

Controlling Antibiotic Residues in Fish & Fishery Products



Design & Details of NRCP & PHT

-MPEDA



THE MARINE PRODUCTS EXPORT DEVELOPMENT AUTHORITY (MPEDA)

- **MPEDA is a Statutory body under the Ministry of Commerce & Industry, Govt. of India, entrusted with the overall development & promotion of export of fish and fishery products from the country.**
- **Involved in the development of infrastructure for fishing, aquaculture and processing activities**
- **Involved in ensuring traceability of fishery products exported.**

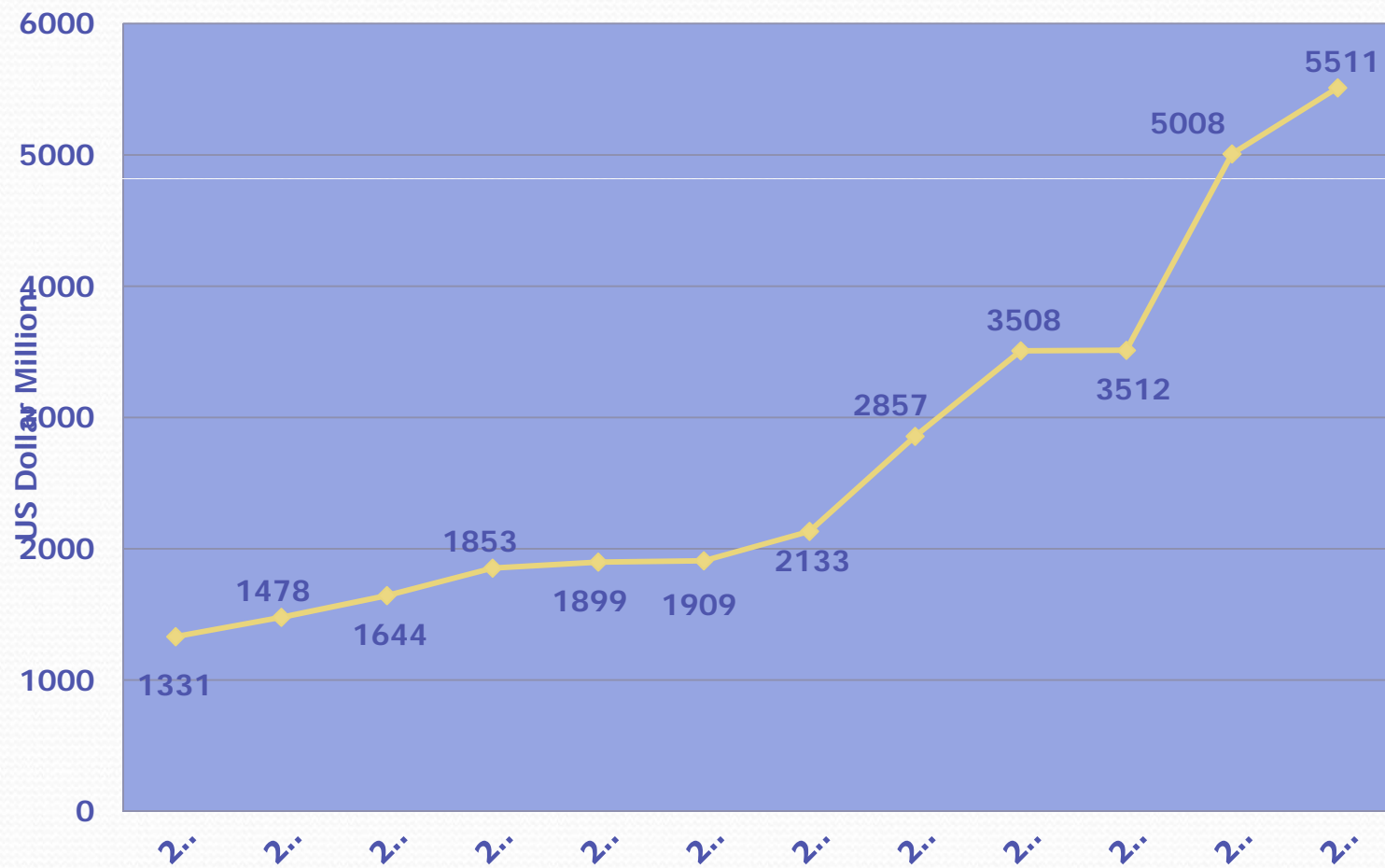


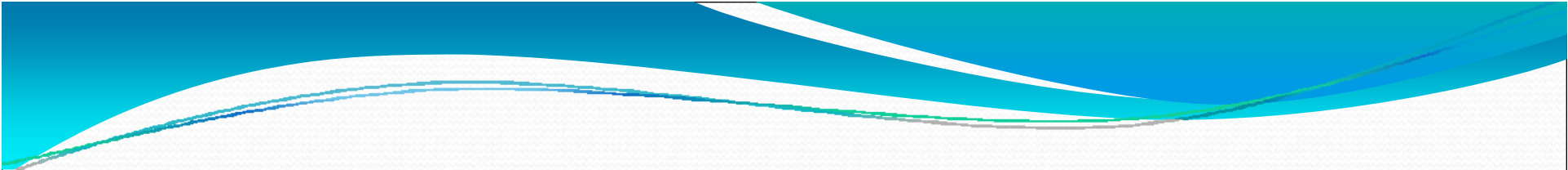
SOCIETIES UNDER MPEDA

- **RGCA** (Rajiv Gandhi Centre For Aquaculture) – Research & development
- **NETFISH** (Network for Fish Quality Management & Sustainable Fishing)- Extension education – Capture fisheries
- **NACSA** (National Centre for Sustainable Aquaculture) – Extension education for BAP/BMP, Aqua Societies

INDIAN SEAFOOD EXPORT

Export Performance since 2003-04 (in Mil. US\$)





Residue Control Measures implemented by MPEDA at primary production level:

- 1. National Residue Control Plan (NRCP) for aquaculture Products**
- 2. Pre-Harvest Testing (PHT) of aquaculture products.**

India's Residue Monitoring Programme (RMP):

- Started in the year 1998 as RMP.
- It is a mandatory requirement for exports to EU.
- The work was started with the analysis of pesticide & antibiotic residues.
- Analysis of other parameters were included in subsequent years.
- Subsequent to the visit of FVO mission in 2003 the name RMP was changed to National Residue Control Plan (NRCP).

MPEDA - Residue Control activities:

- Testing of samples under NRCP. (LC MSMS)
- Pre-harvest testing of Aquaculture produce (by ELISA/LC-MSMS).
- Awareness campaigns in aqua farming areas in all the maritime states.
- Monitoring of farming activities and hatchery operations.
- Promoting Sustainable Aquaculture through NaCSA & Societies.

MPEDA - Residue Control activities Contd:

- **Promoting Best Management Practices (BMPs) in aquaculture.**
- **Testing of hatchery seeds at hatchery level prior to release for culture to farmers.**
- **Designated Residue Monitoring Officers at all Regional offices & Regional Centers of MPEDA.**

NRCP - Role of Field Offices:

- Collection & dispatch of samples from the hatcheries/ farms / feed mills to the designated labs.
- Creating awareness among the farmers on the adverse effects due of usage of Antibiotics/VMPs in farming operations.
- Provide guidance/training to hatcheries to produce seeds without the usage of antibiotics.
- Investigation/surveillance of farms, hatcheries and processing plants, in case of non-compliant results

IMPLEMENTATION OF NRCP

Field Offices of MPEDA (28):

- Regional Centers - 7
- Sub-Regional Centers - 5
- Satellite Centers - 2
 - Sample collection
 - Communication of test results
 - Inspection of hatcheries / farms / feed mills
- Regional Offices - 6
- Sub-Regional offices - 8
 - Sample collection
 - Communication of test results
 - Inspection of processing plants

MPEDA Quality Control Laboratories –

❖ Labs involved in implementation of **NRCP & PHT**:

- (i) QC Laboratory - **Cochin** (Kerala)
- (ii) QC Laboratory - **Bhimavaram** &
- (iii) QC Laboratory- **Nellore** (Andhra Pradesh).

❖ **MPEDA Lab** involved in commercial operation:
(iv) **QC Laboratory, Bhubaneswar**
(operated on management contract by an NABL
accredited private lab).



The Labs are equipped with high precision analytical instruments like LC-MSMS, HPLC, GC, GC-MS/GC-MSMS, ICP-MS, AAS, etc

- The Labs are **NABL Accredited** (as per *ISO/IEC 17025:2005* - by *National Accreditation Board for Testing & Calibration Laboratories*, since 2006 onwards).
- All Labs are: - **EIC approved** also for testing of fish & fishery products (commercial samples) and
 - also **ISO 9001:2008 certified**.

National Residue Control Plan (NRCP) for Aquacultured Products:

Objectives:

- To establish a system for monitoring of the residues of Veterinary Medicinal Products (Aquaculture drugs) and Environmental contaminants.
- To establish a system of corrective actions and control in the event of residues/contaminants.
- To ensure that the aquaculture products exported from India meet the prescribed regulatory requirements of the importing countries like EU.

N R C P:

**Planning –
sampling strategy, sampling level etc**

**NRCP schedule
for Field Offices**

**Drawing of samples &
forwarding to the Lab**

Analysis of Samples

**Repeat of Test
in case
of positive cases
(for confirmation)**

Results (online)

***Alert Information (automatic)*
In case of Non-compliant sample**

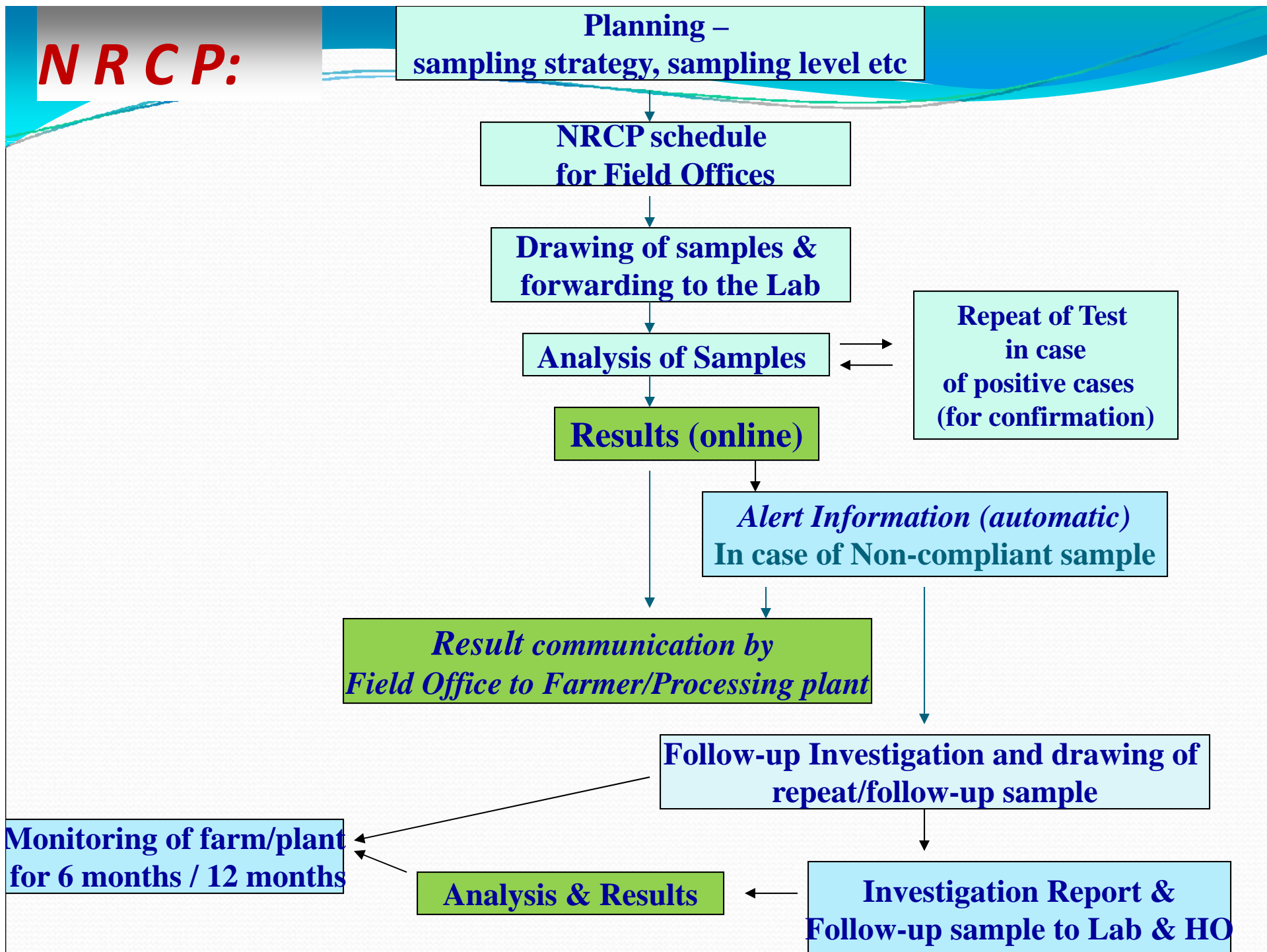
***Result communication by
Field Office to Farmer/Processing plant***

**Follow-up Investigation and drawing of
repeat/follow-up sample**

**Monitoring of farm/plant
for 6 months / 12 months**

Analysis & Results

**Investigation Report &
Follow-up sample to Lab & HO**



NRCP - Substances/Residues monitored

(ref: 96/23/EC – Annexe I & II)

- GROUP-A Substances * *(unauthorized substances, having anabolic effect used in Aquaculture):*

1. Group A1 - Stilbenes / Stilbene derivatives,

2. A3 - Steroids

3. A6 - (i) Nitrofurans metabolites

(ii) Chloramphenicol

(iii) Nitroimidazoles

(Compounds included in Annex IV to Council Regulation (EEC) No 377/90)

NRCP - Substances/Residues monitored (*cont'd....*)

- GROUP – B: (*VETERINARY DRUGS & ENVIRONMENTAL CONTAMINANTS*)

- Antibacterial substances,

(Group B1) Sulphonamides, TC/OTC/CTC, Oxolinic Acid, etc).

Other veterinary drugs

(B2a) Anthelmintics (Ivermectin)

Environmental contaminants & other substances

(B3a) Organochlorine Pesticides (11 compounds) &
Poly-Chlorinated Bi-phenyls (PCBs, - 6 compounds)

(B3c) Chemical Elements (Hg, Cd, As, Pb)

(B3d) Mycotoxins (Aflatoxins B1 & B2)

(B3e) Dyes (MG & LMG)

e-NRCP

Complete NRCP program is on line –

- All activities and documentation are done fully on-line.
- Test reports are generated on-line, on entering of analytical results and are transmitted automatically to the MPEDA Field Offices for communication to the Customers (Farmers/Hatcheries/Processing Plants).
- Separate alert information on residue positive (non-compliant) samples are also generated automatically and transmitted to the concerned Field Centers/Offices and EIC/EIAs.

Minimum sampling levels and frequencies:

(ref: 96/23/EC – Annexe: IV, Chapter 3.)

Group A: one third of the total samples:

- all the samples must be taken at farm level, at all stages of farming, including fish which is ready to be placed on the market.

Group B: two third of the total samples:

- the sampling should be carried out:
- (a) preferably at the farm, fish ready to be placed on the market for consumption;
- (b) either at the processing plant, or at wholesale level, on fresh fish, on condition that tracing-back to the farm of origin, in the event of positive results.

In all cases, samples taken at farm level shall be taken from a minimum of 10 % of registered sites of production and at least 1 per 100 tonnes of annual production.

NRCP - Sampling Pattern -Example

Type of sample	No. of farms enrolled with MPEDA	Aqua-culture Production (M/T)	Total throughput of EU approved processing plants (RM)	No. of hatcheries in operation & feed mills	No. of samples to be analysed	Criteria for sampling
(Shrimp) <i>P. monodon</i> , <i>P. indicus</i> & <i>L. Vannamei</i>	40177	327305	--	--	3984	Based on 10% of registered farms
<i>M. rosenbergi</i> (Scampi)		3546	--	--	36	1 sample per every 100 MT of production
Freshwater fishes	--	--	4412	--	45	based on throughput in approved export(EU) establishments (1:100)
TOTAL					4065	
Hatchery & Feed Samples						
Feed Samples	-	-	-	11	44	4 samples from each feed-mill.
Hatchery Seed	-	-	-	197	197	1 sample per every registered hatchery.
GRAND TOTAL					4306	

Type of Sample	Total number of samples to be tested	Break up of samples proposed to be tested				
		Group A substances			Group B substances	
		Farms	Hatchery	Factories / Feed mills	Farms	Factories
Shrimp	3984	1328	--	--	1328	1328
Scampi	36	12	--	--	12	12
Fish	45	15	--	--	15	15
Sub Total	4065	1355	--	--	1355	1355
Feed	44	22	--	22	--	--
Hatchery Seed	197	--	197	--	--	--
TOTAL	4306	1377	197	22	1355	1355

NRCP Instructions:

- 1. Samples shall be collected by the designated residue monitoring officers(RMOs) only from farms enrolled under the Marine Products Export Development Authority (MPEDA). *(ref: 96/23/EC – Article: 2)***
- 2. Collection of sample shall be unforeseen, unexpected and effected at no fixed time and on no particular day of the week . *(ref: 96/23/EC – Annex III,clause 1) .***
- 3. Sampling at farm level shall be - that a minimum 10% of the registered sites of production is covered in the yearly Plan, as all the registered farms in a State need to be covered over a period of time. *(ref: 96/23/EC – Annex IV, chapter: 3) .***
- 4. Number of samples to be collected from the processing plants under the RO/SRO shall be based on the production capacity and/or actual production of each processing plant.**
- 5. Farms reported with residue positive cases and processing plants reported with rejections have to be closely monitored and subjected to stringent and frequent sampling. *(ref: 96/23/EC – Article 23)***

NRCPP Instructions: Contd..

6. Sampling procedure/strategy shall be as per the instruction contained in *Annex: III & IV, EU Directive 96/23/EC.*
7. More samples may be drawn from Farms situated in areas reported/suspected with presence/use of unknown chemicals/substances or indications of fraudulent activities, disease out breaks etc,. *(ref: 96/23/EC – Article 13) .*
8. Sampling levels: *(ref: 96/23/EC – Article: 11)*

Shrimp farms	:60 - 90 days & 15 days prior to harvest.
Scampi farms	:60-90 days, 90-120 days & 15 days prior to harvest.
Fish farms	:at any stage of production & 15 days prior to harvest.
9. Samples from the farm: details of medication within the last 4 weeks before sampling should be collected and indicated in the register as well as the slip/format accompanying the sample. *(ref: 96/23/EC – Article: 13) .*
10. Processing plants - multiple samples on the same day for different parameters are allowed, provided the farms from which the Processing Plant has purchased the raw material are different.

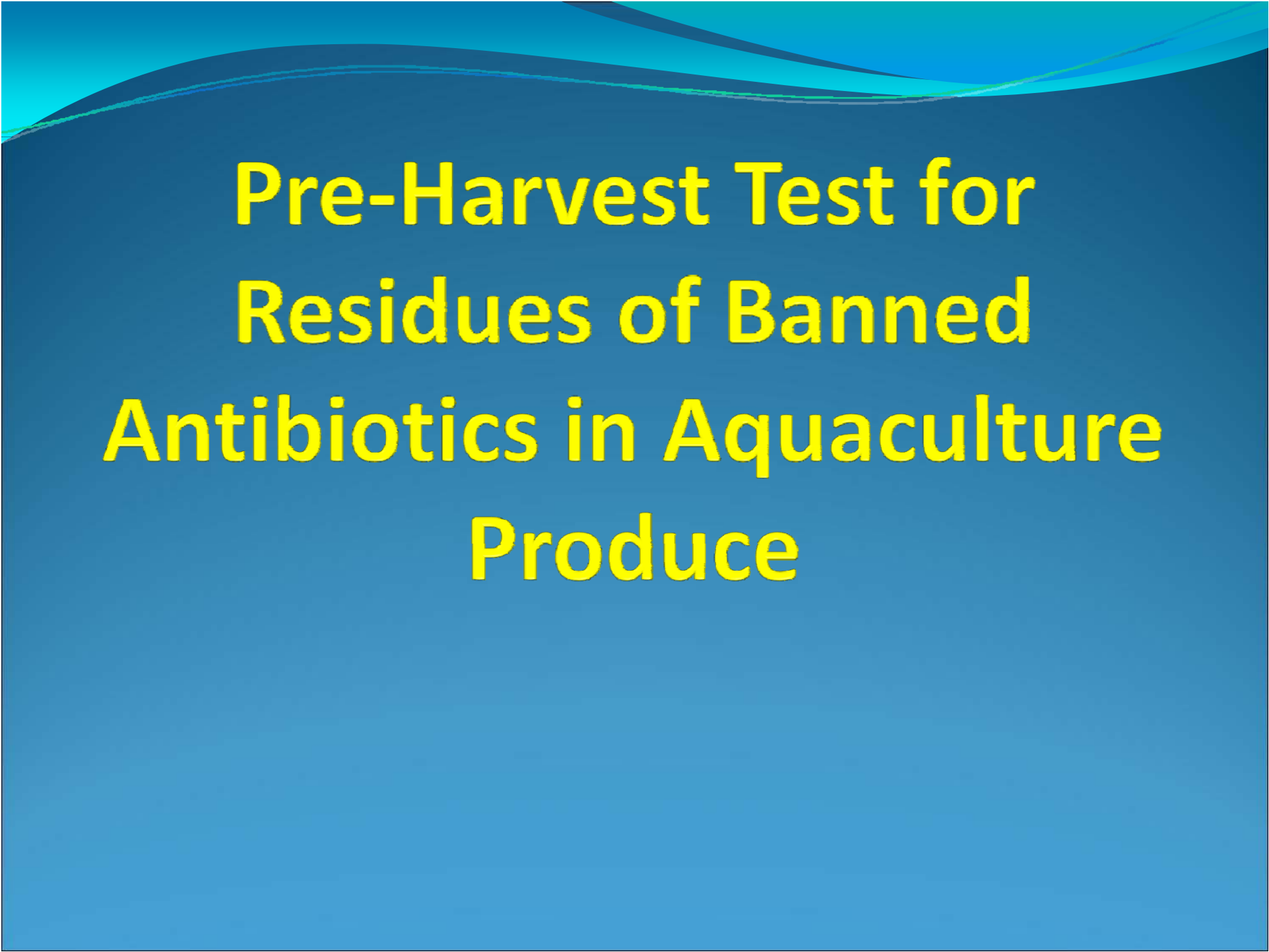
NRCP Instructions:

- 11. Samples:** collected in Polythene bags and properly labeled to maintain the sample integrity and traceability. The container/packing must be officially sealed prevent the substitution.
- 12.**Signature of the farmer or his representative shall be obtained in the original sampling report. Original sampling report has to be kept with the field office and ensure that unauthorized persons cannot access the original report.
- 13.**Register of samples: RO/SRO and RC/SRC shall maintain the register of samples collected and dispatched to the respective Laboratory.
- 14.**RO/SRO shall note the name of the farm and identification/enrolment number in respect of each sample drawn from a processing plant, from the records of the processing plant. *(96/23/EC – Articles: 11 & 12)* .
- 15. Drawing of samples:**
 - from the processing plant shall be done by the residue monitoring officer of MPEDA.
 - In respect of farms - supervision of netting and actual selection of the samples shall be done by the MPEDA officer and not by the farm representative.
- 16. Quantity (net weight)** of sample drawn shall be 500 gm in case of farm / processing plant and 20 - 25 gm in case of hatchery seed.

NRCP Instructions:

17. Samples shall be forwarded to the respective MPEDA Laboratory within 3(three) days of collection so as to reach the laboratory within 30(thirty) hours of dispatch.
18. Samples are to be collected and delivered to the QC Laboratory concerned before 20th of every month as per monthly target/allocation.
19. Results of the tests communicated from the respective laboratory shall be recorded in the specified columns of the register.
20. Follow up actions in case of Non-compliant (residue positive) results:
The RC/SRC/RO/SRO concerned has to:
 - (i) Automatic alerts sent to Competent Authority EIC to carry out follow up action
 - (ii) Alert the processors/exporters, not to procure the raw material from the farm reported with non-compliant (residue positive) result.
 - (iii) Collect follow-up sample(s) for analysis.

(ref: 96/23/EC – Article: 16)
21. Repeat samples are to be drawn from farms / processing plants from where residue violations are reported and such farms are to be subjected to more stringent checks at least for a period of twelve months. *(ref: 96/23/EC – Article: 18)*



Pre-Harvest Test for Residues of Banned Antibiotics in Aquaculture Produce

Objectives of PHT

- To establish a system for monitoring residues of banned aquaculture drugs in pre harvested aquaculture products.
- To ensure that the aquaculture products exported from India are free from residues of banned antibiotics.



PHT

Procedure in brief

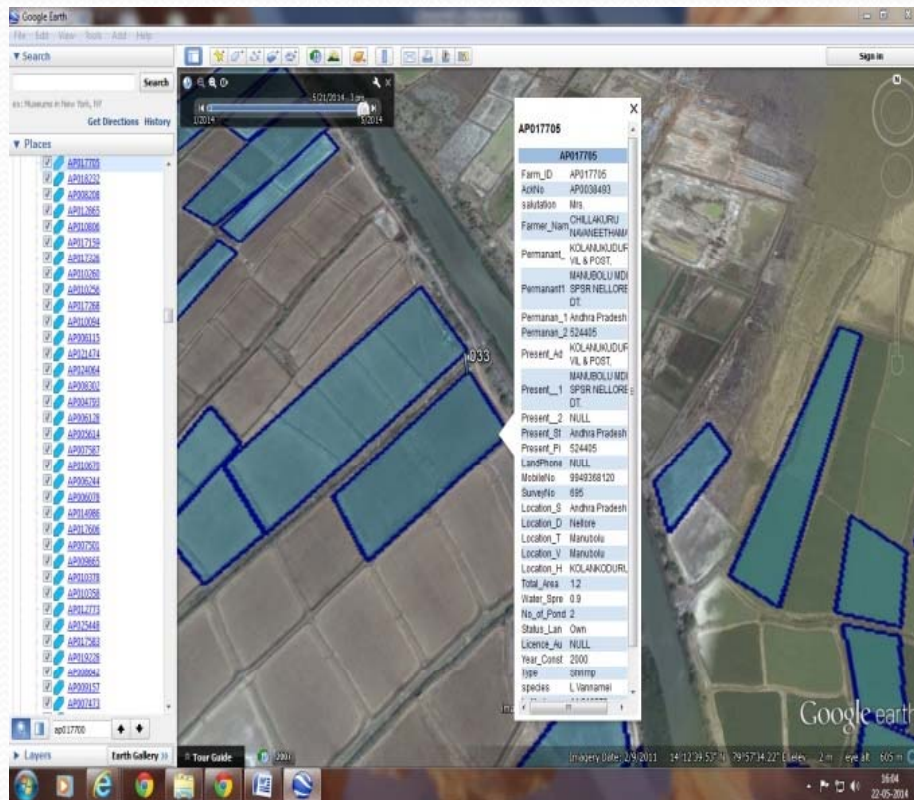
- Request for sampling by farmer to the nearest ELISA lab
- Sample collection using GPS /GIS system for correct identification of farm
- Checking of the GPS waypoints with GIS database.
- Generating mis-match report if the waypoints do not match with database.
- An alert is generated & the data is checked by GIS section at HO & decision is taken on acceptance / rejection of sample.
- Sample acceptance at lab
- Generation of excess production alert to concerned field office & HO if farmer has requested for certification of more quantities than normal.


PHT Procedure in brief


- **Based on the alert, field office conducts a farm verification & recommends / denies the excess production request.**
- **Sample allocation**
- **Sample preparation**
- **ELISA analysis**
- **Reporting of result & issue of PHTC if the sample is ELISA negative.**
- **If ELISA positive, sample is sent to the nearest MPEDA LC MSMS lab for confirmation.**
- **Based on the result from the LC MSMS lab, the sample is declared compliant/ non compliant.**

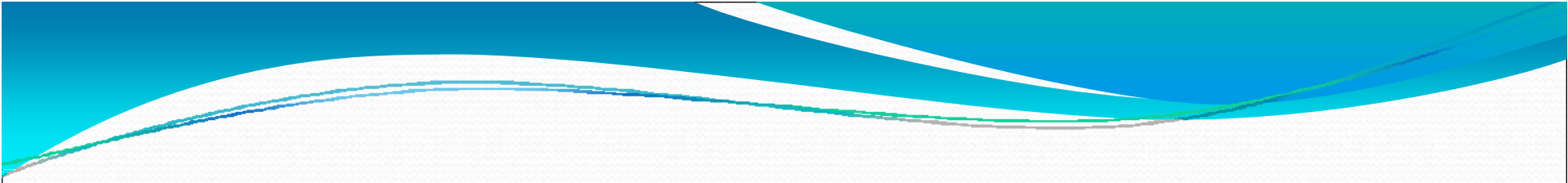
Use of Geographic Information System (GIS) in sampling

- Enrolment of aquaculture farms in India has been carried out by the field offices & the National Centre for Sustainable Aquaculture (NaCSA) of MPEDA.
- NaCSA / field offices have collected details and way points of farms by GPS.
- GIS section of MPEDA has marked the specific way points of GPS in Google earth.



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- **The Sample collector can locate the exact farm by using GPS.**
 - **The farm from which sample is collected can be identified by use of GIS and GPS system.**
 - **GIS system shows the details of enrolled farms including the details of enrolment number, farmer name, address, location of farm, species cultivated etc.**
 - **Cast netting is commonly used for collecting samples from ponds.**
 - **Samples collected from different corners of pond are pooled together to make a sample of 250 g.**
 - **250g of sample is packed in a sterile polythene plastic bag.**
 - **Each sample is marked with a sample code/ identification number of farm**

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- **All samples are transported to the laboratory with ice.**
 - **Weight will be checked and the samples are coded once it reaches the laboratory**
 - **Samples are tested for antibiotics residues.**

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- Under the PHT the % of positives have been showing a downward trend from (0.20%) 2013, (0.17%) 2014, (0.13%) 2015
 - Under NRCP the % of positives has been in the range of 7.75% (2013) to 1.22% (2015)

Suggestion

- **Even though both these systems help in monitoring the presence of antibiotic residues the effectiveness is based on the action taken by the stakeholders with regards to the produce that is tested positive.**
- **Most of the international inspectors have recommended to try & reduce the availability of the banned antibiotics rather than testing for the presence of the banned antibiotics as this adds to cost.**
- **We (All concerned organizations & Govt. Ministries) may take concerted efforts to try & reduce the availability of the banned antibiotics.**

