

# RESPONSIBLE USE OF DRUGS IN COASTAL AQUACULTURE



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# BACKGROUND

- Antibiotics are drugs of natural or synthetic origin that have the capacity to kill or to inhibit the growth of microorganisms. Abs sufficiently non-toxic to the host are used as chemotherapeutic agents in the treatment of infectious diseases of humans/ animals/ plants.
- Needed in treatments of diseases in animals, fish/ other aquatic animals caused by bacteria/ other microorganisms.
- Occurrence of antibiotic residues and development of antimicrobial resistance in food producing animals created food safety concerns in humans.
- Though many national/ International govts. including FAO, WHO have raised the issue of irresponsible use of abs in production sectors, aquaculture sector has not witnessed control over antibiotic use.
- Many govts. around the world have introduced/ changed/ tightened national regulations on use of abs in general and particularly in aquaculture sector.

# 1. Origin of Antibiotics in Seafoods

- *As in other animal production sectors, abs are used in aquaculture during production and processing, mainly to prevent (prophylactic use) or treat (therapeutic use) bacterial diseases.*
- *Frequency of using antibiotics and or chemicals are reported from farms, hatcheries & processing units.*
- Use of poultry feed wherein antibiotic is an ingredient
- Hatcheries use to avoid/ treat microbial infections in water storage & when larval / pl developments hampered
- Enrichment of live larval feeds with antibiotics to enhance quality (bio-encapsulation)
- Egg custard in hatcheries (larval feed)
- Bactericide mixtures for disinfection are used in food, fish processing equipments

# Antibiotics in Indian Aquaculture

- Many unsustainable technologies/ practices resorted to during transformation of traditional system to commercial enterprise
- To sustain higher levels of intensification, farmers resorted to indiscriminate use of wide variety of drugs/ chemicals/ probiotics/ antibiotics etc to enhance productivity of water, increase, promote resistance/ growth and protect against diseases like white spot virus etc in the larval and grow out stages.
- They were used largely out of ignorance and lack of awareness on their direct/ indirect impacts on the produce, environment and consumers.

# Impact of Antibiotic Residues

## DIRECT

- Nitrofurans are carcinogenic and known to cause cancer and many other serious diseases
- Antibiotics root out the entire population of micro fauna including the beneficial microbes
- Excessive exposure to Chloramphenicol on handling cause severe hazards including fatal aplastic anemia.

## INDIRECT

- Accumulation of residues pose risks to consumers
- Development of antibiotic resistance in bacteria pose risks in human disease treatments
- Seafood industry – Heavy economic loss
- Aquafarms
- Environment

# Impact of Antibiotic Residues on Seafood Consumers

- Cultured aquatic animals are consumed with high level of preference. antibiotic residues accumulated cause allergies / toxic effects.
- Residues of chloramphenicol cause aplastic anemia & leukemia - in turn lead to very serious bone marrow / infectious diseases (eg. hepatitis).
- Leads to antibiotic resistance in bacteria that are pathogenic to humans and eventually makes the antibiotics ineffective in treating specific microbial diseases in humans (eg. recent report on presence of antimicrobial-resistant *Salmonella* in seafoods)

## 2. World Fish Trade : Long Term Trends

- Seafood industry witnessed remarkable changes in the production and consumption of food fish over the last three decades.
- While capture fisheries is almost static, aquaculture production has been increasing to meet current global consumption.
- Aggregate fish consumption projected to grow at the rate of 1.5% in 2020
- Additional 40 million MT fish and seafood will be needed by 2030 just to sustain today's levels of consumption - FAO.
- Aquaculture production is expected to bridge the gap in future demand for food fish supplies (reaching about 50-60%).

### 3.Impacts of Antibiotics on SF Industry

#### Detention of Consignments

- While the expectations are so, detection of nitrofurans & other abs metabolites in internationally traded aquacultured products in the recent past has caused much concern
- Nitrofurans are forbidden to be used as vet. medicine in EU vide Council Regulation 2377/90 since 1993 (furazolidone in 1995)
- Resulted in slowdown of shrimp imports causing economic loss to producers
- Created negative reflections in farmed shrimps, fish and other aquaculture products.
- Many Indian seafood consignments were detained by EU due to the presence of antibiotic residues in cultured products.



# Classification of Notifications



**Alert Notification** – is sent when a food or feed presenting a serious risk is on the market when a rapid action is required – initiate required measures – withdrawal / recall



**Information Notification** – concerns a food or feed on which a risk has been identified, but does not require rapid action

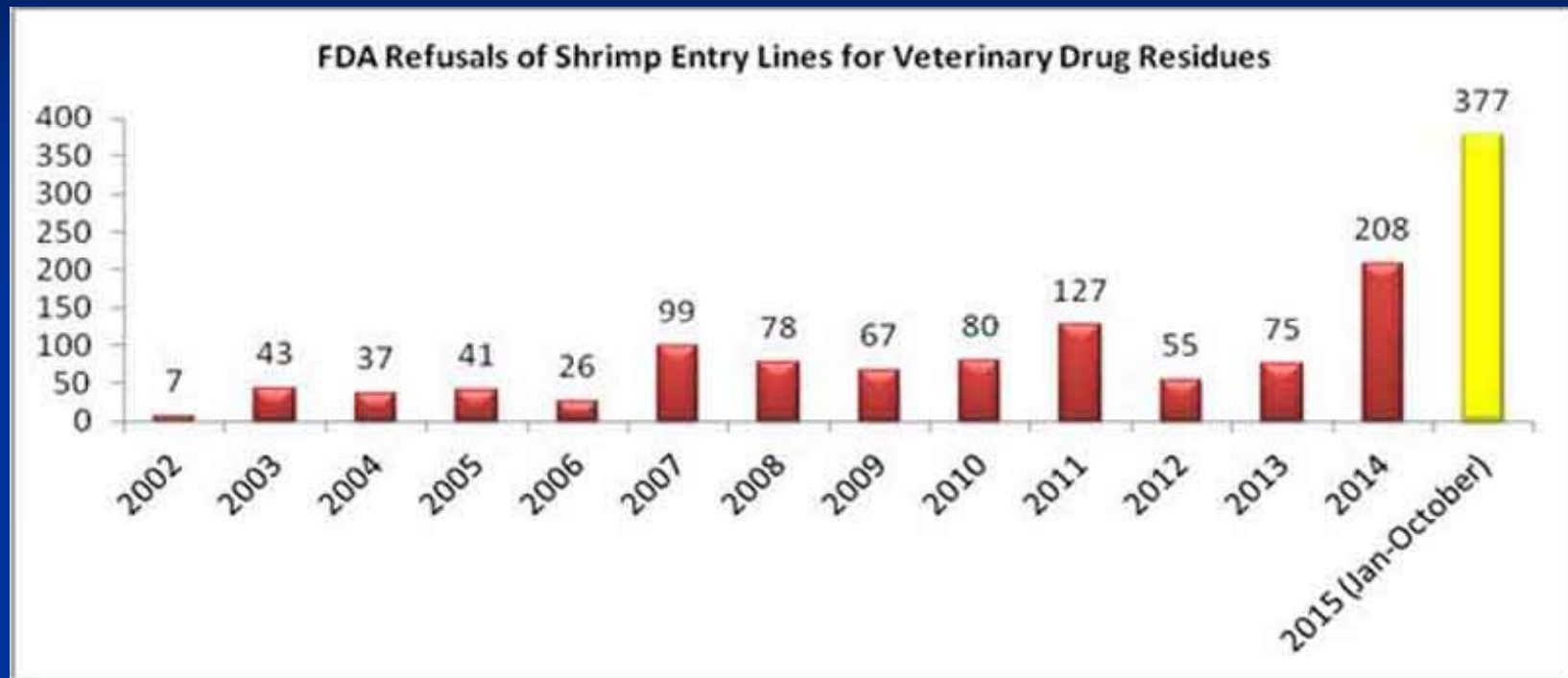


**Border rejections Notification** – concerns a food or feed that was refused entry in to the Community due to risk to human or animal health



**News Notification** -- concerns any type of information related to the safety of food or feed which has been communicated as an alert/Information/border rejection, but judged interesting for the food and feed control authorities in the Member states

## 4. FDA Refusals of Shrimps Entry Lines for Veterinary Drug Residues 2002-2015 (Oct)



- FDA's refusals of shrimp in 2015 substantially exceed the agency's actions over the prior thirteen years. As the table below indicates, the 377 shrimp refusals in just the first nine months of 2015 exceed the total number of refusals for the six years between 2002 and 2007, the four years between 2008 and 2011, and the three years between 2012 and 2014.

## 5. India's Position

Out of 17 shrimp refusals involved shipments from six different companies located in India, Malaysia and China., two were reported from India :

- ❑ A company (M/s. Key Key Exports) listed on Import Alert for nitrofurans on 17 September, 2015, but not currently listed on Import Alert, had two entry lines refused for shrimp contaminated with both nitrofurans and veterinary drug residues in the New York District.
- ❑ A company (M/s. RDR Exports) listed on Import Alert for nitrofurans on 9 October, 2015, but not currently listed on Import Alert, had one entry line refused for shrimp contaminated with nitrofurans in the Los Angeles District.
- ❑ Importantly, detentions were from a few specific locations.

## 6. Impacts of AB on SF Industry

### Huge **Economic Loss**

- The economic loss on rejections of seafoods due to antibiotic residues is very high.
- Indian seafood exports aggregated to 10,51,243 MT valued at Rs. 33,441.61 Cr (US\$.5511.12 mill) during 2014-2015 of which 3,57,505 MT were shrimps worth US\$. 3,709.76 mill (67.31% of export value)
- Shrimp Aquaculture Production 4,34,588 MT (76.45% of export value)
- USA, SEA countries, EU, Middle East and Japan are the other major markets for Indian shrimps.

# Impacts of AB on SF Industry

## Economic Loss (Cont.)

To satisfy the importers on the antibiotic levels the following steps are mandatory which involves heavy expenditure

- Residue Monitoring Plan to be submitted every year
- Regular FVO / USFDA inspections from EU/US on quality of seafood produced / processed.
- Mandatory tests for antibiotics on each consignment and certificate at the origin
- Controls tests on large number of samples on each consignment at EU borders & port of disembarkation – detention until completion very costly in fees and time
- Eg. in Belgium 7 tests samples for shipments up to 500 master cartons and 15 samples for shipments having 1200 to 3200 master cartons. The cost for analysis for chloramphenicol by GLC is about US\$ 120 per sample.

# Impacts of AB on SF Industry

## Economic Loss (Cont.)

- Stay of containers in demurrages for 2-4 weeks until the tests are completed – very expensive
- All crustacean consignments from India to EU must be analysed at origin for Nitrofurans and related substances (from October-2009)
- Proposal of EU to increase the imports product to be checked from 10 to 20% - could cause huge delays reaching the end consumers in addition to heavy expenditure on tests and demurrages
- Recent stipulation of EU on destroying cargos that exceed the MRLs rather than returning to the country of origin leading to total loss of value of the consignment. Certain other countries have also adopted such stipulation.

# Impact of Antibiotic Residues in Aquafarms

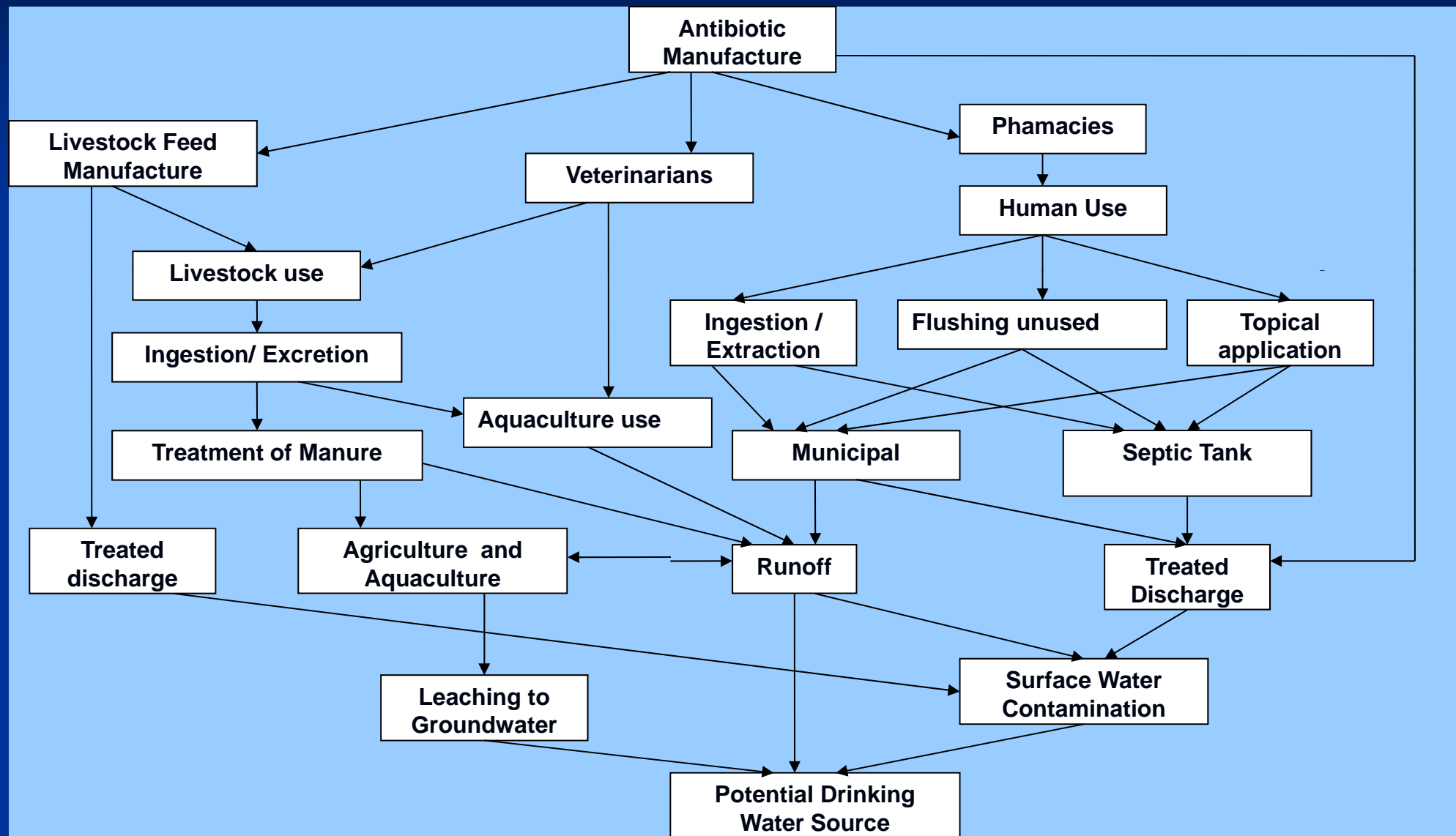
- Antibiotics root out the entire population of micro fauna including the beneficial microbes
- Stimulation of resistance - as bacterial pathogens of aquatic organisms grow with the surrounding temp, aquafarms in tropical regions have to be cautious.
- Nutrient enrichment
- Effect on sediment biochemistry
- Increased demand on antibiotics increases complexity of effluent treatment
- Health of farm workers
- International trade difficulties arising from drugs residues

# Impact of Antibiotics on Environment

- Discharge from aquafarms, veterinary impacts and human inputs are the main sources
- Veterinary excreta used as fertilizer (up to 75% of antibiotics in feed pass unaltered in feces).
- Resist biological decomposition (found to be intact in sewage sludge) & increases resistant bacterial load.
- Large portion of antimicrobials used in marine cage culture reached sediments below cages, antimicrobial resistance developed in sediment bacteria & persisted.
- Development of transferable antimicrobial resistance by fish pathogens and environ bacteria - in *Vibrio* and *Pseudomonas* isolates of sediments beneath cage sites
- Toxicity and resistance to non-target species, the impact being more in breeding grounds.



# Antibiotics in the Environment



## 7. Govt Norms on Antibiotics and Pharmacologically Active Substances

**Due to the ill effects of residues of antibiotics & other pharmacologically active substances in humans, Govt of India vide order No.722(E) dated 10-07-2002 of the Ministry of Commerce & Industries has banned the use of 20 antibiotics and other PA substances in the culture, hatchery feeds, pre-processing / processing of seafoods and their prescribed Maximum Permissible Residual Levels (MRLs) is ‘ *NIL* ’**

## 8. List of Banned Antibiotics and other Pharmacologically Active Substances

1. All Nitrofurans including Furaladone, Furazolidone, Furfylfuramide, Nifuratel, Nifursoxime, Nifurprazine, Nitrofurantoin, Nitrofurazone, all their derivatives
2. Chloramphenicol
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. Diethylstilbesterol (DES)
18. Fluroquinolones
19. Sulfonamide drugs (except approved sulfadimethoxine, sulfabromomethazine and sulfaethoxyrpyidazine)
20. Glycopeptides

## 9. MPRLs Stipulated by the Govt. on Certain ABs & PA Substances

Government of India vide the same order notified the Maximum Residual Limits (MRLs) for certain antibiotics and other pharmacologically active substances in fish and fishery products as given below which may be revised by the Govt from time to time:

A Antibiotics and PA Substances			
SI No	Antibiotics	MRL (ppm)	Remarks
1	Tetracycline	0.10	However, if the MRLs fixed by the importing countries are more stringent than the prescribed limits, the standards specified by those countries will be compiled with.
2	Oxytetracycline	0.10	
3	Trimethoprim	0.05	
4	Oxolinic Acid	0.30	

# 10. MPRLs Stipulated by the Govt. on Certain ABs & PA Substances (Cont)

B.	Substances having anabolic effect and unauthorized substances	MRL (ppm)
1	Stilbenes, stilbene derivatives and their salts & esters.	Nil
2	Steroids	Nil
C.	Veterinary Drugs	
1	Antibacterial substances, including quinolones	Nil
2	Anthelmintic	Nil
D.	Other Substances and Environmental Contaminants	
1	Organochlorine compounds including PCBs	Nil
2	Mycotoxins	Nil
3	Dyes	Nil
4	Dioxins	4 picogram per gram, fresh weight

# 11. MPRLs Stipulated by the Govt. on Certain ABs & PA Substances (Cont)

E.	Pesticides	MRL (ppm)	F.	Heavy Metals	MRL (ppm)
1	BHC	0.3	1	Mercury	1.0
2	Aldrin	0.3	2	Cadmium	3.0
3	Dieldrin	0.3	3	Arsenic	75
4	Endrin	0.3	4	Lead	1.5
5	DDT	5.0	5	Tin	250
			6	Nickel	80
			7	Chromium	12

## 12. Responsible Use of Drugs

- **Aquaculture is still the fastest growing food-production sector, but disease is a primary constraint & severe restrictions imposed by buyer countries restrain farmers from use of drugs leads to crop loss.**
- **Responsible use of drugs is the need of the hour for sustainable aqua production & product trade.**
- **Could be achieved by enforcing appropriate regulatory procedures & development of quality assurance programs**
- **Implementing adequate risk management measures (by on-site inspection, verification of drug residues, vector analysis, feed control, future directions etc)**
- **Introduction of new grow-out techniques, use of beneficial chemicals & microbes, BMPs etc**

## 13. Regulation of Coastal Aquaculture

- The CAA was set up by the Govt of India to regulate coastal aquaculture by registration of farms and hatcheries.
- Implements Govt policies, guidelines & practices regulatory procedures etc. through code of practices
- Verification and confirmation of the farms in lieu to the CAA Act are done by the District and State level Committees
- Farms < 5 ha can practice modified extensive type of farming or improve/enhance the production through improved technologies
- Farms > 5 ha can have similar production but should have ETS with area not less than 10% of the total area
- Farms > 10 ha should have EMP and EIA



## 14. Regulation of Chemicals and Drugs

- Inspect shrimp hatcheries and coastal aquafarms to ensure that they conform to guidelines prescribed by government
- Ascertain their environmental impact; order demolition of any units causing damage to environment
- Set and enforce standards for inputs used in coastal aquaculture
- Conduct awareness and capacity building programs

# Schedule-II: Format for Testing of Samples for Antibiotics

## Form I - Notice of intention to have sample analyzed [See regulation 14(2)]

To

.....  
.....

Take notice that it is intended to have analysed the sample of \* .....  
..... which has been take today,  
the..... day of ..... from .....

\*Specify the place from where the sample is taken.

Name and designation of the .....  
person who takes the samples .....

(Seal)

Date .....

# Format for Testing of Samples

## Form II Memorandum to Govt Analyst [See regulation 14(5) (b)]

From

.....  
.....

To

Government Analyst,

.....  
.....

The portion of sample described below is sent herewith for analysis under section 12 of Coastal Aquaculture authority Act, 2005.

The portion of the sample has been marked by me with the following mark:

Details of the portion of sample taken.

Name and designation of persons who sends sample  
(Seal)

Date .....

# Format for Testing of Samples

## Form III Report by the Analyst [See regulation 14(6)]

Report No .....

Date .....

I hereby certify that I ..... the Analyst duly designated by the  
CAA Act received on the ..... day of ..... from\* .....  
..... a sample of ..... for analysis.

The seal/marks, were compared and they tallied/did not tally with the specimen  
seal/marks fit/not fit for analysis.

I have analyzed the aforementioned sample on ..... the result is as follows:

\*\* .....

Signed this ..... day of ..... address .....

Signature (Analyst)

To

.....

.....

\* Here write the names of the officer/authority from whom sample was obtained.

\* Here write full details of analysis and refer to method of analysis.

## 15. Steps Taken By CAA on Regulation of Chemicals and Drugs used coastal aqua

- Banned the use of the 20 antibiotics / chemicals in aquaculture and hatchery operations which were notified by Govt of India.
- Inspect coastal aquafarms and hatcheries with a view to ascertain their environmental impact; order demolition of any coastal aquafarm / hatchery which is causing pollution.
- Advocate practice of site specific farm health plan for routine preventive treatments with bio-secure facilities, regular monitoring & cluster approach, which reduces need for disinfection/ reactive treatments using drugs
- Creating awareness among the shrimp hatchery/ farm operators by conducting a series of campaigns through out the country and requested them to stop using banned antibiotics.
- Educate the farmers to resort to site specific, animal specific probiotics and bio-remediation methods in place of antibiotics
- Advocating the farmers to introduce BMPs/GAqPs (through clusters/ village-level approach) to avoid diseases / usage of antibiotics

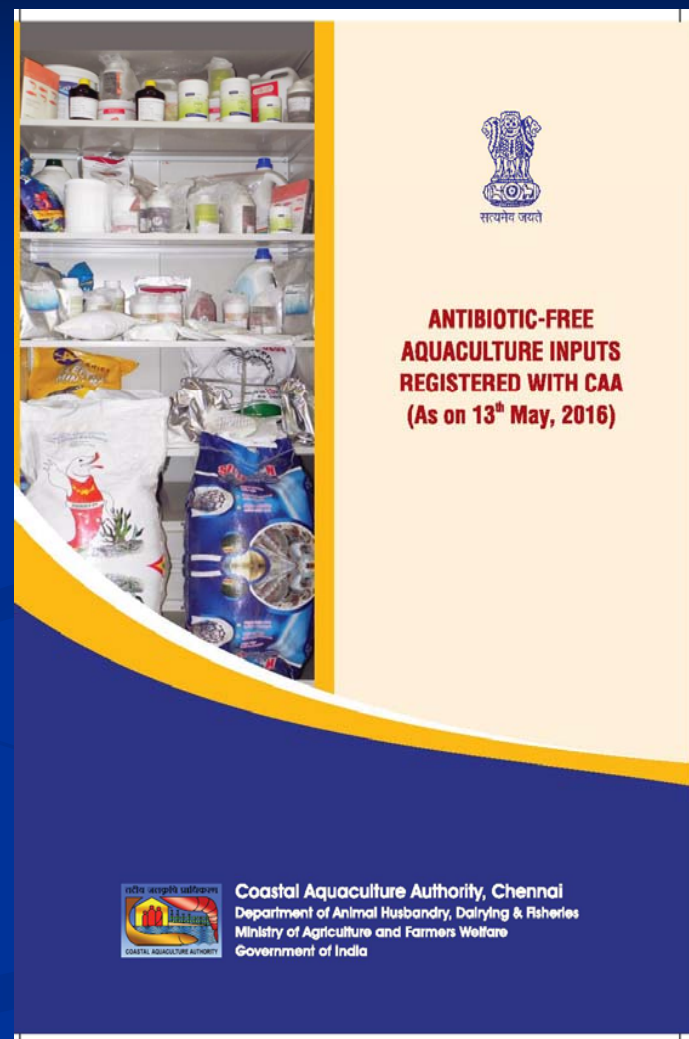
## 16. CAA on Regulation of Chemicals & Drugs

### **Registration of Antibiotic-free Aquaculture Inputs**

- Concerns raised by the DAHD&F and Department of Commerce as well as the Seafood Exporters over the reported large scale rejection of seafood meant for exports in recent times due to detection of antibiotics in the products
- The Authority at the 54<sup>th</sup> meeting held on 26<sup>th</sup> August 2015 decided to register all the aquaculture inputs to the effect that they are free of antibiotics of concern as per the provisions under the Coastal Aquaculture Authority Act, 2005 and Rules and Guidelines thereunder.
- A public notice to this effect as approved by the Authority was issued on 14<sup>th</sup> October, 2015 stating that the aqua farmers and hatchery operators will be permitted to use only the registered inputs in their facilities and consequently all manufacturers/ distributors of aquaculture inputs were directed to register each of their product with CAA by submitting test reports from accredited labs that they are free from the antibiotics of concern - Chloramphenicol & Nitrofurantoin parent compounds and metabolites [Furazolidone - AOZ, Furaltadone - AMOZ, Nitrofurantoin - AHD and Nitrofurazone (Semicarbazide) - SEM].

## 17. Registration of Antibiotic-free Aquaculture Inputs (Cont)

- ❑ The said products were registered under 8 categories in two lists, the first one on 16-02-2016 (258 products of 46 companies) and the second one updating the 1<sup>st</sup> list with additional products received till 13-05-2016
- ❑ A total of 654 products from 95 manufacturers/ distributors have been registered as antibiotic-free as on 13-05-2016 and Certificates of Registration were issued.
- ❑ The list of the said products was hosted in CAA website on 13-05-2016 and printed as a booklet which is being circulated among the coastal States and Central government officials, stakeholders and the companies who have registered their products.



## 18. Registration of Antibiotic-free Aquaculture Inputs

### List of Products Registered under Different categories

Batch	Period Regn	Total No. of Inputs Registered under various categories								Total No of Inputs	Total No. of Manufacturer/ Distributor
		Feed Additive	Probiotic	Feed Larva I	Feed Adult	Chemical	Disinfectant	Immunostimulant	Drug		
I	26-11-2015 to 16-02-2016	75	73	37	27	30	11	04	01	258	46
II	17-02-2016 to 13-05-2016	203	103	04	20	43	12	09	02	396	49
Total		278	176	41	47	73	23	13	03	654	95



## 19. Registration of Antibiotic-free Aquaculture Inputs

### Registration Under Progress

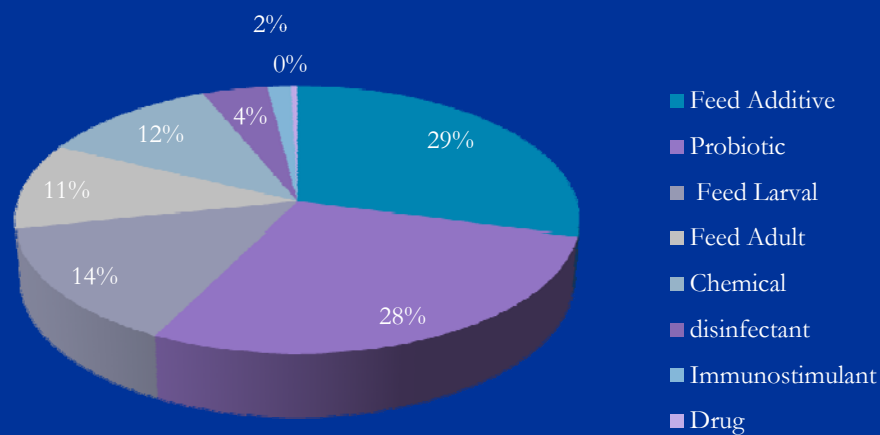
Processing of applications for the 3rd Batch of products for registration is under progress. Out of 165 applications received from 17<sup>th</sup> May till 20<sup>th</sup> September 2016, 165 products of 31 Manufacturers/ Distributors are qualified for registration on approval as detailed below:

Batch	Period Regn	Total No.of Inputsregistered under various categories								Total No of Inputs	Total No Manuf acturer /Distri butor
		Feed Additive	Probiotic	Feed Larval	Feed Adult	Chemical	Disinfectant	Immunostimulant	Drug		
III	16-05-2016 to 20-09-2016 (under Progress)	66	41	07	11	21	16	03	0	165	31

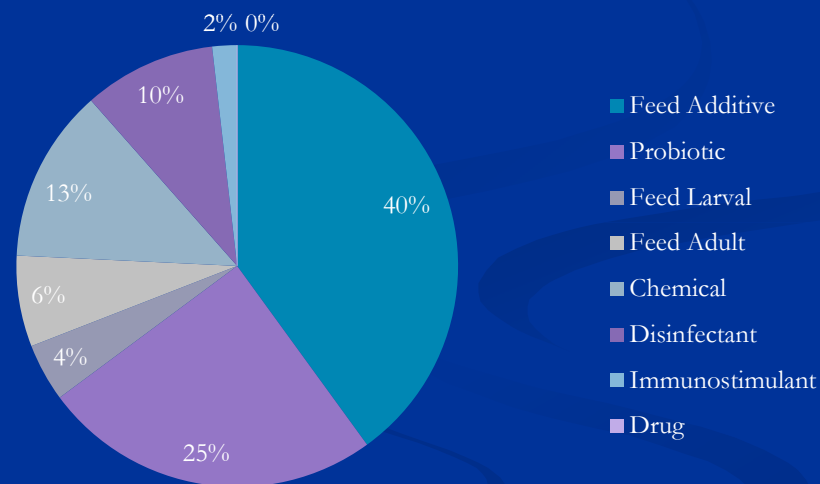
## 20. Registration of Antibiotic-free Aquaculture Inputs

### List of Products for which Registration is under Progress

Percentage of Inputs Registered  
Under different Categories



Percentage of Inputs Registration  
Under Progress



## 21. Steps Taken By CAA on Regulation of Chemicals and Drugs (Cont)

- **Creating awareness among the shrimp hatchery / farm operators by conducting a series of awareness programmes through out the country against the use of banned antibiotics.**
- **Educate the farmers to resort to site specific animal specific probiotics and bio-remediation methods in place of antibiotics**
- **Advocating the farmers to introduce BMPs (through clusters/ village-level approach) to avoid diseases / usage of antibiotics**





## BENEFICIAL CHEMICALS ALTERNATE TO ANTIBIOTICS

- Use of site specific, animal specific probiotics benefits in reducing disease/ improving production
- Iodine compounds help in reducing stress due to low DO (brown/pink gill problems)
- Use of zeolite (health stone) @ 200-400 kg/ha/week especially in the later stage of culture period benefit in absorbing  $\text{NH}_4$ ,  $\text{H}_2\text{S}$ ,  $\text{SO}_2$  &  $\text{CO}_2$ , bacteria, suspended dirty substances in pond. The cations in zeolite are mobile and capable of undergoing ion exchange. More effective in fresh water
- Use of alum @ 1- 10 ppm during culture period improves water quality by lowering turbidity of pond water and the suspended colloidal particles (pathogens & waste material). While dissolving, it reacts with water to produce Aluminum hydroxide, which precipitates to the pond bottom

# Issues of Ethoxyquin

- Japanese authorities rejected shrimps from India in June-August, 2012 on detection of ethoxyquin, to the level of 0.02-0.04 ppm against Japan's newly introduced health standards to levels up to 0.01 ppm.
- About 200 containers from countries including Vietnam were under rejection.
- Ethoxyquin is one of the most popular and an effective anti-oxidant used worldwide to avoid rancidity in fishmeal, an important component of shrimp feed.
- Hit aquaculture farmers and exporters in Odisha and West Bengal wherein 60 % of the black tiger shrimp produced in these regions is exported to Japan.
- The commerce ministry has rushed a delegation comprising Chairman & Resident director from MPEDA and the Director of EIC. However, large quantities of Indian seafood exports are still detained in Japan which has caused a setback to exports

# ROLE OF GAqPs/ BMPs IN RESPONSIBLE USE OF DRUGS IN AQUACULTURE

- Selection of good site with all required amenities
- Broodstock screening for potential size and to avoid vertical transmission of disease.
- Hatchery operation – single brooder treatment
- Bio-security measures to avoid vertical/ horizontal transmission of disease.
- Reservoirs and ETS for water intake/ treatment
- Pond preparation - Soil & Water Culture
- Seed selection (SPF), transportation, stocking
- Water quality management
- Pond bottom management
- Biological monitoring
- Feed management
- Shrimp Health management
- Maintenance of farmer group discipline
- Better harvest and post harvest handling
- Keeping farm daily record book
- Environmental awareness

# Advantages of BMPs in Aquaculture

- Optimal utilization of resources
- Optimization of production, productivity and returns
- Improving quality of produce and social acceptance (antibiotics, drugs, chemicals are avoided)
- Ecological sustainability
- Restrain salinization of fresh water.
- BMPs together with Cluster approach will improve food safety

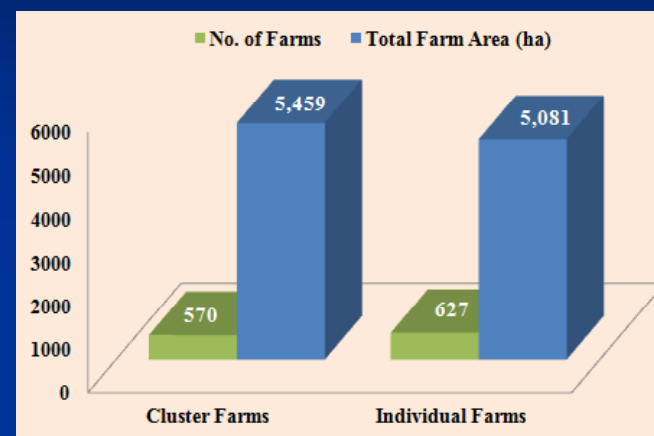


## 22.Cluster Management & Networking

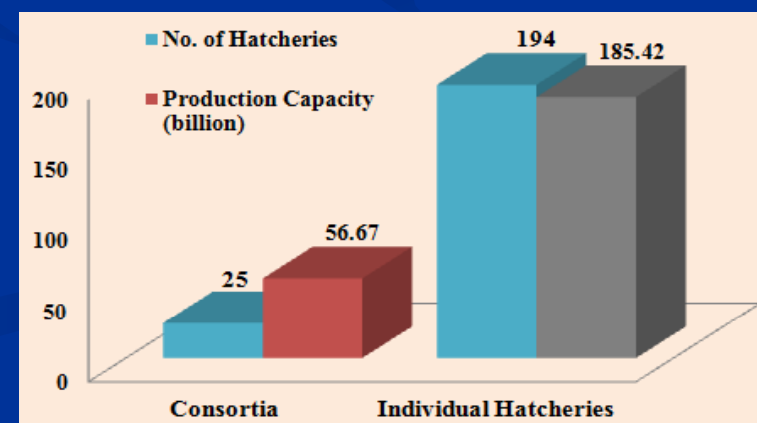
Shrimp farmers were motivated to form co-operatives / associations or self-help groups and formation of an Apex body of Shrimp Farmers associations in the State/ District

- Facilitates increased interaction between farmers and all the stakeholders (Farmers and hatchery, Farmers and processors / buyers, Farmers and government organisations, Farmers and scientists, Farmers and banks etc)
- Leads to exchange of technology, synchronised farming operations, supply of inputs, cooperation in water use & waste management, shrimp health management, common facilities for monitoring water quality , shrimp & feed, etc
- Better understanding of problems and issues through Networking and information sharing
- Cooperation in traceability / record maintenance
- Cooperation in harvesting to facilitate better harvest and post harvest practice sale of product etc.

Cluster farming in *L. vannamei*



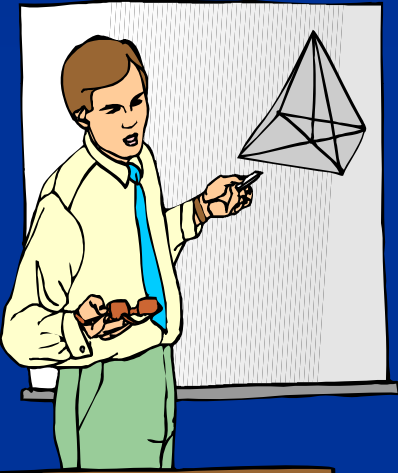
Consortia in SPF *L. vannamei* Hatcheries





## 23. Conclusion

The future of aquaculture depends on the production of safe and wholesome products, and not just more, cheap food.



- The information and knowledge base on the hazards/ risks involved in the use of antibiotics in aquaculture should be improved and communicated to the aqua farmers through information dissemination.
- BMPs in brood stock management, seed production and farming of fish/ shellfish should be taught to the farmers to enable them adopt drug-free aquaculture.
- Vision can be translated into reality only if the farmers, exporters and all other stake holders sincerely co-operate. Let us all work together to take advantage of the opportunities on the growing seafood demand through sustainable aquaculture.
- Future is positive for seafoods produced by BMPs.



**Come,  
Let us promote Sustainable Aquaculture  
for health, wealth and prosperity**

**COASTAL AQUACULTURE AUTHORITY  
(Dept of Animal Husbandry, Dairying & Fisheries)  
Ministry of Agriculture and Farmers Welfare  
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Thank you

