

F. No. 1-100/SP(PAR)- Notification/Enf/FSSAI/2014(part file)  
**Food Safety and Standards Authority of India**  
(A Statutory Authority established under the Food Safety & Standards Act, 2006)  
(Regulation division)  
**FDA Bhawan, Kotla Road, New Delhi-110 002**

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Dated, the 29<sup>th</sup> March, 2019

**Subject: Direction under Section 16 (5) of Food Safety and Standards Act, 2006 regarding compliance of Food Safety and Standards (Contaminants, toxins and Residues) Second Amendment Regulations, 2018 published in the Official Gazette of India on dated 20th July, 2018 vide Notification No. 1-100/SP(PAR)- Notification/Enf/FSSAI/2014.**

Reference is drawn to Food Safety and Standards (Contaminants, toxins and Residues) Second Amendment Regulations, 2018 published in the Official Gazette of India dated 20th July, 2018 vide Notification No. 1-100/SP(PAR)-Notification/Enf/FSSAI/2014. Based on the representation received from various stakeholders highlighting some important technical issues, the time line for compliance of said Food Safety and Standards (Contaminants, toxins and Residues) Second Amendment Regulations, 2018 was further extended up to 1<sup>st</sup> April, 2019.

2. Meanwhile, inputs/ representations were received from the stakeholders in respect of the challenges in complying with Tolerance Limits of the antibiotics and veterinary drugs and the same were referred to the Scientific Panel on Antibiotic Residues. Based on the recommendation of the Panel and with the approval of the competent authority the following has been decided:

3. Clause (2) of sub-regulation 2.3.2 of said amendment regulation and tolerance limit of 43 antibiotics and veterinary drugs for the food mentioned in clause (4) of sub-regulation 2.3.2 of said amendment regulation listed in Annexure-1(for which panel has not recommended any change) shall be enforced from 1<sup>st</sup> April, 2019.

4. However, compliance for other antibiotics and veterinary drugs of clause (4) is extended till further order. Meanwhile, the Food Authority will continue working on the regulation in respect of the remaining antibiotic/ Veterinary drugs for their possible deletion or changes in Tolerance limits or changes in antibiotic/ Veterinary drug-commodity combination. However, such modifications, if any, on the regulation shall follow the due process of amendment including stakeholders consultation.

5. This issues with the approval of the Competent Authority in exercise of the power vested with Food Authority under Section 16(5) of Food Safety and Standards Act, 2006.

(Pawan Agarwal)  
Chief Executive Officer, FSSAI

To

1. All Food Safety Commissioner
2. All Authorised Officer, FSSAI
3. All Central Designated Offices of FSSAI

Copy for information to:

1. PPS to Chairperson, FSSAI
2. PS to CEO, FSSAI
3. All Directors, FSSAI

Annexure-1

“(4) The antibiotics and veterinary Drugs specified in column (2) shall not exceed the tolerance limit specified in column (4) for the article of food in column (3) of the Table below, namely: -

S. No.	Name of the antibiotics and veterinary drugs	Food	Tolerance limit (mg/Kg)
(1)	(2)	(3)	(4)
1.	Ampicillin	(I) All edible animal tissues (II) Fats derived from animal tissues (III) Milk	0.01
2.	Amprolium	(I) All edible animal tissues except fish (II) Fats derived from animal tissues	0.01
3	Apramycin	(I) All edible animal tissues except fish (II) Fats derived from animal tissues (III) Milk	0.01
4.	Albendzole	Species not specified	
		Muscle	0.1
		Liver	5.0
		Kidney	5.0
		Fat	0.1
		Milk	0.1
		Fish	0.1
5.	Cloxacillin	(I) All edible animal tissues (II) Fats derived from animal tissue	0.01
6.	Chlortetracycline/Oxy tetracycline/Tetracycline	Cattle	
		Muscle	0.2
		Liver	0.6
		Kidney	1.2
		Milk	0.1
		Muscle	0.2
		Giant prawn( <i>Paeneus monodon</i> )(muscle)	0.2
		Pig	
		Muscle	0.2

S. No.	Name of the antibiotics and veterinary drugs	Food	Tolerance limit (mg/Kg)	
(1)	(2)	(3)	(4)	
		Liver	0.6	
		Kidney	1.2	
		Poultry		
		Muscle	0.2	
		Liver	0.6	
		Kidney	1.2	
		Eggs	0.4	
		Sheep		
		Muscle	0.2	
		Liver	0.6	
		Kidney	1.2	
		Milk	0.1	
		7.	Ceftiofur	Cattle
Muscle	1.0			
Liver	2.0			
Kidney	6.0			
Fat	2.0			
Milk	0.1 mg/l			
Pig				
Muscle	1.0			
Liver	2.0			
Kidney	6.0			
Fat	2.0			
8.	Cephapirine	(I) All edible animal tissues except in fish.	0.01	
		(II) Fats derived from animal tissues		
9.	Clopidol	(I) All edible animal tissues except in fish.	0.01	
		(II) Fats derived from animal tissues		
10.	Closantel	Cattle		
		Muscle	1.0	
		Liver	1.0	
		Kidney	3.0	
		Fat	3.0	
		Sheep		
		Muscle	1.5	
		Liver	1.5	
Kidney	5.0			
Fat	2.0			
11.	Cefphactril	(I) All edible animal tissues except fish.	0.01	
		(II) Fats derived from animal tissues		
		(III) Milk		

S. No.	Name of the antibiotics and veterinary drugs	Food	Tolerance limit (mg/Kg)
(1)	(2)	(3)	(4)
12.	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		
13.	Doramectin	Cattle	
		Muscle	0.01
		Liver	0.1
		Kidney	0.03
		Fat	0.15
		Milk	0.015
		Pig	
		Muscle	0.005
		Liver	0.1
		Kidney	0.03
Fat	0.15		
14.	Diminazene	Cattle	
		Muscle	0.5
		Liver	12.0
		Kidney	6.0
		Milk	0.15
15.	Erythromycin	Chicken	
		Muscle	0.1
		Liver	0.1
		Kidney	0.1
		Fat	0.1
		Eggs	0.05
		Turkey	
		Muscle	0.1
		Liver	0.1
		Kidney	0.1
Fat	0.1		
16.	Flumequine	Cattle	
		Muscle	0.5
		Liver	0.5
		Kidney	3.0

S. No.	Name of the antibiotics and veterinary drugs	Food	Tolerance limit (mg/Kg)	
(1)	(2)	(3)	(4)	
		Fat	1.0	
		Chicken		
		Muscle	0.5	
		Liver	0.5	
		Kidney	3.0	
		Fat	1.0	
		Pig		
		Muscle	0.5	
		Liver	0.5	
		Kidney	3.0	
		Fat	1.0	
		Sheep		
		Muscle	0.5	
		Liver	0.5	
		Kidney	3.0	
		Fat	1.0	
		Trout		
		Muscle	0.5	
		17.	Flunixin	(I) All edible animal tissues except fish (II) Fats derived from animal tissues (III) Milk
18.	Febantel/Fenbendazole/Oxyfendazole	Cattle		
		Muscle	0.1	
		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			

S. No.	Name of the antibiotics and veterinary drugs	Food	Tolerance limit (mg/Kg)
(1)	(2)	(3)	(4)
19.	Ivermectin	Cattle	
		Milk	0.01
		Liver	0.8
		Fat	0.4
		Muscle	0.03
		Kidney	0.1
		Pig	
		Liver	0.015
		Fat	0.02
		Sheep	
		Liver	0.015
		Fat	0.02
		20.	Lincomycin
Milk	0.15		
Chicken			
Muscle	0.2		
Liver	0.5		
Kidney	0.5		
Fat	0.1		
Pig			
Muscle	0.2		
Liver	0.5		
Kidney	1.5		
Fat	0.1		
21.	Levamisole		
		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	

S. No.	Name of the antibiotics and veterinary drugs	Food	Tolerance limit (mg/Kg)
(1)	(2)	(3)	(4)
		Muscle	0.01
		Liver	0.1
		Kidney	0.01
		Fat	0.01
22.	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
		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
23.	Moxidectin	Cattle	
		Muscle	0.02
		Liver	0.1
		Kidney	0.05
		Fat	0.5
		Sheep	
		Muscle	0.05
		Liver	0.1
		Kidney	0.05

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S. No.	Name of the antibiotics and veterinary drugs	Food	Tolerance limit (mg/Kg)
(1)	(2)	(3)	(4)
		Fat	0.5
24.	Meloxicam	(I) All edible animal tissues except fish (II) Fats derived from animal tissues (III) Milk	0.01
25.	Neomycin	Cattle	
		Liver	0.5
		Milk	1.5
		Kidney	10
		Fat	0.5
		Muscle	0.5
		Chicken	
		Liver	0.5
		Eggs	0.5
		Muscle	0.5
		Kidney	10
		Fat	0.5
		Duck	
		Fat	0.5
		Liver	0.5
		Kidney	10
		Muscle	0.5
		Goat	
		Liver	0.5
		Kidney	10
		Fat	0.5
		Muscle	0.5
		Pig	
		Kidney	10
		Liver	0.5
		Muscle	0.5
		Fat	0.5
		Sheep	
		Kidney	10
		Muscle	0.5
		Fat	0.5
		Liver	0.5
		Turkey	
		Liver	0.5
		Muscle	0.5
		Kidney	10
		Fat	0.5
26.	Nicarbazin	Chicken	

S. No.	Name of the antibiotics and veterinary drugs	Food	Tolerance limit (mg/Kg)
(1)	(2)	(3)	(4)
		Kidney	0.2
		Fat/Skin	0.2
		Liver	0.2
		Muscle	0.2
27.	Oxybendazole	(I) All edible animal tissues except in Fish (II) Fats derived from animal tissues	0.01
28.	Oxyclozanide	(I) All edible animal tissues except Fish (II) Fats derived from animal tissues (III) Milk	0.01
29.	Parbendazole	(I) All edible animal tissues except Fish (II) Fats derived from animal tissues (III) Milk	0.01
30.	Praziquantel	(I) All edible animal tissues except Fish (II) Fats derived from animal tissues (III) Milk	0.01
31.	Spectinomycin	Cattle	
		Muscle	0.5
		Liver	2.0
		Kidney	5.0
		Fat	2.0
		Milk	0.2 mg/l
		Chicken	
		Muscle	0.5
		Liver	2.0
		Kidney	5.0
		Fat	2.0
		Eggs	2.0
		Pig	
		Muscle	0.5
		Liver	2.0
		Kidney	5.0
		Fat	2.0
		Sheep	
		Muscle	0.5
		Liver	2.0

S. No.	Name of the antibiotics and veterinary drugs	Food	Tolerance limit (mg/Kg)
(1)	(2)	(3)	(4)
		Kidney	5.0
		Fat	2.0
32.	Sulfadiazine	(I) All edible animal tissues (II) Fats derived from animal tissues (III) Milk	0.01
33.	Sulfanilamide	(I) All edible animal tissues (II) Fats derived from animal tissues (III) Milk	0.01
34.	Sulfaquinoxaline	(I) All edible animal tissues except fish (II) Fats derived from animal tissues (III) Milk	0.01
35.	Sulfadimidine	Cattle	
		Milk	0.025
		No Specified	
		Muscle	0.1
		Fat	0.1
		Kidney	0.1
		Liver	0.1
36.	Sulfa Chloropyrazine	(I) All edible animal tissues except fish (II) Fats derived from animal tissues (III) Milk	0.01
37.	Thiabendazole	Cattle	
		Muscle	0.1
		Liver	0.1
		Kidney	0.1
		Fat	0.1
		Milk	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
		Fat	0.1
		Goat	
		Muscle	0.1

S. No.	Name of the antibiotics and veterinary drugs	Food	Tolerance limit (mg/Kg)
(1)	(2)	(3)	(4)
		Liver	0.1
		Kidney	0.1
		Fat	0.1
		Milk	0.1
38.	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
39.	Trimethoprim	(I) All edible animal tissues except fish (II) Fats derived from animal tissues (III) Milk	0.01
40.	Tylosin	Cattle	
		Muscle	0.1
		Liver	0.1
		Kidney	0.1
		Fat	0.1
		Milk	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
		Kidney	0.1
		Fat/Skin	0.1
		Eggs	0.3
41.	Virginiamycin	(I) All edible animal tissues except in Fish (II) Fats derived from animal tissues	0.01

S. No.	Name of the antibiotics and veterinary drugs	Food	Tolerance limit (mg/Kg)
(1)	(2)	(3)	(4)
		(III) Milk	
42.	Xylazine	(I) All edible animal tissues except fish (II) Fats derived from animal tissues	0.01
43.	Zinc Bacitracin (minimum 60IU/mg dried substance)	(I) All edible animal tissues except in Fish (II) Fats derived from animal tissues	0.01