



F.No.76-2/2015-Tech/AQI (Regn)

Dated 07<sup>th</sup> August, 2019

## Advisory

In exercise of the powers conferred under the Rule 5 (v) of CAA Rules, 2005, the competent authority has approved the requirement for additional documents / information for the issuance of certificate of standards for aquaculture inputs. Accordingly the manufacturers/distributors are required to submit the following documents along with application while applying for certificate of standards for antibiotic-free aquaculture inputs.

1. Duly filled in application for registration of aquaculture inputs (downloaded from CAA website - [www.caa.gov.in](http://www.caa.gov.in))
2. Demand draft of Rs.10,000/- in favour of COASTAL AQUACULTURE AUTHORITY, payable at Chennai, for processing fee per product registration
3. Original antibiotic test report for test done recently (not older than a month) from NABL accredited labs (LC-MS-MS) should be submitted along with the application.
4. Manufacturing process stepwise (Flow chart) along with testing procedures followed within the unit
5. Test sample of the input product of 500g or 500ml dry powder or liquid respectively.
6. Details of the manufacturing facility such as proof of address, certificate of registration of the manufacturing unit/factory etc. from the competent authority.
7. Proof of any process certification
8. Process certification if any that ensures antibiotic-free production
9. Testing process followed within the unit for every batch of production.
10. Details of records maintained at the manufacturing unit, which may be produced on demand
11. Agreement and terms of license between manufacturer and the distributor or retailer as the case may be.
12. Antibiotic-free certificate from the original manufacturer of the products/ingredients as the case may be.
13. The certificate of registration of your company as well as the original manufacturer of the 'ingredients that are used as the case may be.
14. Brochure and labels with content indicating composition, dosage, batch number, expiry date and other details as follows:
  - **Manner of labelling:** Labels on packages or containers of product should contain particulars 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.

- **Use of general terms:** In the contents section general terms like, vitamins, minerals, essential nutrients etc. should not be used, instead scientific name of the specific vitamins, minerals, etc. should be provided.
- **Antimicrobial products should print**
  - a. Warning: to be sold by retail on the prescription of a qualified Aquaculture Practitioner only.
  - b. Mark Rx in red colour displayed conspicuously on the left side of the label
- **Label on the professional's samples:** Every product intended for distribution to the professionals as a free sample shall, while complying with the labelling provisions under clauses mentioned above further bear on the label of the container the words "**Professional's Sample Not to be sold**" which shall be overprinted.
- **The following shall be the general Contents of the label on the container of the aquaculture input**
  1. Name of the product: Trade name of the product should be in capital letters as mentioned in the CAA registration
  2. Net quantity of contents: A correct statement of the net content in terms of weight, measure, volume, number of units of contents, number of units of activity, as the case may be, and the weight, measure and volume shall be expressed in Metric system.
  3. Name(s) and concentrations of ingredient(s): Scientific name of all the contents of the product should be mentioned and concentration expressed as a percentage by volume or number of cells per g or ml in case of live microbes/probiotics,
  4. Indications for use: The purpose for which the product is indicated for use shall be provided clearly. The claims should have the scientific basis and indirect benefits like improved growth or production should not be claimed.
  5. Dosage and Schedule of application: Appropriate dosage and schedule of product application shall be provided by the manufacturer.
  6. 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.
  7. Contraindications (if any): Information like not suitable with any other product or not be used in particular culture systems, species or growth stages shall be clearly mentioned.
  8. Manufacture date: The date of manufacture shall be in terms of month and year
  9. 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'.

10. 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 period shall be mentioned clearly.
11. 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.
12. Indication of 'Aquatic Animal Use Only': The label shall bear a symbol depicting the head of the aquatic animal(s) for which the product is to be administered.
13. 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.
14. Batch number: A distinctive batch number, that is to say, the number by reference to which details of manufacture of the particular batch from which the substance in the container is taken are recorded and are available for inspection. The figure representing the batch number being prefixed 'Batch No.'
15. Import licence number (if imported): Products containing the ingredient (s) imported into the country shall also bear on the label, the license number under which the product is imported, prefixed with 'Import License Number' along with the name and address of the importer.
16. Indication 'Do not contain antibiotics': The label shall have 'Do not contain antibiotics' in the bottom strip with bigger font size in distinct colour.
17. Indication 'Do not contain hormones': The label shall have 'Do not contain hormones' in the bottom strip with bigger font size and continue to maintain the hormone free status in all the batches.
18. CAA registration number: Every product manufactured and/or marketed in India shall bear on its label the number allotted by CAA for that product.

  
Director (Tech)



F.No.76-2/2015-Tech/AQI (Regn)

Dated 07<sup>th</sup> August, 2019

To,

**Manufactures/Distributors of Aquaculture Inputs.**

Sub: Certificate of standards issued by CAA for antibiotic-free aquaculture inputs - Additional documents required -Reg

Sir/Madam,

In exercise of the powers conferred under the Rule 5 (v) of CAA Rule, 2005, the competent authority has approved the requirement for additional documents / information for the issuance of certificate of standards for aquaculture inputs. Accordingly, as manufacturers/distributors of aquaculture products, you are requested to submit the following applicable additional documents to retain the validity of certificate of standards already issued / to process your request for certificate of standards for antibiotic-free aquaculture inputs

1. Details of the manufacturing facility such as proof of address, certificate of registration of the manufacturing unit/factory etc. from the competent authority.
2. Proof of any process certification
3. Process certification if any that ensures antibiotic-free production
4. Testing process followed within the unit for every batch of production.
5. Details of records maintained at the manufacturing unit, which may be produced on demand
6. Agreement and terms of license between manufacturer and the distributor or retailer as the case may be.
7. Antibiotic-free certificate from the original manufacturer of the products/ingredients as the case may be.
8. The certificate of registration of your company as well as the original manufacturer of the ingredients that are used as the case may be.

Further it is informed that you may refer the advisory dated 7<sup>th</sup> August, 2019 published in CAA website on the labelling (copy enclosed) and submit these additional documents for issuance of certificates of standards from CAA.

  
Director (Tech)