *period for reregistration, the extension shall not be later than the*
29 *federal implementation date of the guidance.*

30 (b) *If revisions to the veterinary feed directive causes the FDA*
31 *to revise the Guidance for Industry #213, the secretary shall have*
32 *the authority to promulgate regulations to ensure that California*
33 *law is consistent with the revisions to the guidance.*

34 SEC. 3. No reimbursement is required by this act pursuant to
35 Section 6 of Article XIII B of the California Constitution because
36 the only costs that may be incurred by a local agency or school
37 district will be incurred because this act creates a new crime or
38 infraction, eliminates a crime or infraction, or changes the penalty
39 for a crime or infraction, within the meaning of Section 17556 of
40 the Government Code, or changes the definition of a crime within

1 the meaning of Section 6 of Article XIII B of the California
2 Constitution.

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IX.B.



NATURAL RESOURCES DEFENSE COUNCIL

March 27, 2014

Senator Cathleen Galgiani, Chair
Senate Agriculture Committee
1020 N Street, Room 583
Sacramento, CA 95814
FAX: 916-327-8290

RE: SB 835 (Hill) Antibiotics in Animals – Concerns and Request for Amendments

Dear Senator Galgiani and Committee Members:

On behalf of NRDC (Natural Resources Defense Council) which has 1.4 million members and activists, 250,000 of whom are Californians, we write to express concerns about SB 835 by Senator Hill and to request amendments.

We appreciate Senator Hill’s engagement and leadership on this issue, but have concerns about SB 835 as currently drafted. SB 835 addresses one of the problems with the Food and Drug Administration’s (FDA) voluntary Guidance 213, on which it builds, by making the cessation of “growth promotion” uses, i.e. to speed up animal growth, mandatory. However, SB 835 does not address the central problem with FDA’s guidance, leaving a loophole which would allow the use of antibiotics on animals that are not sick to continue. It could also tether California to the timelines for FDA’s process.

SB 835 does not address all, or even most, uses of antibiotics on animals that are not sick
Even with mandatory cessation of growth promotion uses, we expect to see little to no change in antibiotic use in animal feed and water when animals are not sick. This is because so-called “disease prevention uses” would remain unaddressed. These are uses of antibiotics in the absence of disease, often to compensate for crowded and stressful conditions. Disease prevention uses of antibiotics are very similar to growth promotion uses—they both involve the use of antibiotics in low doses in the feed of large numbers of animals day after day in the absence of disease. Many antibiotics are currently approved for both growth promotion and prevention uses.

Not only do growth promotion uses appear to constitute a small portion of use of antibiotics on animals that are not sick, we expect use to simply shift from the growth promotion label to the prevention label. A New York Times op-ed outlined many of these concerns (attached).

This is not just our opinion. Statements from industry representative and the U.S. Government Accountability Office (GAO) support our analysis. Below is a sampling of statements from industry representatives stating that they don’t expect FDA’s guidance to make an impact on antibiotic use:

- The Animal Health Institute, the animal pharmaceutical trade association, has said about the FDA guidance that “Growth uses of medically important antibiotics represent only a small percentage of overall use, so even if all other factors are static it’s unlikely overall use would be greatly affected.”
- The president of Elanco, the animal health division of Eli Lilly, was quoted in a Wall Street Journal article as saying about the FDA guidance that: “We do not see this announcement being a material event.”
- The CEO of Zoetis, another leading animal health pharmaceutical company, which plans to work with FDA, told the Wall Street Journal that he did not expect the FDA guidance to have an effect on the company’s revenues. The New York Times reported that a spokesperson for the company said that “the new policy was not expected to have a big effect on the revenues of the company because many of its drug products were also approved for therapeutic uses.” FDA includes disease preventive uses in its definition of “therapeutic” uses.

The GAO has noted the overlap between growth promotion and prevention uses and pointed out how current uses can continue under the guise of prevention. Here’s the GAO chart noting the overlap between the two kinds of uses:

Table 4: The Overlap between Growth Promotion and Disease Prevention Uses in Food Animal Antibiotics

Antibiotic class	FDA ranking of the importance of antibiotic class to human medicine	Antibiotic name	Approved uses by animal		
			Cattle	Poultry	Swine
Macrolides	Critically important	Tylosin		X	X
		Erythromycin	X	X	X
Lincosamides	Highly important	Lincomycin		X	X
Penicillin	Highly important	Penicillin G Procaine		X	X
Streptogramins	Highly important	Virginiamycin	X	X	X
Tetracyclines	Highly important	Chlortetracycline	X	X	X
		Oxytetracycline	X	X	X
Pleuromutilins	Highly important	Tiamulin			X
Glycolipids	Not ranked	Bambermycins	X	X	X
Polypeptides	Not ranked	Bacitracin	X	X	X
Quinoxalines	Not ranked	Carbadox			X
Ionophores	Not ranked	Monensin	X	X	
		Lasalocid	X	X	
		Laidlomycin	X		

Source: GAO analysis of FDA data.

Note: An “X” indicates FDA approved growth promotion uses, including weight gain and improving feed efficiency. Light gray shading denotes the overlap between antibiotics approved for growth promotion and disease prevention purposes. Boxes in dark gray denote antibiotics not ranked important to human health by FDA.

Please see the report here: <http://www.gao.gov/assets/330/323090.pdf> (see table at p. 28). In addition, we expect that many veterinarians employed by livestock companies will continue to dispense antibiotics for preventive uses even after growth promotion uses are discontinued. The GAO report also cites an interview with a veterinarian that makes this point (see p. 24).

SB 835 does not include antibiotic use reporting and has no way to track progress in meeting its use reduction goals

Currently FDA collects and reports aggregated sales data from livestock drug manufacturers, but regulators, scientists and the public remain in the dark about specific trends and uses. Reporting of antibiotic use in meat production should include, but not be limited to, the total number of animals given antibiotics in their feed, the total amount of antibiotics used, the target animal species for each antibiotic used, and the purpose of the antibiotic use. Such information is essential for tracking progress in meeting antibiotic use reduction goals and identifying opportunities for reducing high risk uses and trends.

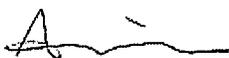
Amendments Requested

We have spoken to the author's office and recommended that the bill curb prevention use of antibiotics. We have also requested that SB 835 be amended to include provisions for reporting on antibiotic use in meat production so that we can track progress in meeting antibiotic use reduction goals and identify opportunities for reducing high risk uses and trends.

As currently drafted, we are concerned that SB 835 would have little to no effect on restricting inappropriate uses of antibiotics in animals and on addressing the growing public health crisis of antibiotic resistance. We look forward to continuing discussions with the author's office.

Thank you for considering our views.

Sincerely,



Avinash Kar
Attorney



Victoria Rome
California Legislative Director



Jonathan Kaplan
Director, Food & Agriculture

Cc: Senator Jerry Hill