

Notice Calling for suggestions, views, comments etc from stakeholders on the draft notification related to tolerance limit of antibiotics and pharmacology active substances.

F.No. 1-100/SP(PAR)- Notification/Enf/FSSAI/2014.- In the Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011, in regulation 2.3 relating to “Residues”, in sub-regulation 2.3.2-

(a) for clause 2, the following may be substituted, namely:-

“The use of any of the following antibiotics and other Pharmacologically active substances shall be prohibited in any unit processing sea foods including shrimps, prawns or any variety of fish and fishery products —

1. Nitrofurans including-

(i) Furaltadone;

(ii) Furazolidone;

(iii) Nitrofurantoin;

(iv) Nitrofurazone.

2. Chloramphenicol.

3. Sulphamethoxazole.

4. *Aristolochia* spp and preparations thereof.

5. Chloroform.

6. Chlorpromazine.

7. Colchicine.

8. Dapsone.

9. Dimetridazole.

10. Metronidazole.

11. Ronidazole.

12. Iprnidazole and other nitromidazoles.

13. Clenbuterol.

14. Diethylstilbestrol (DES).

15. Glycopeptides.

16. Stilbenes and other steroids.

17. Crystal Violet.

18. Malachite Green.”

(b) after clause 3, the following clause shall be inserted, namely:-

(4) The antibiotics in column (2) shall not exceed the tolerance limit specified in column (4) for the food in column (3) of the following tables, namely:-

Table-1
Antibiotics (used in humanbeings and animals)

S. No.	Name	Food	Tolerance limit (mg/Kg)
(1)	(2)	(3)	(4)
1.	Ampicillin	(i) All edible animal tissue (ii) Fats derived from animal tissues (iii) Milk	0.01
2.	Cloxacillin	(i)All edible animal tissue (ii) Fats derived from animal tissues (iii) Milk	0.01
3.	Chloramphenicol	(i) All edible animal tissue (ii) Fats derived from animal tissues (iii)Milk	0.01
4.	Dihydrostreptomycin Sulphate (Dihydrostreptomycin)/ Streptomycin	(i)All edible animal tissue (ii) Fats derived from animal tissues (iii) Milk	0.01
5.	Chlortetracycline Hydrochloride	(I) All edible animal tissue (II) Fats derived from animal tissues	0.01

(1)	(2)	(3)	(4)
		(III) Milk	
6.	Erythromycin Thiocyanate	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
7.	Flumequine	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
8.	Furazolidone	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
9.	Lincomycin	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
10.	Oxytetracycline	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
11.	Salinomycin	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
12.	Spectinomycin Hydrochloride (Spectinomycin)	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
13.	Sulphadiazine	(I) All edible animal tissue (II) Fats derived from animal tissues	0.01

(1)	(2)	(3)	(4)
		(III) Milk	
14.	Sulphathiazole Sodium	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
15.	Trimethoprim	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
16.	Cloxacillin	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
17.	Dicloxacillin	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
18.	Sulfadiazine	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
19.	Sulfanilamide	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
20.	Sulfaguanidine	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
21.	Zinc Bacitracin (minimum 60IU/mg dried	(I) All edible animal tissue (II) Fats derived	0.01

(1)	(2)	(3)	(4)
	substance)	from animal tissues (III) Milk	

Table-2

Antibiotics (for exclusive use in animals)

S.No	Name	Food	Tolerance limit (mg/Kg)
(1)	(2)	(3)	(4)
1.	Amprolium Hydrochloride	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
2.	Apramycin Sulphate	Cattle	
		Kidney	0.01
		Sheep	
		Kidney	0.01
3.	Carbadox	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
4.	Ceftiofur Sodium (Ceftiofur)	Cattle	
		Muscle	1
		Liver	2
		Kidney	6
		Fat	2
		Milk	0.1
		Pig	

(1)	(2)	(3)	(4)
		Muscle	1
		Liver	2
		Kidney	6
		Fat	2
5.	CeftiofurHCl (Ceftiofur)	Cattle	
		Muscle	1
		Liver	2
		Kidney	6
		Fat	2
		Milk	0.1
		Pig	
		Muscle	1
		Liver	2
		Kidney	6
		Fat	2
6.	Cephapirine Benzathine interauterine	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
7.	Clopidol	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
8.	Cloxacillin Benzathine	(I) All edible animal tissue (II) Fats derived from animal tissues	0.01

(1)	(2)	(3)	(4)
		(III) Milk	
9.	Colistin Sulphate	Cattle	
		Fat	0.15
		Muscle	0.15
		Kidney	0.2
		Liver	0.05
		Milk	0.15
		Pig	
		Muscle	0.15
		Fat	0.15
		Liver	0.15
		Kidney	0.2
		Sheep	
		Liver	0.15
		Milk	0.05
		Muscle	0.15
		Kidney	0.2
		Fat	0.15
		Goat	
		Kidney	0.2
		Muscle	0.15
		Liver	0.15
		Fat	0.15
		Rabbit	
		Fat	0.15
		Muscle	0.15

(1)	(2)	(3)	(4)
		Liver	0.15
		Kidney	0.2
		Chicken	
		Kidney	0.2
		Liver	0.15
		Eggs	0.3
		Fat	0.15
		Turkey	
		Muscle	0.15
		Liver	0.15
		Kidney	0.2
		Fat	0.15
10.	Danofloxacin	Cattle	
		Muscle	0.2
		Liver	0.4
		Kidney	0.4
		Fat	0.1
		Pig	
		Muscle	0.1
		Liver	0.05
		Kidney	0.2
		Fat	0.1
		Chicken	
		Muscle	0.2
		Liver	0.4
		Kidney	0.4
		Fat	0.1

(1)	(2)	(3)	(4)
11.	Enrofloxacin	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
12.	Ethopabate	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
13.	Flavophospholipol (Flavomycin)	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
14.	Monensin Sodium (Monensin)	Cattle	
		Muscle	0.01
		Liver	0.1
		Kidney	0.01
		Fat	0.1
		Milk	0.002
		Sheep	
		Muscle	0.01
		Liver	0.02
		Kidney	0.01
		Fat	0.1
		Goat	
		Muscle	0.01
		Liver	0.02
Kidney	0.01		

(1)	(2)	(3)	(4)
		Fat	0.1
		Chicken	
		Muscle	0.01
		Liver	0.01
		Kidney	0.01
		Fat	0.1
		Turkey	
		Muscle	0.01
		Liver	0.01
		Kidney	0.01
		Fat	0.1
		Quail	
		Liver	0.01
		Kidney	0.01
		Muscle	0.01
		Fat	0.1
15.	Moxidectin	Cattle	
		Muscle	0.02
		Liver	0.1
		Kidney	0.05
		Fat	0.5
		Sheep	
		Muscle	0.05
		Liver	0.1
		Kidney	0.05
		Fat	0.5
16.	Sulphaquinoxaline	(I) All edible animal tissue	0.01

(1)	(2)	(3)	(4)
		(II) Fats derived from animal tissues (III) Milk	
17.	Sulfadimidine Sodium	Cattle	
		Milk	0.02
		Not specified	
		Muscle	0.1
		Fat	0.1
		Kidney	0.1
		Liver	0.1
18.	Tilmicosin	Cattle	
		Muscle	0.1
		Liver	1
		Kidney	0.3
		Fat	0.1
		Pig	
		Muscle	0.1
		Liver	1.5
		Kidney	1
		Fat	0.1
		Sheep	
		Liver	1
		Kidney	0.3
		Fat	0.1

(1)	(2)	(3)	(4)
		Chicken	
		Liver	2.4
		Kidney	0.6
		Muscle	0.15
		Fat/Skin	0.1
		Turkey	
		Liver	1.4
		Kidney	1.2
		Muscle	0.1
		Fat	0.25
19.	Tylosin	Cattle	
		Muscle	0.1
		Liver	0.1
		Kidney	0.1
		Fat	0.1
		Pig	
		Muscle	0.1
		Liver	0.1
		Kidney	0.1
		Fat	0.1
		Sheep	
		Muscle	0.1
		Liver	0.1
		Kidney	0.1
		Chicken	
		Muscle	0.1
		Liver	0.1

(1)	(2)	(3)	(4)
		Kidney	0.1
		Fat/Skin	0.1
		Eggs	0.3
20.	Tyvalosin Tartrate	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
21.	Virginiamycin	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01

Table-3

Other Veterinary Drugs

S.No.	Name	Food	MRL (mg/Kg)
(1)	(2)	(3)	(4)
1.	Acepromazine Maleate	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
2.	Albendazole	Species not specified	
		Muscle	0.1
		Liver	5
		Kidney	5
		Fat	0.1
		Milk	0.1

(1)	(2)	(3)	(4)
3.	Amitraz	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
4.	Aspirin	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
5.	Buqarvaquone	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
6.	Buserelin Acetate	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
7.	Butafosfane	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
8.	Butalex	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
9.	Butaphosphan	(I) All edible animal tissue (II) Fats derived from animal tissues	0.01

(1)	(2)	(3)	(4)
		(III) Milk	
10.	Calcium Borogluconate	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
11.	Calcium Magnesium Borogluconate	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
12.	carboprost tromethamine	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
13.	Cefquinone Sulphate	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
14.	Chloral hydrate	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
15.	Claprostenol sodium	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
16.	Cloprostenol Sodium	(I) All edible animal tissue	0.01

(1)	(2)	(3)	(4)
		(II) Fats derived from animal tissues (III) Milk	
17.	Closantel	Cattle	
		Muscle	1
		Liver	1
		Kidney	3
		Fat	3
		Sheep	
		Muscle	1.5
		Liver	1.5
		Kidney	5
		Fat	2
18.	Clenbutrol Hydrochloride (Broncopulmin powder)	Cattle	
		Muscle	0.0002
		Milk	0.00005
		Liver	0.0006
		Kidney	0.0006
		Fat	0.0002
		Horse	
		Muscle	0.0002
		Fat	0.0002
		Liver	0.0006
		Kidney	0.0006
19.	Diethylcarbamazine	(I) All edible animal tissue (II) Fats derived from animal tissues	0.01

(1)	(2)	(3)	(4)
		(III) Milk	
20.	Dimetridazole	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
21.	Dinitolmide	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
22.	Doramectone	Cattle	
		Muscle	0.01
		Liver	0.1
		Kidney	0.03
		Fat	0.15
		Milk	0.015
		Pig	
		Muscle	0.01
		Liver	0.1
		Kidney	0.03
Fat	0.15		
23.	Dexcloprostenolum	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
24.	Flunixin Meglumine	(I) All edible animal tissue (II) Fats derived from animal tissues	0.01

(1)	(2)	(3)	(4)
		(III) Milk	
25.	Halofuginone	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
26.	Haloxon	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
27.	Ivermectin	Cattle	
		Milk	0.01
		Liver	0.1
		Fat	0.04
		Pig	
		Liver	0.015
		Fat	0.02
		Sheep	
		Liver	0.015
		Fat	0.02
28.	Kaolin	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
29.	Ketamine hydrochloride	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01

(1)	(2)	(3)	(4)
30.	Levamisole Hydrochloride (Levamisole)	Cattle	
		Muscle	0.01
		Liver	0.1
		Kidney	0.01
		Fat	0.01
		Pig	
		Muscle	0.01
		Liver	0.1
		Kidney	0.01
		Fat	0.01
		Sheep	
		Muscle	0.01
		Liver	0.1
		Kidney	0.01
		Fat	0.01
		Poultry	
		Muscle	0.01
		Liver	0.1
		Kidney	0.01
		Fat	0.01
31.	Lithium Antimony Thiomalate	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
32.	Luprostiol	(I) All edible animal tissue (II) Fats derived from animal	0.01

(1)	(2)	(3)	(4)
		tissues (III) Milk	
33.	Madramicin	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
34.	Magnesium Hypophosphite	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
35.	Mastijet Flarte	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
36.	Meloxicam	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
37.	Mepyramine	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
38.	Methyl Hydroxybenzoate	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
39.	Nandrolone Laurate	(I) All edible animal tissue	0.01

(1)	(2)	(3)	(4)
		(II) Fats derived from animal tissues (III) Milk	
40.	Niclosamide	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
41.	Nimesulide	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
42.	Nitroscanate	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
43.	Nitroxynil	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
44.	Oxybendazole	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
45.	Oxfendazole	Group MRLs for the sum of fenbendazole, oxfendazole and oxfendazole sulfone (as oxfendazole sulfone equivalents)	
		Cattle	
		Muscle	0.1

(1)	(2)	(3)	(4)		
		Liver	0.5		
		Kidney	0.1		
		Fat	0.1		
		Milk	0.1		
		Pig			
		Muscle	0.1		
		Liver	0.5		
		Kidney	0.1		
		Fat	0.1		
		Sheep			
		Muscle	0.1		
		Liver	0.5		
		Kidney	0.1		
		Fat	0.1		
		Milk	0.1		
		Goat			
		Muscle	0.1		
		Liver	0.5		
		Kidney	0.1		
		Fat	0.1		
46.	Oxyclozanide	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01		
47.	Parbendazole	(I) All edible animal tissue (II) Fats derived	0.01		

(1)	(2)	(3)	(4)
		from animal tissues (III) Milk	
48.	Pentobarbitone	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
49.	Praziquantel	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
50.	Pregnant Mare Serum Gonadotrophin	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
51.	Proligestone	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
52.	Promazine Hydrochloride	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
53.	Propofol	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
54.	Prosolvin	(I) All edible	0.01

(1)	(2)	(3)	(4)
		animal tissue (II) Fats derived from animal tissues (III) Milk	
55.	Rafoxanide	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
56.	Ronidazole	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
57.	Semduramycin Sodium	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
58.	Sulpha Chloropyrazine Sodium	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
59.	Sulphaquinoxaline	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
60.	Suramin	(I) All edible animal tissue (II) Fats derived from animal	0.01

(1)	(2)	(3)	(4)
		tissues (III) Milk	
61.	Thiabendazole ²	Cattle Muscle Liver Kidney Fat Milk Pig Muscle Liver Kidney Fat Sheep Muscle Liver Kidney Fat Goat Muscle Liver Kidney Fat Milk	 0.1 0.1 0.1 0.1 0.1 mg/l 0.1 0.1 0.1 0.1 0.1 0.1 0.1 0.1 0.1 0.1 0.1 0.1 0.1 mg/l
62.	Tiamulin Hydrogen Fumarate	(I) All edible animal tissue (II) Fats derived from animal tissues	0.01

(1)	(2)	(3)	(4)
		(III) Milk	
63.	Totrazuril	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
64.	Tylvalosin tartrate	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
65.	Triclabendazole	Cattle	
		Muscle	0.25
		Liver	0.85
		Kidney	0.4
		Fat/Skin	0.1
		Sheep	
		Muscle	0.2
		Liver	0.3
		Kidney	0.2
		Fat/Skin	0.1
66.	Xylazine HCl	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
67.	Clorsulon	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01

(1)	(2)	(3)	(4)
68.	Diminazene Diaceturate (Diminazene)	Cattle	
		Muscle	0.5
		Liver	12
		Kidney	6
		Milk	0.15 mg/l
69.	Hydrocortisone	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
70.	Phenazone	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
71.	Praziquantel	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
72.	Quinapyramine sulphate	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
73.	Cefpactril Sodium	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
74.	Chlorpyridazine Sodium	(I) All edible animal tissue (II) Fats derived	0.01

(1)	(2)	(3)	(4)
		from animal tissues (III) Milk	
75.	Coligen	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
76.	Doramectone	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01
77.	Tiaprost Trometamoal	(I) All edible animal tissue (II) Fats derived from animal tissues (III) Milk	0.01