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M-I-03-9  
(Revision to M-I-91-4)

June 30, 2003

TO: All Regional Food and Drug Directors  
Attn: Regional Milk Specialists

FROM: Milk Safety Branch (HFS-626)

SUBJECT: Tolerance and/or Safe Levels\* of Animal Drug Residues in Milk (Replaces M-I-91-4 (July 21, 1991) 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 safe levels of animal drug residues in milk. This M-I provides the updated referenced list. This M-I is updating M-I-91-4 and will be reissued when additional toxicological data becomes available.

Several other tolerances for drugs, which may result in residues in milk, are available in 21 Code of Federal Regulations (CFR) Part 556.

**Tolerances (21 CFR 556)**

<u>Drug</u>	<u>ppb</u>	<u>Drug</u>	<u>ppb</u>
Ampicillin	10	Moxidectin	40
Amoxicillin	10	Neomycin	150
Bacitracin	500	Novobiocin	100
Cephapirin	20	Penicillin	0
		(Safe Level-5 ppb)	
Ceftiofur	100 (Marker Residue)	Pirlimycin	400
(Safe Level-50 ppb for Parent Drug)		Sulfadimethoxine	10
Cloxacillin	10	Tetracyclines	300
Dihydrostreptomycin	125	(Including both the sum and the individual residues of chlortetracycline, oxytetracycline and tetracycline)	
Erythromycin	0	Tylosin	50
(Safe Level-50 ppb)			

### Safe Levels in Milk\*

<u>Drug</u>	<u>ppb</u>	<u>Drug</u>	<u>ppb</u>
Ceftiofur (Parent Drug)	50	Sulfamerazine	10
Erythromycin	50	Sulfamethazine	10
Gentamicin	30	Sulfamethizole	10
Penicillin	5	Sulfanilamide	10
Sulfachloropyridazine	10	Sulfapyridine	10
Sulfadiazine	10	Sulfaquinoxaline	10
		Sulfathiazole	10

### Other Drugs (Special Case)

Chloramphenicol: Any residue of this drug in milk is considered actionable. The use of Chloramphenicol in meat, egg, or milk producing animals is prohibited. There is no tolerance or safe level for Chloramphenicol.

\* "Safe levels" are used by FDA as guides for prosecutorial discretion. They do not legalize residues found in milk that are below the safe level. In short, FDA uses the "safe levels" as prosecutorial guidelines and in full consistency with *CNI v. Young* stating, in direct and unequivocal language, that the "safe levels" are not binding -- that they do not dictate any result, that they do not limit the agency's discretion in any way, and that they do not protect milk producers (or milk) from court enforcement action.

"Safe levels" are not and cannot be transformed into tolerances that are established for animal drugs under section 512 (b) of the Federal Food, Drug and Cosmetic Act. "Safe levels" do not (1) bind the courts, the public (including milk producers), or the agency (including individual FDA employees), and (2) do not have the "force of law" of tolerances (or of binding rules).

Copies of this memorandum are enclosed for distribution to Regional Milk Specialists, State Milk Regulatory Agencies, State Laboratory Evaluation Officers, and State Milk Sanitation Rating Officers in your region. This memorandum will also be available on the FDA Web site at <http://www.cfsan.fda.gov> at a later date and should be widely distributed to State Veterinarians, State Veterinary and Pharmacy Boards, Veterinarian Professional Associations, and representatives of the dairy industry and other interested parties.

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