

E-mail

RG-15

GOVERNMENT OF RAJASTHAN  
DRUGS CONTROL ORGANISATION, SWASTHYA BHAWAN  
TILAK MARG, JAIPUR

No. DC/D-1/ Amend-41/ 2015/ 393

Dated:- 29/06/2015

All Asst. Drugs Controller,  
Rajasthan State,

Subj.:- Strict enforcement of drug control regulation in aquaculture –  
regarding.

Ref.:- Joint Drugs Controller (I), New Delhi letter No.  
BD/VET.CELL/ 16.2014 (Pt-1) Dt. 15.05.2015

Reference to subject cited above, Photocopies of letter with enclosures  
are hereby enclosed for compliance and necessary action.

Encl. As above

26/6/15

(K Jayawant)  
Drugs Controller  
Rajasthan, Jaipur  
Dated:-

No. DC/D-1/ Amend-41/ 2015/

Copy to :- Joint Drugs Controller (I), FDA Bhawan, Kotla Road, New Delhi in ref.  
of letter No. BD/VET.CELL/ 16.2014 (Pt-1) Dt. 15.05.2015

✓ Incharge, Sewer Room to pl. e-mail this letter  
with enclosure to all ADC's.

Encl.:- As above

(K Jayawant)  
Drugs Controller  
Rajasthan, Jaipur

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कायदा  
औषधि नियंत्रक (राज.) जयपुर  
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28 MAY 2015  
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V.G.S  
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BD/VET.CELL/16.2014(Pt-1)  
Directorate General of Health Services  
Central Drugs Standard Control Organization  
FDA Bhawan, Kotla Road, New Delhi  
O/o DCG(I)

Dated: 15 MAY 2015

To,  
All State/UT Drugs Controllers

Sub: Strict enforcement of drug control regulation in  
aquaculture-regarding.

Sir,

The Member Secretary, Coastal Aquaculture Authority, Ministry of Agriculture, Government of India has written to this office vide letter No. F. No. 57-09/2010-Tech dated 08/01/2015 (Attached herewith) stating that the Coastal Aquaculture Authority has notified in the guidelines for Regulating Coastal Aquaculture (Annexure I to CAA Rules, 2005). It contains the list of antibiotics and other pharmacologically active substances banned for use in shrimp culture and the Maximum Permissible Residue Levels for Fish and Fishery Products.

This is being forwarded herewith for necessary action.

Yours Faithfully,

V.G.S

(Dr. V.G.Somani)

Joint Drugs Controller (India)

Copy to:

1. All Zones/ Sub Zones of CDSCO for necessary follow up with the concerned licensing authorities located under your jurisdiction
2. Member Secretary, Coastal Aquaculture Authority, Ministry of Agriculture, Government of India, 2<sup>nd</sup> Floor, Shastri Bhawan Annexe, No. 26, Haddows Road, Chennai-600006
3. Under Secretary (Drugs), Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi.
4. Veterinary Council of India A- Wing, IInd Floor, August Kranti Bhawan, Bhikaji Cama Place, New Delhi - 110066

Cr No-2

FTS-2808/21412/19/1/14

तटीय जलकृषि प्राधिकरण  
कृषि मंत्रालय  
भारत सरकार



दूसरी मंजिल, शास्त्री भवन अनेक्स  
स.26, हडोस रोड, चेन्नै-600 006  
तमिलनाडु, भारत

2<sup>nd</sup> Floor, Shastri Bhavan Annexe  
No.26, Haddows Road, Chennai - 600 006  
Tamil Nadu, INDIA.

COASTAL AQUACULTURE AUTHORITY  
Ministry of Agriculture  
Government of India

दूरभाष / Phone : +91 44 2821 3785  
फैक्स / Fax : +91 44 2821 6552, 2825 0956  
ईमेल / e-mail : aquaauth@vsnl.net, aquvaaauth@bsnl.in  
वेबसाइट / Website : http://www.caa.gov.in

F. No. 57-09/2010-Tech.

Dated the 8<sup>th</sup> January, 2015.

To

✓ **Dr. G.N. Singh,**  
Drug Controller General (India),  
Central Drugs Standard Control Organization,  
CDSCO Headquarters, FDA Bhavan, Kotla Road,  
**NEW DELHI -110 002.**  
Tel. No. 011-2323 6965/Fax No.: 2323 6973.  
E-mail: dci@nic.in.

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*DI (Urney)*

Sir,

Sub: Strict enforcement of drug control regulations in aquaculture – Regarding.

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The use of antibiotics and other pharmacologically active substances in various culture activities needs to be closely monitored, primarily from the food safety point of view as well as from the export angle. The need to have an effective system in place for drug control throughout the country is increasingly felt to ensure safety of fish and fishery products exported from the country which in turn would contribute to the sustainability of aquaculture production/ exports and also to protect the livelihood of the shrimp/fish farmers.

In this context, it may be pointed out that the health authorities of major importing countries frequently visit India to assess the standards and condition on the use of chemicals and antibiotics prevalent in the primary production sector both capture and culture. The developed countries impose stringent control measures on imports to ensure safety of the consumer arising out of use of such drugs present in the food products.

The use of antibiotics in shrimp culture is strictly prohibited as their use may result in development of human pathogens resistant to such drugs which will pose serious threat to human beings. In view of this, the Coastal Aquaculture Authority, established under an Act of Parliament, viz. The Coastal Aquaculture Authority Act, 2005 has already notified in the Guidelines for Regulating Coastal Aquaculture (Annexure I to CAA Rules, 2005) the list of antibiotics and other pharmacologically active substances banned for use in shrimp culture as well as the Maximum Permissible Residue Levels for Fish and Fishery Products (copy enclosed).

The above facts are brought to your kind notice with a request to instruct the pharmaceutical companies not to sell these banned antibiotics and drugs to shrimp farms and hatcheries. Action taken on this matter may kindly be intimated to us to apprise the Members of the Authority regarding implementation of this ban.

Encl.: As stated above.

Yours faithfully,  
*P. Ravichandran*  
8/1/2015  
(P. Ravichandran)  
Member Secretary

**Table 5 : List of Antibiotics and other pharmacologically active substances banned for using in shrimp aquaculture**

Sl. No.	Antibiotics and other Pharmacologically Active Substances
1	Chloramphenicol
2	Nitrofurans including : Furaltadone, Furazolidone, Furfuramide, Nifuratel, Nifuroxime, Nifurprazine, Nitrofurantoin, Nitrofurazone
3	Neomycin
4	Nalidixic acid
5	Sulphamethoxazole
6	Aristolochia spp and preparations thereof
7	Chloroform
8	Chlorpromazine
9	Colchicine
10	Dapsone
11	Dimetridazole
12	Metronidazole
13	Ronidazole
14	Ipronidazole
15	Other nitroimidazoles
16	Clenbuterol
17	Diethylstilbestrol (DES)
18	Sulfonamide drugs (except approved Sulfadimethoxine, Sulfabromomethazine and Sulfaethoxypyridazine)
19	Fluroquinolones
20	Glycopeptides

**Appendix**  
**Maximum Permissible Residual Levels**  
**for Fish and Fishery Products**

**A. Antibiotics and other Pharmacologically Active Substances**

Substance	Maximum Permissible Residual Level (ppm)
1. Chloramphenicol	Nil
2. Nitrofurans including : Furaladone, Furazolidone, Furylfuramide, Nifuratel, Nifuroxime, Nifurprazine, Nitrofurantoin, Nitrofurazone	Nil
3. Neomycin	Nil
4. Nalidixic acid	Nil
5. Sulphamethoxazole	Nil
6. Aristolochia spp. and preparations thereof	Nil
7. Chloroform	Nil
8. Chlorpromazine	Nil
9. Colchicine	Nil
10. Dapsone	Nil
11. Dimetridazole	Nil
12. Metronidazole	Nil
13. Ronidazole	Nil
14. Iprnidazole	Nil
15. Other nitroimidazoles	Nil
16. Clenbuterol	Nil
17. Diethylstilbestrol (DES)	Nil
18. Sulfonamide drugs (except approved Sulfadimethoxine, Sulfabromomethazine and Sulfaethoxyipyridazine)	Nil
19. Fluroquinolones	Nil
20. Glycopeptides	Nil
21. Tetracycline	0.1
22. Oxytetracycline	0.1
23. Trimethoprim	0.05
24. Oxolinic acid	0.3

Substance	Maximum Permissible Residue Levels (ppm)
<b>B. Substances having anabolic effect and unauthorised substances</b>	
1. Stilbenes, stilbene derivatives and their salts and esters.	Nil
2. Steroids	Nil
<b>C. Veterinary drugs</b>	
1. Antibacterial substances, including quinolones	Nil
2. Anthelminthic	Nil
<b>D. Other substances and environmental contaminants</b>	
1. Organochlorone compounds including PCBs	Nil
2. Mycotoxins	Nil
3. Dyes	Nil
4. Dioxins	4 picogram per gram, fresh weight
<b>E. Pesticides</b>	
1. BHC	0.3
2. Aldrin	0.3
3. Dieldrin	0.3
4. Endrin	0.3
5. DDT	5.0
<b>F. Heavy Metals</b>	
1. Mercury	1.0
2. Cadmium	3.0
3. Arsenic	75.0
4. Lead	1.5
5. Tin	250.0
6. Nickel	80.0
7. Chromium	12.0