सत्यमेव जयते

CAA Guidelines

for the issuance of Certificate of Compliance for

Antibiotic-Free Aquaculture Inputs

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तटीय जलकृषि प्राधिकरण

COASTAL AQUACULTURE AUTHORITY

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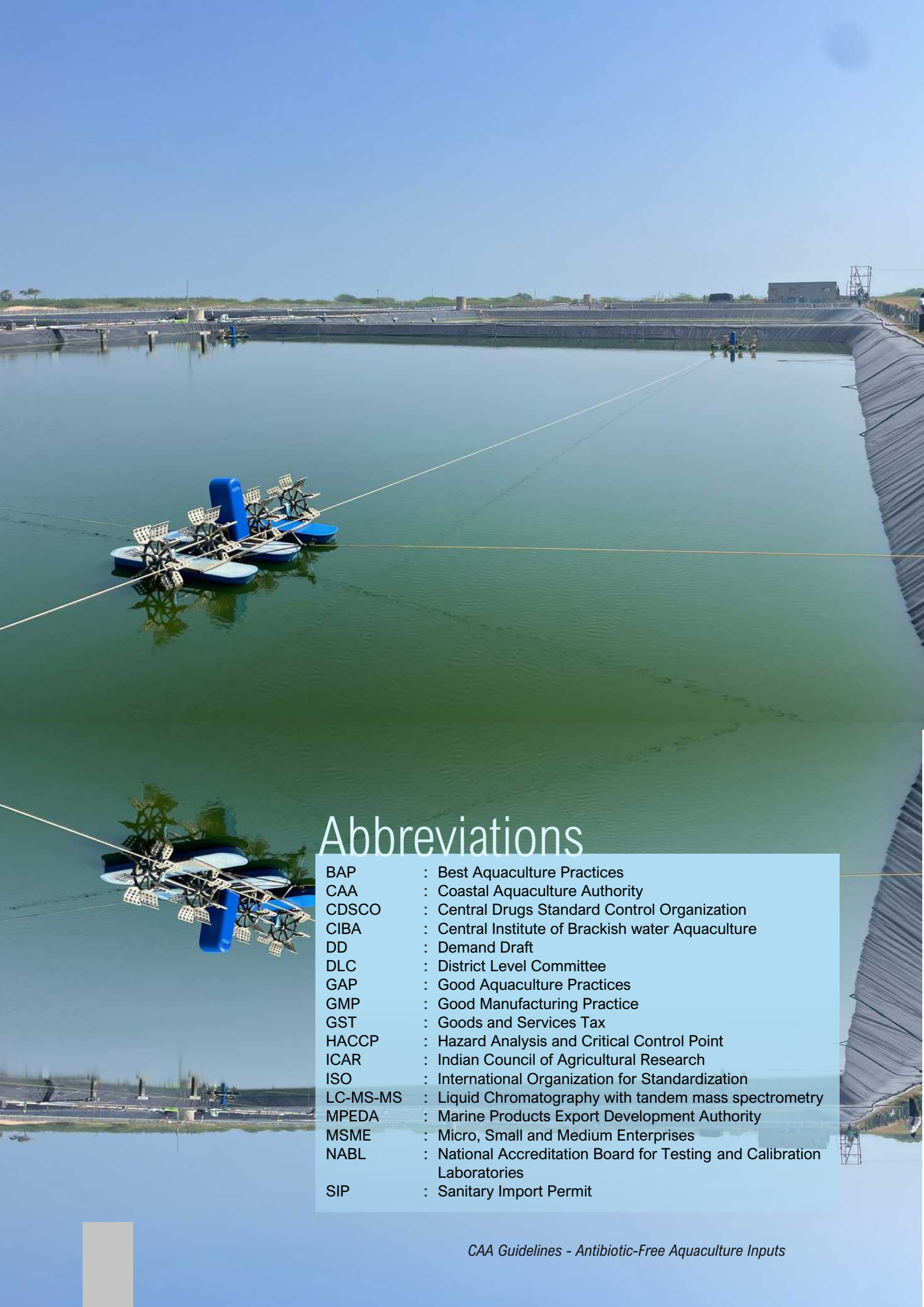


Abbreviations

BAP	:	Best Aquaculture Practices
CAA	:	Coastal Aquaculture Authority
CDSCO	:	Central Drugs Standard Control Organization
CIBA	:	Central Institute of Brackish water Aquaculture
DD	:	Demand Draft
DLC	:	District Level Committee
GAP	:	Good Aquaculture Practices
GMP	:	Good Manufacturing Practice
GST	:	Goods and Services Tax
HACCP	:	Hazard Analysis and Critical Control Point
ICAR	:	Indian Council of Agricultural Research
ISO	:	International Organization for Standardization
LC-MS-MS	:	Liquid Chromatography with tandem mass spectrometry
MPEDA	:	Marine Products Export Development Authority
MSME	:	Micro, Small and Medium Enterprises
NABL	:	National Accreditation Board for Testing and Calibration Laboratories
SIP	:	Sanitary Import Permit

INTRODUCTION

One of the functions of Coastal Aquaculture Authority (CAA), as provided under Rule 5(v) of CAA Rules, 2005 framed under the Coastal Aquaculture Authority Act, 2005 is to fix standards for all coastal aquaculture inputs viz. seed, feed, growth supplements and chemicals/medicines for the maintenance of the water bodies and the organisms reared therein and other aquatic life. Further, the Guidelines (Annexure-I) issued under CAA Rules clearly states that chemicals should be avoided in shrimp ponds as feed additives, disinfectants and also pesticides, chemotherapeutants and antibiotics/drugs. Use of antibiotics in shrimp culture is strictly prohibited and the list of antibiotics and other pharmacologically active substances is listed in the Guidelines.

In exercise of the powers conferred under the Rule 5 (v) of CAA Rules, 2005, read with clause (f) of Subsection 2 of Section 25 of CAA Act, 2005, the Coastal Aquaculture Authority (CAA) has decided that aquaculture inputs like larval and farm feed, feed additives, chemical disinfectants, other chemicals, drugs, probiotics, immune- stimulants, etc., should be certified when they are proven antibiotics free. In this connection, all the aquaculture input manufacturers (indigenous) and distributors (imported) are required to get their products certified as per the terms and conditions provided in this guidelines for issuance of Certificate of Compliance for antibiotic-free aquaculture inputs.

The following is the List of Antibiotics of concern that are required to be tested in each product:

A. Chloramphenicol

B. Nitrofuran parent compounds

   I. Furazolidone

   II. Furaltadone

   III. Nitrofurantoin

   IV. Nitrofurazone

C. Nitrofuran Metabolites

   V. 3-amino-oxazolidinone [AOZ]

   VI. 3-amino-5-morpholinomethyl-1-3-oxalodin [AMOZ]

   VII. 1-aminohydanton [AHD]

   VIII. Semi carbazide [SEM].

This guidelines is in suppression of all the earlier advisories on the subject issued by this Authority and has been prepared incorporating the requirement for additional documents / information for the issuance of Certificate of Compliance for antibiotic-free aquaculture inputs. Accordingly the anufacturers/distributors are required to follow the procedures prescribed below and submit the following documents along with application while applying for Certificate of Compliance for antibiotic-free aquaculture inputs.

Note: - The products that are already certified shall comply with the requirements of the new advisory within the specified timeline of 90 calendar days.

1 APPLICABILITY

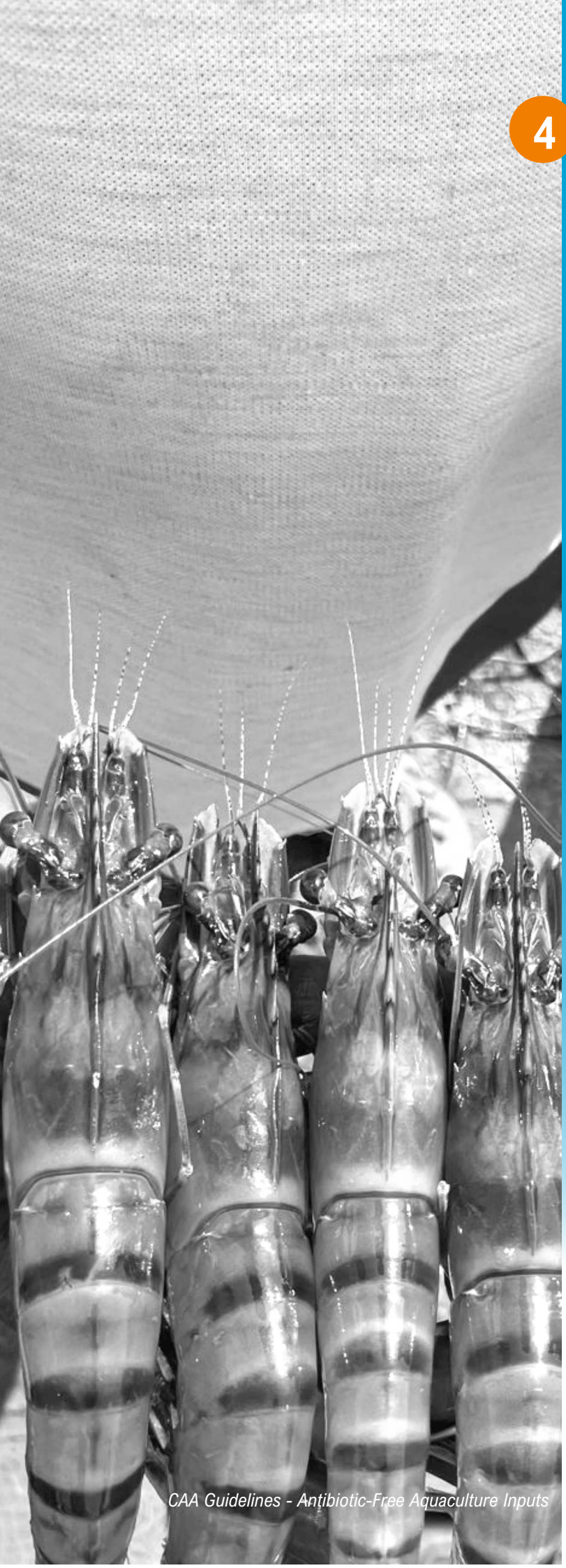
All the products intended for the use in Coastal Aquaculture unless exempted specifically under section Nine (9) of this advisory, herein after called “Products”, shall be covered under this advisory and required to comply with the requirements and obtain Certificate of Compliance for antibiotic-free aquaculture inputs. Hence both Indian manufacturers and importers/distributors of overseas aquaculture inputs and other supplements for aquaculture use shall obtain “Certificate of Compliance” for antibiotic-free aquaculture inputs, herein after called “Certificate”. The Certificate is not transferable.

2 VALIDITY

The Certificate is valid for a period of Five (5) years from the date of issue/certification which shall be renewable for a further period on compliance to the requirements prescribed in section Six (6) of this advisory.

3 FEE

A non-refundable processing fee of Rupees Ten (10) thousand (Rs.10,000/-) for each application shall be paid in the form of DD drawn in favour of “Coastal Aquaculture Authority (CAA)”.



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LABELLING STANDARD FOR AQUA INPUTS

a) Labels on packages or containers of products in addition to other statutory requirements on labelling, without any duplication, shall contain particulars prescribed below that shall be printed and appear in a conspicuous position on the container in which the substance is packed and every other covering in which that container is packed.

b) Labels shall clearly indicate the basic composition of the product, dosage, batch number, expiry date and other important details as given below and Brochures if available (Brochures are compulsory with the products in case limited information is made available on the label).

c) In the contents section generic terms like, vitamins, minerals, essential nutrients etc. should not be used, instead specific scientific name of vitamins, minerals, etc. should be provided.

d) The label shall contain but not limited to the following details

1. Name of the product: Trade name of the product shall be in capital letters or prominent font as mentioned in the CAA Certificate.
2. Net quantity of contents: A correct statement of the net content in terms of weight, measure, volume, number of units of contents and number of units of activity, as the case may be, shall be indicated. The indicated values shall be in Metric system.
3. Name(s) and composition of ingredient(s): Scientific name of all major ingredients of the product should be mentioned with approximate concentration, composition expressed in appropriate unit as applicable.
4. Recommendations for use: The label shall clearly indicate the intended benefit, prescribed dosage and schedule of application to achieve the desired benefit.
5. Method of application: Method of product application as feed top dressing, broadcasting throughout the pond or any other method shall be provided. Pre-treatments like, soaking in water or overnight fermentation, if any before application shall

also be clearly mentioned. (This can be limited to brochure to save space in the label and brochure is compulsory with such product).

6. Contraindications (if any): Information like not suitable with any other product or not to be used in particular culture systems, species or growth stages shall be clearly indicated with pictorial representation in the label.
7. Batch number: A distinctive traceable batch number in which the product was produced at the manufacturing unit shall be indicated on the label. The details of such batches and retention sample shall be available at the manufacturing facility for traceability. The figure representing the batch number shall be prefixed with 'Batch No'.
8. Import licence number (if imported): Products manufactured with imported ingredient (s) and products as a whole imported and marketed in India shall bear on the label, the license number / Sanitary Import Permit (SIP) number, wherever applicable, under which the product is imported, prefixed with 'Import License Number' / SIP Number and contact details of the company importing and marketing the product shall be clearly mentioned.
9. Manufacture date: The date of manufacture shall be in terms of month and year.
10. Expiry date: The date of expiry shall be in terms of month and year and it shall mean that the product is recommended till the last day of the month. The date of expiry shall be prefixed with 'Expiry date. In case required "Best Before" in terms of month and year shall be indicated depending on the products.
11. Storage conditions: Appropriate storage conditions like cool, dark place, avoiding from sun light etc., required to maintain the potential of the product till the expiry date shall be mentioned clearly.
12. Indication of 'Not for Human Consumption': The label shall have 'Not for Human Consumption' in the bottom strip with bigger font size to avoid any possible consumption by humans.
13. Indication of 'Aquatic Animal Use Only': The label shall bear a SYMBOL depicting an appropriate image of the aquatic animal(s) for which the product is to be administered.
14. Name and address of manufacturer: Complete name and address of the manufacturer shall be provided as submitted to Coastal Aquaculture Authority (CAA) including the name of the place/village, taluk, district, state and the PIN code.
15. Indication 'Do not contain antibiotics": The label shall have 'Do not contain antibiotics' in the bottom strip with bigger font size conspicuously displayed in a box with distinct colour.
16. CAA Certification number: Every Aquaculture product except those exempted under section 9 of this guidelines, manufactured and/or marketed in India shall bear on its label the certification number issued by CAA for that product with a caption in bold letters as "CAA Certified Antibiotic-free Product".

5 CERTIFICATION PROCESS

a) General Requirements

The following are the documents in general required for both manufacturers and importers.

1. Separate Application for each product, in the prescribed form number 'X' for Certificate for aquaculture inputs (downloaded from CAA website - www.caa.gov.in) shall be submitted for each products along with all the following required documents as applicable.
2. Antibiotic test report of the product in ORIGINAL for test done not older than a month from the date of submission of application, for the presence of antibiotics, their parent compounds and metabolites as prescribed in the introduction from any NABL accredited Government or private laboratory with a scope for testing said antibiotic residues using LC-MS-MS method.
3. Retention sample of not less than 500g or 500ml of each product from each batch of manufacturing / importing shall be retained at the manufacturing/ distribution unit for a period not exceeding the expiry of such product. Documentary evidence on such sample retention such as scanned copy of the latest page of the sample retention record for each product which shows the details of the latest sample stored and photographs of such storage facility along with an undertaking for the retention of product samples in the prescribed format. All the certified products shall be subjected to a random testing by CAA at least once before the expiry of its certification.
4. A Declaration in the prescribed format in non-judicial stamp paper from the manufacturer / importerauthorizing the CAA / any person, team or committee authorized by the Authority to enter and inspect the storage premises / manufacturing facility of the company and to collect product samples at any time without any prior notice.
5. An undertaking from the applicant company in the prescribed format stating that they shall reimburse the cost of the samples collected by CAA to the end user concerned.
6. The manufacturer may design their own seal/ tamper proof mechanism to ensure the same is not duplicated by any other party. It

shall be mentioned in the application to CAA by the applicant to confirm the genuineness of the product while sampling.

7. All the required documents as required by CAA should be submitted before completion of 60 calendar days from the date of receipt of application at CAA failing which the application shall be closed as defective under an intimation to the applicant and the processing fee of rupees Ten (10) thousand (Rs.10,000/-) shall be forfeited and deposited to CAA's accounts. (If closed as defective the application is to be submitted afresh.)Time line for disposing the application for Certificate shall be within 90calendar days from the date of receipt of application at CAA.

b) Products Manufactured in India

The companies that are producing aquaculture inputs and other supplements for aquaculture use shall obtain Certificate i.e., Certificate shall be issued only to the manufacturers in the case of products manufactured in India. The following documents are required in addition to those prescribed in 5 (a).

1. Details of Company/Firm

The applicant company shall submit any/all of the following documents:

- Company incorporation proof (Address proof for company)
- MSME
- GST certificate

2. Details of the manufacturing facility

The applicant company shall submit any/all of the following documents:

- Certificate of Registration of the manufacturing unit/factory etc. from the competent authority.
- Licence to work as factory
- Proof of any facility certification
- Any process certification such as ISO, BAP, GAP, HACCP etc.

3. Other Documents

The applicant company shall submit the following documents:

a. Detailed process flowchart shall be, but not limited to the checkpoints that are linked with testing process as a part of the In-process Quality control system adopted by the manufacturer in the production.

b. Process certification that ensures antibiotic free production or a notarized self-declaration in the prescribed format on Rs.100/- non judicial stamp paper for antibiotic free ingredients as well as production process.

c. List of records maintained in the unit pertaining to the product and production process.

d. In case, the product is manufacturedunder an agreement as merchant manufacturer, in a facility not owned by the applicant, copy of such agreement shall be submitted. In such case the responsibility of compliances shall be on both the parties.

c) Products Imported from Abroad and Distributed in India

The companies that are importing aquaculture inputs and other supplements for aquaculture use shall obtain the Certificate of Compliance i.e., Certificate of Compliance shall be issued to the importers only, inthe case of products imported to India. The following documents are required in addition to those prescribed in 5 (a).

1. Details of Company/Firm

a) Proof of registration of the importing company in India. The documents generally accepted for the same are: certificate of incorporation, Importer Licence, MSME, GST etc.

b) Health certificate/veterinary certificate showing antibiotic-free status of the product while importing or any antibiotic-free certificate form competent authority of the country of origin

c) Details or list of records maintained by the importer on the imported products. (The originals may be produced on demand).

d) Copy of Authorization for distributing the product / copy of the agreement between the overseas principal manufacturer and Indian Company importing.

2. Documents fromthe manufacturer

a) Manufacturing process stepwise (Flow chart) along with testing procedures followed within the unit or any such relevant document form the overseas manufacturer.

b) Any process certification such as ISO/ BAP/ GMP/ HACCP for the overseas manufacturer.

c) Proof of any facility certification

6 RENEWAL OF VALIDITY

The Certificate is valid for a period of Five (5) years. It shall be renewed at the end of the validity period of Five (5) years by furnishing the following required documents. The renewed validity will be for a further period of Five (5) years.

a) Application in the prescribed form number 'X-A' for renewal of Certificate for aquaculture inputs (downloaded from CAA website - www.caa.gov.in) shall be submitted three (3) months before the expiry of such Certificate with the following.

b) A non-refundable processing fee for Rupees Ten (10) thousand (Rs.10,000/-) as prescribed in section Three (3) of this advisory, shall be paid in the form of DD drawn in favour of Coastal Aquaculture Authority (CAA) for each application for renewal.

c) The defect rectification and additional documentary requirements shall be submitted 45 calendar days before expiry of such certification failing which the application shall be closed as defective at CAA and the processing fee of Rupees Ten (10) thousand (Rs.10,000/-) shall be forfeited and deposited to CAA's accounts under an intimation to the applicant. If closed as defective the application is to be submitted afresh.

d) Antibiotic test report of the product in ORIGINAL for test done not older than a month from the date of submission of application, for the presence of antibiotic, their parent and metabolites as prescribed in the introduction from any NABL accredited Government or private laboratory with a scope for testing said antibiotic residues using LC-MS-MS method.

e) Revised labels and brochures, in case of any change adhering to the conditions of Section 4 of this advisory

f) A notarized self-declaration in the prescribed format on Rs.100/- non judicial stamp paper for antibiotic free ingredients as well as production process and that the product composition, name, period of expiry, dosage, method of application and all other aspect of the product furnished at the time of Certification remains the same is also required from the manufacturer of the products.

7 ENFORCEMENT MECHANISM

a) Inspection Committee headed by the Director (Tech), CAA including representatives from the following institutions

- DLC / Department of Fisheries of State concerned
- Representative for CDSCO not below the rank of Assistant Drug Inspector.
- Representative from Marine Products Export Development Authority (MPEDA)
- Representative from ICAR-Central Institute of Brackish water Aquaculture (ICAR-CIBA)

b) The terms of reference for the committee is to randomly inspect the storage/manufacturing facilities of the manufacturers or importers as the case may be for conforming the compliance.

c) A Task Force shall be constituted by CAA including Representative from CAA, Representative from DLC and Representative from MPEDA, for the inspection and monitoring of aquaculture inputs manufactured and marketed in India.

d) Task force constituted by CAA shall collect product samples,but not limited to CAA certified products, randomly from manufacturing facility / storage facility, aqua shops, farms, hatcheries, etc. The manufacturer/importer company shall reimburse the cost of the sample collected by CAA to the facility from where the sample is collected.

In case of products for which the seal/tamper proof mechanism declared by the manufacturer, the Task force shallduring sampling,open the packaging of the product for ensuring the intactness of the seal/tamper proof mechanism amalgamated with the packaging as mentioned in the application and samples shall be sealed in the presence of the Task Force committee to ensure the genuineness of the product at the time of submission for testing.

e) The CAA representative of the task force shall submit the samples collected by task force to the laboratoriesempanelled and approved by the competent Authority. The list of the empanelled Laboratories shall be hosted in CAA websiteThe empaneled laboratories shall submit the report to CAA directlyfor necessary action as prescribed in section 8

f) The frequency of collection of sample and testing of a product shall be reduced if it maintains antibiotic-free status in multiple tests conducted by CAA over a period of two consecutive years.

g) CAA shall develop a protocol for sampling and testing outlining the roles of the task force.

8 PENAL PROVISION FOR NONCOMPLIANCE

a) In case, any aquaculture input being tested positive/reported by competent authorities under national regulatory programme (such as NRCP programme) for antibiotic residues, the Certificate of such product shall stand suspended with immediate effect and such product shall be delisted from the active list of CAA certified aquaculture inputs.

b) The competent Authority of CAA shall suspend the marketing of such products for the use in Coastal Aquaculture for such period as it deems fit for contravening the provisions of Article 11.7 & 11.8 of the Guidelines for Regulating Coastal Aquaculture issued as Annexure I under Chapter II of CAA Rules 2005.

c) The Authority shall, after providing reasonable opportunities for being heard from manufacturer or importer of such product, impose the penal provision as provided under Section 14 of CAA Act, 2005 for contravention of Article 11.7 & 11.8 of the Guidelines for Regulating Coastal Aquaculture issued as Annexure I under Chapter II of CAA Rules 2005.

d) In case of repeated violations, the Authority shall ban the manufacturing and marketing of such product/ facility and manufacturer.

9 PRODUCTS EXEMPTED FROM ANTIBIOTIC-FREE TEST COMPLIANCE OF REPORT FOR OBTAINING CAA CERTIFICATE

The products that are exempted from submitting an antibiotic-free test report for obtaining Certificate of Compliance are listed below. The list will be updated with inclusions or deletions of products from time to time.

1. Benzalkonium chloride
2. Bleaching powder
3. Bromide
4. Calcium cyanamide
5. Calcium hypochlorite
6. Calcium oxide
7. Calcium Peroxide
8. Calcium Phosphorus
9. Cetalkonium chloride
10. Cetrimide
11. Cetrimonium
12. Cetylpyridinium chloride
13. Chelated Magnesium
14. Chelated Potassium
15. Cobalt
16. Copper
17. Copper oxychloride
18. Didecyldimethylammonium chloride
19. Dolomite
20. EDTA
21. Formalin
22. Formic acid
23. Free Amine
24. Glutaraldehyde
25. Hcl
26. Hydrogen peroxide
27. Iodide
28. Iodine/iodophors
29. Iron
30. Lime
31. Liquid chlorine
32. Magnesium
33. Magnesium oxide
34. Manganese
35. Methylbenzethonium chloride
36. Mono hydrochloride
37. Peracetic acid
38. Phosphate
39. Potassium
40. Potassium monopersulphate
41. Potassium permanganate
42. Propionic acid
43. Silicon dioxide
44. Sodium
45. Sodium Carbonate Peroxyhydrate
46. Sodium chloride
47. Sodium hydroxide
48. Sodium hypochlorite
49. Sodium nitrate
50. Sodium perborate
51. Sulphate
52. Sulphur
53. Zeolite
54. Zinc

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