File No: j-16001/1/2022-Fy (E-20194)
Government of India
Ministry of Fisheries, Animal Husbandry & Dairying
Department of Fisheries

Chandralok Building, Janpath, New Delhi-110001
Dated the 23rd May, 2023.

To,

The Member Secretary,
Coastal Aquaculture Authority (CAA), Chennai

Subject: Guidelines for the Health Monitoring, Disease Surveillance and Specific Pathogen Free (SPF) Certification of Coastal Aquaculture Establishments and Stocks in India_ regarding.

Madam,

I am directed to enclose herewith a copy of the approved Guidelines for the Health Monitoring, Disease Surveillance and Specific Pathogen Free (SPF) Certification of Coastal Aquaculture Establishments and Stocks in India for information and necessary action.

2. These guidelines outline the broader requirements for the Health Monitoring, Disease Surveillance and Specific Pathogen Free (SPF) Certification of Coastal Aquaculture Establishments and Stocks in India. These guidelines shall apply to all Brood Stock Multiplication Centers (BMCs), Nucleus Breeding Centers (NBCs) and SPF polychaete production unit mandatorily. However, any coastal aquaculture facility including hatchery that intends to engage in the production of SPF seed / stock with SPF certification may follow these guidelines on voluntary basis.

3. In this regard, with the approval of Competent Authority, it has been decided that the Coastal Aquaculture Authority (CAA) shall be entrusted the role of Competent Authority for the purpose of implementation of these Guidelines. The Coastal Aquaculture Authority shall execute these functions of Competent Authority on the administrative side on behalf of the Department of Fisheries, Government of India and not under the Coastal Aquaculture Authority Act, 2005.

4.This issues with the approval of competent authority and these guidelines shall come into force with immediate effect.

Encl: As above:

Yours faithfully

(Nilesh Anil Pawar)
Deputy Director (Aquatic Quarantine)
Email:nilesh.pawar85@dof.gov.in: Phone: +91 11 23310351

Copy for Information to:

1. Secretaries In-Charge of fisheries of all Coastal States/UTs
2. Director/Commissioner of fisheries of all coastal States/UTs
3. Joint Secretary (Trade), Department of Animal Husbandry & Dairying, New Delhi
4. Chief Executive, NFDB, Hyderabad
5. Chairman, MPEDA, Kochi
6. Project Director, RGCA-MPEDA, Sirkali
7. DDG (Fisheries Science), ICAR, New Delhi
8. Director, ICAR-CIBA, Chennai
9. Director, ICAR-NBFGR, Lucknow
10. All officers of Animal Quarantine & Certification Services (AQ&CS)
11. All India Shrimp Hatchery Association (AISHA)

Guidelines for the Health Monitoring, Disease Surveillance and Specific Pathogen Free (SPF) Certification of Coastal Aquaculture Establishments and Stocks in India

1. Introduction:

1.1 The Growing Aquaculture Sector in India necessitates the safeguarding of the sector from the impact of diseases and pests, through risk analysis, risk mitigation measures, inspection and certification, and implementation of mitigation response arrangements for Indian Aquaculture Sector. These guidelines not limited to but outlines broader requirements for the Health Monitoring, Disease Surveillance and Specific Pathogen Free (SPF) Certification of Coastal Aquaculture Establishments and Stocks in India.

1.2 The requirements of the SPF facilities such as BMC/NBC etc, encompasses the following:

i. Bio Security measures and its Audit

ii. Continuous Health Monitoring and Disease Surveillance

2. Applicability:

2.1 The guidelines shall apply to: -

i. any Brood Stock Multiplication Centers (BMCs), Nucleus Breeding Centers (NBCs) and SPF polychaete production unit mandatorily.

ii. Any coastal aquaculture facility including hatchery that intends to engage in the production of SPF seed / stock with SPF certification on voluntary basis.

2.2 The Department of Fisheries, Government of India shall make these guidelines mandatory for any coastal aquaculture facility or stock as it deems fit and required for sustainable coastal aquaculture.

3. Bio Security

The prevention of diseases in aquaculture requires the definition and implementation of a biosecurity strategy, specific for each facility, culture system and sanitary zone.

"Biosecurity is a strategic and integrated approach that encompasses the policy and regulatory frameworks (including instruments and activities) that analyse and manage risks in the life and health of candidate species including associated environmental risk".

4. Biosecurity measures:

The basic elements of a biosecurity programme include the physical, chemical and biological methods necessary to protect the facilities from the consequences of all diseases that represent a high risk. The biosecurity audit is a useful tool to examine, how well those biosecurity measures are executed in every facility. The priority areas of strict biosecurity measures include areas such as:

a) Site / location
b) Water intake
c) Source water treatment
d) Compartmentalization, Zonation and physical separation or isolation with different levels of bio security
e) Sanitation and personnel hygiene
f) Movement of personnel between compartments and zones
g) Live /fresh / frozen feed sources
h) Introduction of new Aquaculture sources or genetic materials
i) Dispatch & loading
j) Entry and Exit of Vehicle, Personnel and visitors within and into the facility
k) Others

5. Verifiable in-house bio-security audit of the facility

5.1 Various levels, zones, compartments and strategies for biosecurity shall be employed at the facility depending on the size and design of the facilities and the diseases of concern.

5.2 A quarterly in-house evaluation of the biosecurity measures shall be undertaken by the operator and necessary corrective measures shall be implemented based on the audit report.

5.3 The quarterly audit report shall be verified by the authorized personnel during inspection and sampling of the facility

5.4 A record of the Bio Security audit and the vetting of the same by the authorized personnel shall be maintained as proof for SPF certification.

6. Continuous Health Monitoring and Disease Surveillance

6.1 A SPF animal/ facility can be defined as one coming from a population that has tested negative for specific pathogens for at least a continuous period of two years (a surveillance programme must be in place), that is raised in highly biosecure facilities (i.e. with appropriate water treatment and an enclosed environment) following biosecure management measures and has been fed with biosecure feeds.

6.2 Continuous Health monitoring and Disease surveillance is the essential component of health management Programme of any SPF production facility. SPF quality assurance means that the status of freedom from Specific Pathogens of the candidate species is monitored on a continuous basis. The chain of custody sample collection, laboratory testing and its results are the tools that guarantee the freedom from pathogen/ disease status of the stock. Necessary contingency plan shall be put in place so that prompt action can be carried out in controlling disease outbreak and preventing further spreading of disease.

6.3 Apart from this, the facility shall also be equipped with a wet lab and microbiology, laboratory for undertaking routine screening of the facility, water, animal, algae and other feeds to assess the health status. An appropriate Microbiological Index (MI) for each species-specific facility shall be developed and declared by the competent authority for the purpose of reference.

6.4 Health monitoring and Disease surveillance and testing shall be on the basis of the World Organization for Animal Health's (OIE) aquatic animal health code on disease

surveillance (Chapter 1.4, Article 1.4.6). The procedures laid down in the latest OIE - Manual of Diagnostic Tests for Aquatic Animal shall be followed in all the testing procedures.

6.5 The continuous health monitoring and disease surveillance shall be in two stages:

i. A robust in-house health monitoring and disease surveillance programme conducted by the operator himself; and

ii. Chain of custody sampling and testing by the empanelled agency which can be govt. or private, proficient and competent to do the sample collection and testing.

7. In-house health monitoring and disease surveillance programme

7.1 The respective facilities shall implement an in house health monitoring and disease surveillance Programme to monitor the health status of their stocks and assess the quality of the post larvae with appropriate frequency for sampling and testing. The results of the in-house tests should be maintained appropriately at the facility.

The in-house health monitoring and disease surveillance involves 3 levels of examination:

i. Examination of stock for general health condition, sex determination, staging of ovarian development, moult staging, removal of sick/moribund individuals,

ii. Examination of larval stages by microscope. Checking bacterial flora of normal or moribund animals; and

iii. Disease screening of brood stock and PPL by PCR, histopathology and or any other relevant advanced technique.

7.2 The screening shall be conducted by qualified and certified technologists using RT PCR or the latest PCR technique in accordance with the procedures laid down in the latest OIE - Manual of Diagnostic Tests for Aquatic Animals.

7.3The frequency of sampling and sample size for each candidate species shall be as declared by the competent authority.

7.4 The general guide on the frequency of sampling with a sample size of 20 samples each during every sampling for the maintenance of in house disease surveillance protocol is given below:

Screening Number	Screening frequency (Days of Operation)	Probable range of Weight. (g)	Parameters to be tested	Confirmatory screening
1st	30	2 to 3	All OIE listed and non OIE listed pathogens of concern shall be screened through PCR method	Confirmatory screening shall be through Histopathology and sequencing of PCR products following detection
2nd	60	13 to 15		
3rd	90	22 to 28		
4th	120	33 to 37		
5th	150	42 to 48		
6th	180	50 to 53		
To be continued..				

7.5 In the event of occurrence of any disease/pathogen the facility operator shall immediately isolate and contain the operation of such compartment (s) in such a way not contaminate the other areas of the facility and report the same to the Competent Authority immediately.

8. Chain of custody sampling and testing

8.1 Empaneled agencies for chain of custody sampling and testing

8.1.1 The competent authority shall empanel and authorize Government or Quasi Government organizations such as CIBA, RGCA, NBFGR, Fisheries Universities, OIE referral laboratories or private agencies, who are accredited by National Accreditation Board for Testing and Calibration Laboratories (NABL) and qualified at the National or International ring test for multiple pathogens screening, for chain of custody sampling and testing for diseases/pathogens of concern as notified by the Competent Authority. The terms and conditions and qualifying criteria shall be declared by the competent authority from time to time.

8.1.2 The competent authority shall authorize the empaneled and authorized agencies following a roaster system to collect samples for testing at specified intervals from the concerned facilities. Collection of sample and testing by an empaneled agency for two consecutive times from any facility shall be avoided to ensure the transparency in the sampling and testing.

8.1.3 The empaneled and authorized agency for chain of custody sampling and testing shall report their test results as soon as available, in the prescribed format and mode, to the competent authority, maintaining the confidentiality of the same.

8.1.4 The samples shall be drawn, stored and tested by the authorized personnel / Laboratory of empaneled and authorized agency. The operator shall not in any way draw the sample and submit for third-party testing under this program.

8.1.5 The empaneled agencies shall also be authorised to verify the quarterly in-house biosecurity audit and the in-house screening results and for vetting those reports.

8.1.6 The competent authority shall fix a fee for chain of custody sample collection and testing and pay the same to the empaneled agencies.

8.2 Disease surveillance process

8.2.1 The general guide on the frequency of sampling, sample size and maintenance of in chain of custody sampling and testing protocol is as given below:

Screening Number	Screening frequency (Days of Operation)	Sample Sets	Probable range of Weight. (g)	Parameters to be tested	Confirmatory screening
1st	30	60	2 to 3	All OIE listed and non OIE listed pathogens of concern shall be screened through PCR method	Confirmatory screening shall be through Histopathology and sequencing of PCR products following detection
2nd	90	60	22 to 28		
3rd	180	60	50 to 53		
4th	360	60			
5th	540	60			
6th	720	60			
SPF Accreditation					
7th	900	20			
8th	1080	20			

8.2.2 The new facilities shall be scheduled for sampling during the months 1, 3, 6, 12, 18, and 24 months. The sample size of initial 3 samplings of months 1,3,6 shall be with 60 sample sets each during each sampling.

8.2.3 Surveillance and Testing shall be continued at months 12, 18, and 24 with 60 sample sets during each sampling to acquire SPF certification or as specified in the latest OIE - Manual of Diagnostic Tests for Aquatic Animals or as prescribed by the Competent Authority.

8.2.4 The sample size, frequency of sampling, SOP for collection of samples, type, methodology or procedure and assay of testing shall be as prescribed in the latest OIE - Manual of Diagnostic Tests for Aquatic Animals and to be declared by the competent authority for each candidate species. Sampling regime shall include all life stages on the facility.

8.2.5 Upon successful SPF accreditation of the facility and the stock, the surveillance and testing after a continuous period of two years, it shall be scheduled once in every 6 months with 20 sample sets each during each sampling or as specified in the in the latest OIE - Manual of Diagnostic Tests for Aquatic Animals or as prescribed by the Competent Authority.

8.2.6 In the event of a disease occurrence if any or an affirmative positive sample set reported by the empaneled agency/ by the operator, the referral lab shall be notified at the shortest time possible by the operator/empaneled agency/ competent authority, to confirm the same and the unit shall be suspended by Competent Authority pending confirmation by referral laboratory.

8.2.7 On confirmation of disease occurrence or of a confirmative positive sample set by the referral lab, the competent authority shall engage with the Technical Monitoring Committee, shall subject the infected facility for inspection by a subcommittee of experts to ensure the biosecurity arrangements and shall cause

the facility to destroy the entire infected stock and incinerate the same in their presence to contain the spread of the infection.

8.2.8 In the event of disease occurrence or of a confirmative positive sample set by the referral lab in a particular compartment, the competent authority shall decide on the vigorous chain of custody sampling and testing to ensure that the other compartments in the facility are free from the said infection, provided there are sufficient biosecurity measures in place to prevent such contamination. The additional fee or charges as decided by the competent authority for the same shall be collected from the operator of the facility.

9. Certification, Monitoring and Regulation

9.1 Certification Process

9.1.1 The SPF Facilities / Stocks shall be subjected to the disease surveillance for the purpose of SPF certification. The following procedure shall be adopted for issuing SPF certification by the Competent Authority:

9.1.2 The operator of any facility engaged in the production of SPF stocks of fish or aquatic organisms shall apply for the SPF certification of the facility and stocks contained in it.

9.1.3 The fee or charge for health monitoring, disease surveillance and SPF certification shall be fixed by the competent authority and shall be paid in advance by the facility operator concerned to the competent authority.

9.1.4 Candidate species used for stocking in this facility must originate from a certified SPF facility.

9.1.5 In the case of new facility, the facility shall be allowed to sell /ship /export the candidate species as High Health (HH) stock with health documents on successful completion of three negative sample sets during the 1st, 3rd and 6th month with 60 sample sets each. But the stocks will not be certified as SPF stocks.

9.1.6 On successful completion of 12, 18, and 24 months with 60 sample sets each, tested negative within a continuous period of two years, the stock and the facility shall be accredited with Specific Pathogen Free (SPF) status.

9.1.7 The accreditation of Specific Pathogen Free (SPF) status to the facility and authorization to sell the stocks as High Health (HH) / Specific Pathogen Free (SPF) shall be issued by the Department of Fisheries, Ministry of Fisheries, Animal Husbandry and Dairying, Government of India.

9.1.8 In the event of a disease occurrence or confirmatory positive sample set, The Specific Pathogen Free (SPF) status of the facility and stocks automatically stands withdrawn.

9.1.9 The facility shall follow the prescribed disinfection and dry out process of the compartment or the entire facility as the case may be for a period of one month and shall start the operation and the process of health monitoring and disease surveillance for SPF Certification.

9.2 Monitoring and Regulation

9.2.1 Referral laboratories

i. The competent authority shall notify the list of referral laboratories from time to time.

ii. In order to qualify for participating in this Programme, the laboratory shall be NABL accredited and qualified in the National or International ring test for multiple pathogen screening of fish and aquatic organisms. The Department of Fisheries, Ministry of Fisheries, Animal Husbandry and Dairying, Government of India is empowered to grant exemption of this condition on need basis.

iii. The cost of the travel by the authorized personnel of the referral laboratory for the sample collection and testing shall be incurred by the respective institutions.

9.2.2 The Technical Monitoring Committee

i. The Department of Fisheries, Ministry of Fisheries, Animal Husbandry and Dairying, Government of India, may appoint a Technical Monitoring Committee to oversee the implementation of this health monitoring, disease surveillance and SPF certification program.

ii. The Technical Committee constituted to oversee the operation of aquatic quarantine facility, shall be the Technical Monitoring Committee to oversee the effective implementation of this health monitoring, disease surveillance and SPF certification.

iii. The Technical Monitoring Committee shall assist the competent authority in deciding on the matters relating to fixation of the sample size, frequency of sampling, SOP for collection of samples, fixation of fee or charges, constitution subcommittees for inspection and culling of the infected stocks, suspension of activity of a facility in part or full in the event of disease detection, grievance redressal and dispute under this program.

iv. Appeal if any on the decision of the competent authority shall be made to the Department of Fisheries, Ministry of Fisheries, Animal Husbandry and Dairying, Government of India and the decision shall be final.

9.2.3 Non Compliance:

i. If any Stock or facility is detected with infection of the OIE listed pathogen(s) or non-OIE listed pathogen(s) of concern, then the operations of such facility shall be suspended forthwith by the Competent Authority pending confirmation of the same by the Referral Laboratory. Upon confirmation of Infection by the Referral Laboratory, the operation of such facility shall be stopped by the Department of Fisheries, Government of India on recommendations of the Competent Authority for a period not exceeding 6 months from the date of initial detection of infection. After resumption of operations, the Department of Fisheries, Government of India may allow

such facility to sell its stocks as High Health Stocks on the basis of satisfactory evidence to the effect that the stocks are free of OIE listed pathogen(s) or non-OIE listed pathogen (s) of concern for a continuous period of 6 months and on the recommendations of the Competent Authority.

ii. Further, the SPF certificate of such stock/facility shall stand automatically revoked from the date of confirmation of the infection and the same will be reinstated by the Department of Fisheries, Government of India on the recommendations of the Competent Authority, only after completion of continuous period of 2 years of freedom from any disease, from the date of resumption of operations, on the basis of satisfactory evidence to the effect that the stocks are free of OIE listed pathogens or non-OIE listed pathogens of concern during the interim period.

iii. Noncompliance if any on the part of the facility or operator shall be liable for suspension or cancelation of the permission to operate the facility.

10. Competent Authority

10.1 The Department of Fisheries, Ministry of Fisheries, Animal Husbandry and Dairying, Government of India shall

i. notify competent authority from time to time for the effective implementation of this Health Monitoring, Disease Surveillance and SPF Certification programme.

ii. notify the list of referral laboratories from time to time

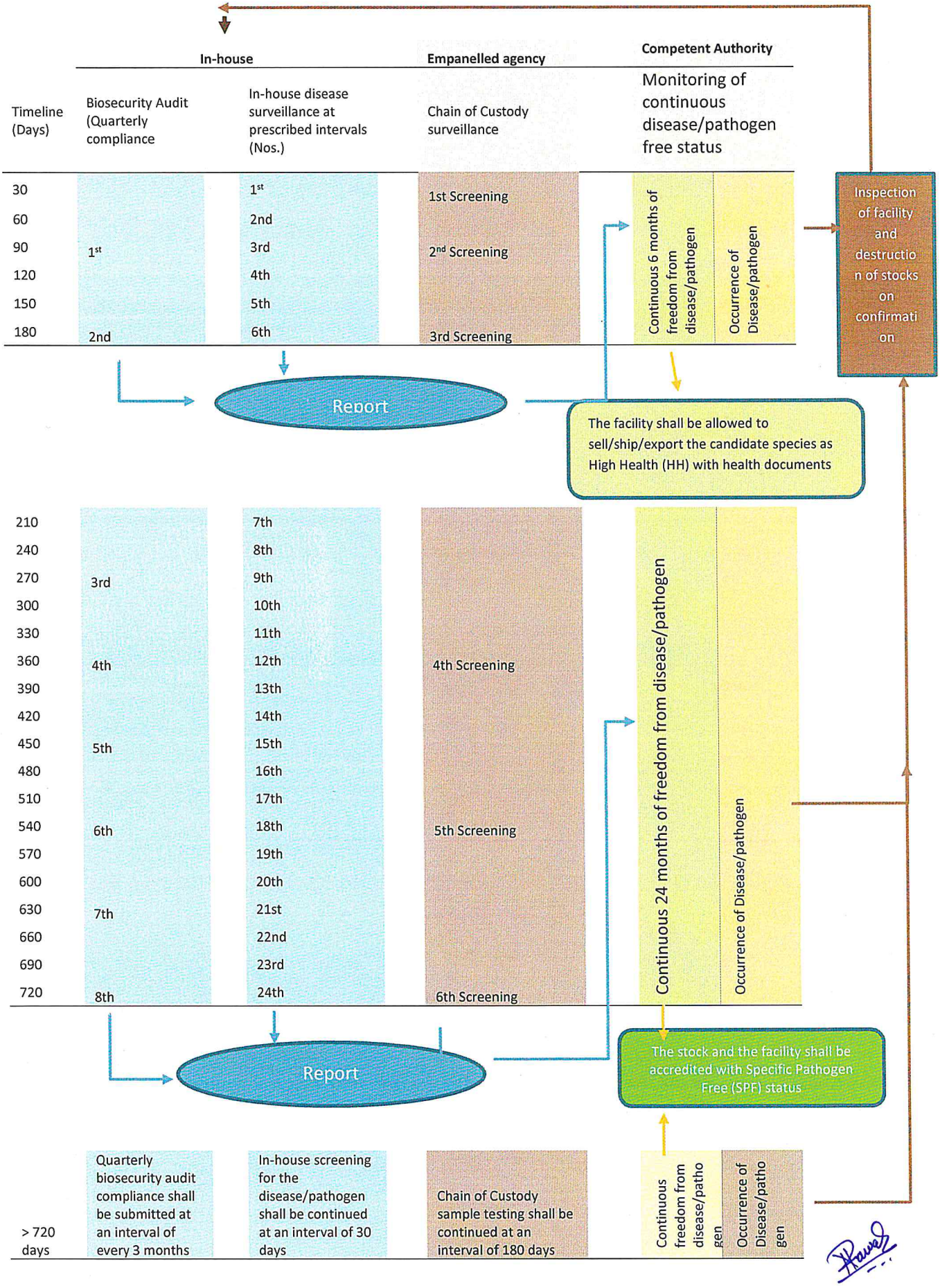
iii. notify the pathogens of concern, methodology or procedure and assay of testing of that pathogen or any other matter connected therewith, Microbiological Index (MI) for each species-specific facility, in consultation with the Technical Advisory committee of National Surveillance Programme for Aquatic Animal Diseases.

iv. issue the accreditation of Specific Pathogen Free (SPF) status to the facility and authorization to sell the stocks as High Health (HH)/ Specific Pathogen Free (SPF).

v. suspension/ cancellation/ revoking of permission to operate

10.2 The Coastal Aquaculture Authority shall be the competent authority for the matters connected with the following:

i. Empanelment of Agencies for the chain of custody sampling and testing
ii. Terms and conditions of empanelment
iii. Creation of roaster of empaneled agencies for chain of custody sampling and testing
iv. Fixation of any fee or charges under this Programme
v. The sample size, frequency of sampling, SOP for collection of samples
vi. Scrutiny of test reports and recommendation
vii. Coordination and follow up measures in case of a disease occurrence or a positive sample set
viii. Suspension of the activity of facility in the event of a disease occurrence or confirmatory positive sample set
ix. Any other administrative and operational matters
x. The Coastal Aquaculture Authority shall execute these functions of Competent Authority on the administrative side on behalf of the Department of Fisheries, Government of India and not under the Coastal Aquaculture Authority Act, 2005.


In-house
Empanelled agency
Competent Authority
Timeline (Days)
Biosecurity Audit (Quarterly compliance
In-house disease surveillance at prescribed intervals (Nos.)
Chain of Custody surveillance
Monitoring of continuous disease/pathogen free status
30
60
90
120
150
180
1st
2nd
1st
2nd
3rd
4th
5th
6th
1st Screening
2nd Screening
3rd Screening
Continuous 6 months of freedom from disease/pathogen
Occurrence of Disease/pathogen
Inspection of facility and destruction of stocks on confirmation
Report
The facility shall be allowed to sell/ship/export the candidate species as High Health (HH) with health documents
210
240
270
300
330
360
390
420
450
480
510
540
570
600
630
660
690
720
3rd
4th
5th
6th
7th
8th
7th
8th
9th
10th
11th
12th
13th
14th
15th
16th
17th
18th
19th
20th
21st
22nd
23rd
24th
4th Screening
5th Screening
6th Screening
Continuous 24 months of freedom from disease/pathogen
Occurrence of Disease/pathogen
Report
The stock and the facility shall be accredited with Specific Pathogen Free (SPF) status
> 720 days
Quarterly biosecurity audit compliance shall be submitted at an interval of every 3 months
In-house screening for the disease/pathogen shall be continued at an interval of 30 days
Chain of Custody sample testing shall be continued at an interval of 180 days
Continuous freedom from disease/pathogen
Occurrence of Disease/pathogen