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M-I-18-9
(Replaces M-I-05-5)

February 12, 2018

TO: Director, Office of State Cooperative Programs
Attn: All Staff, Division of Milk Safety

FROM: Milk and Milk Products Branch (HFS-316)

SUBJECT: Tolerance And/Or Target Testing Levels Of Animal Drug Residues In Milk (Replaces M-I-05-5 (September 27, 2005) And Identifies It As "INACTIVE")

The 1991 National Conference on Interstate Milk Shipments made changes to the Grade "A" Pasteurized Milk Ordinance (PMO) establishing Appendix N. This Appendix references the publication of tolerances and/or target testing levels of animal drug residues in milk. This M-I provides the updated referenced list. This M-I is replacing M-I-05-5 and will be reissued when additional toxicological data becomes available.

Tolerances[1]
Antimicrobials

Drug	ppb[2]	Drug	ppb[2]
Amoxicillin	10	Neomycin	150
Ampicillin	10	Novobiocin	100
Bacitracin	500	Penicillin[5]	0
Cephapirin	20	Pirlimycin	400
Ceftiofur[3]	100	Sulfadimethoxine	10
Cloxacillin	10	Tetracyclines[6]	300
Dihyrdrostreptomcyin	125	Tylosin	50
Erythromycin[4]	0		

[1] Tolerances for new animal drugs in milk are found in 21 CFR 556
[2] Note that 1 ppb = .001 ppm or 1 ppm = 1000 ppb
[3] The tolerance was established for the marker residue, not the parent compound
[4] A target testing level of 50 ppb has been established for erythromycin
[5] A target testing level of 5 ppb has been established for penicillin
[6] This tolerance includes both the sum and the individual residues of chlortetracycline, oxytetracycline and tetracycline.

Other Drugs

Drug	ppb[1]	Drug	ppb[1]
Clopidol	20	Moxidectin	40
Eprinomectin[2]	12	Thiabendazole	50
Fenbendazole[2]	600	Tripelennamine	20
Flunixin[2]	2		

[1] Note that 1 ppb = .001 ppm or 1 ppm = 1000 ppb
[2] The tolerance was established for the marker residue, not the parent compound

Appendix N of the PMO states: “"Target testing levels" are used by FDA as guides for prosecutorial discretion. They do not legalize residues found in milk that are below the target testing levels. In short, FDA uses the "target testing levels" as prosecutorial guidelines and in full consistency with CNI v. Young. They do not dictate any result; they do not limit FDA's discretion in any way; and they do not protect milk producers, or milk from court enforcement action.
“Target testing levels" are not and cannot be transformed into tolerances that are established for animal drugs under Section 512 (b) of the *FFD&CA* as amended. "Target testing levels" do not:

1. Bind the courts, the public, including milk producers, or FDA, including individual FDA employees; and
2. Do not have the "force of law" of tolerances, or of binding rules.”

Under CNI v. Young, FDA is not precluded from taking action against a product with a residue level below the “target testing levels”, nor is FDA unable to exercise enforcement discretion when the target testing levels are exceeded. FDA will make this determination depending on circumstances and available evidence on a case-by-case basis.

NOTE: For some drugs that do not have an established tolerance, FDA has provided drug residue levels referred to as “target testing levels” to assist with method development and enforcement prioritization Target testing levels are not the same as a tolerance level because a formal human food safety evaluation has not been performed to determine target testing levels. FDA considers drug residue levels above tolerance to be potentially harmful to human health and they are publicly available. FDA reserves the right to take action on residues below the target testing level if necessary. Target testing levels are set by FDA based on available science. They are not determined by the detection limits of commercially available test methods.

Target Testing Levels in Milk

Drug	ppb[1]	Drug	ppb[1]
Erythromycin	50	Sulfamethazine	10
Gentamicin	30	Sulfamethizole	10
Penicillin	5	Sulfanilamide	10
Sulfachloropyridazine	10	Sulfapyridine	10
Sulfadiazine	10	Sulfaquinoxaline	10
Sulfamerazine	10	Sulfathiazole	10

[1] Note that 1 ppb = .001 ppm or 1 ppm = 1000 ppb

Extra-label use of sulfonamide drugs in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomethazine and sulfaethoxypyridazine) is prohibited by 21 CFR 530.41

This coded memorandum provides an editorial correction to M-I-05-5 as the term “safe level” is being replaced with “target testing level”. This editorial correction has also been incorporated into other NCIMS documents. Because of these changes, M-I-05-5 will be identified as “INACTIVE”

An electronic version of this memorandum is available for distribution to FDA Milk Specialists, Milk Regulatory/Rating Agencies, Laboratory Evaluation Officers, and Milk Sanitation Rating Officers. The electronic version should be widely distributed to State Veterinarians, State Veterinary and Pharmacy Boards, Veterinarian Professional Associations, representatives of the dairy industry and other interested parties and will be available on the FDA Web site at http://www.fda.gov at a later date.

If you would like an electronic version of this document prior to it being available on the CFSAN Web Site, please e-mail your request to Robert.Hennes@cfsan.fda.gov

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Milk and Milk Products Branch