Document No. EIC/Feed Additives and Premixtures/Ex. Inst./January/2014/Issue-1

EXECUTIVE INSTRUCTIONS FOR APPROVAL AND MONITORING OFESTABLISHMENT FOR FEED ADDITIVES & PREMIXTURES FOR EXPORT

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1. INTRODUCTION

The requirements for the approval of the establishments to process feed additives and premixtures meant for export have been order Vide No. S.O. 3523 (E) and notification Vide no. S.O. 3524 (E) dated 28th November, 2013 laying down requirements for feed hygiene which encourage the development of guides to good practice on hygiene and the application of Hazard Analysis Critical Control Points(HACCP) principles/FAMI-QS/CGMP.

The requirements for the approval of the establishment to process/ manufacture feed additive or premixtures meant for export have been notified vide GOI Notification S.O 3524 (E) dated 28th November, 2013, on the basis of which the establishment processing/manufacturing feed additives or premixtures meant for export are being approved by the Competent Authority (Export Inspection Council (EIC) of India for European Union (EU) and Export Inspection Agencies (EIAs) for non EU).

The Primary responsibility for meeting the health requirements/specifications of importing countries and also those specified in the GOI Notifications lies with the processor/manufacture themselves, for which the establishments are required to plan and implement detailed HACCP based process control (own check system) and to maintain necessary records.

The role of EIC/EIAs is to exercise official control by approving the establishment and implementing an effective surveillance system to ensure compliance with requirements as per the Notification No S.O 3524 (E) dated 28th November, 2013.

The requirement of regulation (EC) No. 1831/2003, Regulation (EC) No. 183/2005, Regulation (EC) No 1331/2008, Article 11 of Regulation (EC) 178/ 2002, Commission Directive 2008/84/EC, Directive 87/153/EEC, Directive 2002/32/EC and Directive 70/524/EEC are also taken into consideration during preparation of this executive instruction.

2. SCOPE OF APPROVAL

This document applies to the activities of establishment processing feed additives or premixtures at all stages production, including primary production of the above and up to and including, the placing of feed additives and premixtures in the international market.

The aim of this document is to ensure safety of feed additives and premixtures to:

a. Minimize the risk of adulterated feed additives and premixtures entering the feed/food chain;
b. Enable an operator to implement the feed hygiene and
c. Provide measures to ensure that other applicable regulatory feed safety requirements shall be met.

The description of terms and definitions are used given in **Annexure-XXIII and XXIV.**

3. PROCEDURE FOR APPROVAL OF ESTABLISHMENT

3.1 Application for Approval

3.1.1 The establishment intending to process feed additives or premixtures for export shall submit the application for approval in the prescribed format in duplicate along with documents given at 3.1.3 to the office of EIA under whose jurisdiction the establishment is situated. Applicant must seek the scope of approval the establishment and specify in the application form as per **Annexure-I** along with functional group as per **Annexure—XXIX.**

3.1.2 Application fee of Rs. 5,000/- and applicable service tax shall be paid by the applicant by way of demand draft drawn in favour of the Export Inspection Agency concerned along with the application form.

3.1.3 The application shall be accompanied by the following documents:

a. HACCP Manual (including the Sanitary Standard Operating Procedures (SSOP), process flow chart with product description and manufacturing details in each step and also plumbing diagram).

b. In the case of establishment meant for export to the EU, attested/certified copy of test report in respect of water complying with EC directive No.98/83/EEC dated 3.11.1998 to be used in process/manufacture

c. However, in the case of establishment meant for export to the Non-EU, attested/certified copy of test report in respect of water complying with IS: 4251 to be used in process/manufacture.

d. In all cases, the samples of water shall be drawn by representative of EIA or EIC approved laboratory and tested in any of the EIA's/ EIC approved laboratory.

e. Layout plan of the establishment (site plan and building plan preferably in A-4 size)

f. Attested/Certified copies of documents proving legal identity of the applicant establishment.

g. Attested/certified copy of lease agreement for the premises and building, where ever applicable.

h. Attested/Certified copy of registration certificate issued by Competent Authority/Any Government of India recognized authority/agency in respect manufacturer or processor. (If not available at the time of applying for approval, this may be submitted before grant of approval).

i. Bio-data of the technical person (s) with attested copies of degree certificate(s), experience certificate(s) and appointment letter/certificate of employment from the establishment

j. An Undertaking and Guarantee in the formats as per annexure-I-A and I-B

k. Attested/Certified copy of consent letter issued by Pollution Control Board (PCB) concerned. (In case the consent letter is not available at the time of applying for approval this shall be submitted before the grant of final approval. However, in such cases copy of the application made to PCB shall be submitted at the time of filing application for approval to EIA.

l. Attested/ Certified copy of the order allotting Importer Exporter Code (IEC) number.

Note: In case where a non EU approved establishment submits application for the approval for exports to the EU countries, the documents which were submitted earlier need not be submitted again, if there is no change.

3.2. Categories of feed additives and premixtures for which approval granted –

The following categories of feed additives and premixtures are covered vide Notification No. S.O. 3523 (E) dated 28th November, 2013 for which establishment may be granted approval.

(1) Manufacturing or handling of feed additives listed below :

Sl. No.	Additives	Remarks
(a)	Antibiotics	All additives in the group
(b)	Coccidiostats and other medicinal substances	All additives in the group
(c)	Growth promoters	All additives in the group
(d)	Vitamins, pro-vitamins and chemically well-defined substances having a similar effect	All additives in the group
(e)	Trace elements	All additives in the group
(f)	Enzymes	All additives in the group
(g)	Micro-organisms	All additives in the group
(h)	Carotenoids and xanthophylls	All additives in the group
(i)	Substances with antioxidant effects	Only those with a fixed maximum content
(j)	Proteins obtained from microorganisms belonging to the group of bacteria, yeasts, algae, lower fungi	All additives in the group
(k)	Co-products of the manufacture of amino acids by fermentation	All additives in the group
(l)	Amino acids and their salts	All additives in the group
(m)	Hydroxy analogues of amino acids	All additives in the group

(2) Premixtures prepared from type of additives listed below:

Sl. No.	Additives	Remarks
(a)	Antibiotics	All additives in the group
(b)	Coccidiostats and other medicinal substances	All additives in the group
(c)	Growth promoters	All additives in the group
(d)	Vitamins, pro-vitamins and chemically well-defined substances having a similar effect	A and D
(e)	Trace elements	Cu and Se

(3)Premixtures prepared from type of additives listed below

S. No.	Additives	Remarks
(a)	Vitamins, pro-vitamins and chemically well-defined substances having a similar action	All additives in the group except for vitamins A and D
(b)	Trace elements	All additives in the group except for Cu and Se
(c)	Carotenoids and xanthophylls	All additives in the group
(d)	Enzymes	All additives in the group
(e)	Micro-organisms	All additives in the group
(f)	Substances with antioxidant effects	Only those with a fixed maximum content

Feed business operator shall ensure that establishment under their control are approved by the competent authority, where such establishments carry out one of the following activities:

a. Manufacturing for export of feed additives covered vide GOI Notification No. S.O. 3523 (E) dated 28th November, 2013
b. Manufacturing for export of premixtures prepared using feed additives.

3.3Processing of application for approval

3.3.1 Applications received shall be scrutinised by the EIA office where it has been received and the discrepancies/ shortcomings observed should immediately be communicated to the applicant for rectification. A copy of application along with HACCP manual/Feed Additives and Premixtures Quality System **(**FAMI-QS), other relevant documents and comments of the Officer In-charge of Sub-Office (as applicable) shall be forwarded to In-charge of the EIA within seven working days after receiving it complete in all respect.

Adequacy audit of the HACCP manual and SSOPs shall be carried out by an EIA officer, having adequate knowledge of HACCP/ FAMI-QS authorised by In-charge of the EIA. The adequacy audit report along with observations shall be forwarded to the In-charge of the EIA within five working days.

After further scrutiny at EIA, deficiencies, if any, observed in the HACCP manual shall be communicated by the EIA to applicant for rectification.

3.3.2 Applications complete in all respect, along with HACCP documentation shall be forwarded by the EIA to the Convener of Inter Departmental Panel (IDP) for arranging assessment of the establishment.

3.4 Assessment of the establishment

3.4.1 The IDP (as decided by Competent Authority) shall carry out assessment of the establishment within 15 days of receipt of their application complete in all respect.

While processing activities are in progress, the IDP shall visit the establishment to assess the infrastructure, equipment facilities, processing methods adopted by the unit and implementation of HACCP/FAMI-QS based feed safety management system. Based on the satisfactory assessment report of the IDP, the approval shall be granted to the establishment by the Competent Authority.

In cases where a non-EU approved establishment submits application for the approval to process or manufacture feed additives or premixtures meant for export EU countries, the IDP may conduct assessment of infrastructure facilities and HACCP/FAMI-QS implementation of the establishment, if satisfied recommend for the approval of the establishment for export to EU.

3.4.2 The composition of IDP shall be as constituted by EIC from time to time.

3.4.2.1 The members of the IDP will be decided by the In-charge of the EIA from the composition of IDP as constituted by EIC. The EIA representative of the IDP (Convener) shall be an officer of the level of Deputy Director (Technical) having background (qualification and experience) of food/ agriculture/veterinary sciences.

Note In unavoidable circumstances, the senior most Assistant Director (Technical) having enough experience and qualification may be nominated as the Convener of the panel by In-charge, EIA.

While constituting the IDP, experience and expertise of the members in the field of feed additives shall be considered.

3.4.2.2 The quorum of IDP shall be two and may consist of EIA representative as convener, representative from State Animal Husbandry Department, Agricultural and Processed Food Products Export Development Authority(APEDA), Bureau of Indian Standards (BIS), Food Safety and Standards Authority of India(FSSAI), Ministry of Agriculture, College of Veterinary Sciences or any technical expert.

3.4.3 The IDP shall assess the establishment and report in the prescribed format. In case the IDP finds any deficiency during its assessment, the same shall be recorded in the non-conformity report which shall be counter signed by the representative of the establishment as a token of acceptance. Additional suggestions for improvement, if any, shall be given to the processor separately, the implementation of which shall not be a part of the approval procedures.

The IDP convener shall submit the assessment report and recommendations of the IDP to the In-charge of EIA within three days of completion of the visit to the applicant's establishment. In case verification of rectification of the deficiencies is needed the same may be undertaken as per the time frame prescribed by the IDP (maximum three months).The said report shall be submitted to the In-charge of EIA within three days of verification. The recommendations of the IDP shall clearly state whether the applicant’s establishment is recommended for approval or not with its production or manufacturing capacity with its scope.

3.4.4 The report of the IDP visit shall be examined by the In-charge of EIA and same may be forward to EIC, in case the establishment is meant for export to EU, with a clear cut recommendation. Whereas, for Non EU the In-charge of EIA will grant approval.

3.4.4.1 EIAs shall allot an approval number to the establishment in the following manner

•EIA-Mumbai – FAPM/01/Establishment No. / Year of Approval
•EIA-Kolkata – FAPM /02/Establishment No. / Year of Approval
•EIA-Kochi – FAPM /03/Establishment No. / Year of Approval
•EIA-Delhi – FAPM /04/Establishment No. / Year of Approval
•EIA-Chennai – FAPM /05/Establishment No./ Year of Approval
("Establishment No" shall be allotted in serial order i.e., 001, 002 etc.)
For example: for the first approved establishment at EIA-Mumbai in the year 2014, the establishment shall be allotted approval No. "FAPM/01/001/2014".

Open a file with 4 parts: Part A, Part B, Part C and Part D.

"Part A" shall bear the Approval Number followed by suffix "A" (e.g. "FAPM/01/001/2014- A"). This file shall contain approval documents such as application for approval/renewal, IDP assessment reports, approval of additional facilities and other correspondence relating to the establishment.

"Part B" file shall bear the approval number followed by suffix 'B'. (e.g. "FAPM/01/001/2014-B") This file shall contain copies of monitoring reports, supervisory visit reports, NCR (Non Conformity Report), suggestions for improvements and laboratory test reports.

"Part C" file shall bear approval number with suffix 'C' (e.g. "FAPM/01/001/2014- C") and shall have copies of Certificate for Export (CFE) issued by the establishment and Health Certificates issued by EIA.

"Part D" file shall bear approval number with suffix 'D'(e.g. "FAPM/01/001/2014- D") and have details of foreign complaints including all relevant papers and details of action taken regarding "ON ALERT" etc.

All records of file A and D shall be kept as permanent records. However records of File B and C shall be kept for at least three years.

3.4.4.2 In case the IDP does not recommend approval and if agreed to, the In-charge of EIA shall convey the same to the applicant, within seven days of the receipt of the IDP report, along with the reasons for which applicant establishment has not been considered fit for approval.

3.4.4.3 In case the deficiencies observed and recorded by the IDP which can be rectified within a reasonable time (maximum of three months), a copy of Non-Conformity Report (NCR) shall be given to the unit for rectification and thereafter verification by either IDP or Convener of IDP as may be decided by IDP. Once verified and found satisfactory and recommended for approval, the actions as per clause 3.4.4 shall be followed.

3.5. Action to be taken by Export Inspection Council (EIC)

3.5.1 In case of the establishment meant for export to EU, on receipt of the recommendations of the In-charge of EIA, the technical division in EIC shall submit the same to the Director (I&Q/C) for approval. Approval of Director (I&Q/C) shall be simultaneously conveyed to the In-charge of EIA to enable issuance of a formal letter to the establishment. Establishment shall be approved from the date of approval given by Director (I&Q/C).

3.5.2. Certificate of approval shall be issued by EIC. The certificate under normal circumstances shall be valid for a period of two years from the date of approval by Director (I&Q/C).

3.5.3 Once the Director (I&Q/C), grants the approval to the establishment the name of the establishment shall be updated in the official website of EIC and shall forward their name to the Mission of India, in Brussels for taking up the matter with EC for inclusion of its name in third country establishment list with copies to all concerned including Customs and EIA.

3.5.4 Once approved, the establishment shall be allowed to process/manufacture feed additives or premixtures in their establishment for all destinations including EU.

3.5.5 From the date of approval, concerned EIA shall start issuing of health certificate to the establishment.

4. PERMISSION TO PROCESS AND PACK FEED ADDITIVES OR PREMIXTURES FOR EXPORT BY MERCHANT EXPORTER

4.1 Approved establishments shall be permitted to process and pack feed additives or premixtures for export by one or more merchant exporters, depending upon their production capacity. However, a maximum of three merchant exporters only are permitted at a given time.

4.2 Approved feed additives or premixtures establishments and the merchant exporters shall also be permitted to export “on account” of Export Houses, Trading Houses, Star Trading Houses or Super Star Trading Houses only. However, it may be ensured while issuing Certificates for Export (CFE) for such “on account” export, the column no.1 of the certificate should contain the details of the exporter as well as the “ on account” exporter.

4.3 Establishments intending to process and pack feed additives or premixtures on behalf of merchant exporter should submit their application to the EIA concerned as per the format given at **Annexure-XII** along with a fee as prescribed in clause 20 and also the documents specified therein. Application complete in all respect shall be considered by EIA, based on the production capacity vis–a –vis the requirements of the merchant exporter(s).

4.4 Approval to process/handle feed additives or premixtures meant for export by the merchant exporter is given by the EIA concerned as per the format given at **Annexure-XIII.**

4.5 Certificate for Export (CFE) issued by the approved establishment meant for export for the merchant exporter/ Export House has to be countersigned by the EIA concerned, for which a fee as prescribed in clause 20 has to be paid for each certificate by the processor to the EIA.

The EIA may collect the monitoring fee directly from the merchant exporter on request from the approved establishment.

4.6 When an approved processor requests EIA for cancellation of permission given to process and pack feed additives or premixtures for any merchant exporter, the permission shall be withdrawn using format given at **Annexure XIV.**

5. PROCEDURE FOR RENEWAL OF APPROVED ESTABLISHMENT

The approved establishment shall be renewed for a period of two years. An application for renewal shall be submitted in prescribed format **Annexure-IV** to the concerned EIA at the latest four months before the date of expiry of approval. At the time of application, the applicant shall send the following particulars and documents directly to the EIA including those specified in 3.1.3

a. A copy of the approval certificate issued earlier for export;

b. Any other new information which has become available with regard to the evaluation of the safety in use of the feed additives/premixtures and the risks of the feed additive/premixtures to animals, humans or the environment;

c. Where appropriate, a proposal for amending or supplementing the conditions of the original authorization;

d. Whether any change in the scope, the same may be included.

e. Latest water test report as per IS 4251 or EC 98/83 (as applicable).

f. Undertaking and Guarantee.

6. CONDITION FOR APPROVAL

6.1 In order to be approved establishment should meet conditions relevant to their operations, infrastructure facilities, equipment, personnel, production, quality control, storage and documentation to ensure both safety and product traceability.

6.2 The competent authority may grant approval if it appears, from the on-site visit, that the establishment meets all the infrastructure and equipment requirements and satisfactory implementation of HACCP.

6.3 No feed additive or premixture shall be approved for export unless the applicant for such approval has adequately and sufficiently demonstrated meeting the requirements specified in the rules and condition specified in the instructions issued by the EIC, from time to time.

6.4The feed additive satisfies the requirements of rule 11(3) of GOI notification and bear at least one of the characteristics specified in the rule 11(4) of GOI notification.

6.5 The feed additive or premixture shall not-

i. have an adverse effect on animal health, human health or the environment,
ii. be presented in a manner which may mislead the user,
iii. harm the consumer by impairing the distinctive features of animal products or mislead the consumer with regard to the distinctive features of animal products

6.6 The feed additives or premixture shall-

i. favorably affect the characteristics of feed,
ii. favorably affect the characteristics of animal products,
iii. favorably affect the colour of ornamental fish and birds,
iv. satisfy the nutritional needs of animals,
v. favorably affect the environmental consequences of animal production,
vi. favorably affect animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feeding stuffs.
vii. have a coccidiostatic or histomonostatic effect

Note- Antibiotics, other than Coccidiostats or histomonostats, shall not be covered.

7. PROCEDURES FOR EXTENSION OF SCOPE OF APPROVED ESTABLISHMENT

7.1 The approved establishment seeking enhancement of its scope for new activities etc. shall submit application in the prescribed format along with relevant documents to the controlling office of EIA. An application fee of Rs. 2,000/- and service tax as applicable by way of demand draft drawn in favour of the EIA should be enclosed. The establishment wishing to add one or more of the activities as per **Annexure-XXVIII** shall seek approval from EIA for each activity along with functional group as per **Annexure-XXIX.** At the time of application, the applicant shall send the following particulars and documents to the EIA;

a. name and address of the establishment;

b. the identification of the feed additive, a proposal for its classification by category and functional group as per **Annexure-XXVIII & XXIX** and its specifications, including, purity criteria where ever applicable,

c. a description of the method of production and intended uses of the feed additive, of the method of analysis of feed additive according to its intended use and, where appropriate, of the method of analysis for the determination of the level of residues of the feed additive, or its metabolites in food;

d. a copy of the studies which have been carried out and any other material which is available to demonstrate that the feed additive satisfies the criteria.

e. proposed conditions for the feed additive for export must be labelled as per requirements and, where appropriate, specific conditions for use and handling (including known incompatibilities), levels of usage in complementary feeding stuffs and animal species and categories for which the feed additive is intended;

f. for authorization for new scope for which the applicants seeks permission must submit in writing that products for additives falling within the scope of finished products to be exported will not contain Genetically Modified Organism (GMOs).

7.2 Application received shall be scrutinized and the discrepancies / shortcomings observed shall be immediately communicated to the applicant for rectification. In case of the approval of enhancement of its scope, the revised HACCP plan addressing the new activity shall be submitted to the concerned EIA along with the process flow chart for verification. Adequacy audit of the HACCP manual with respect to the additional activities shall be done by Officer authorized by EIA.

8. CATEGORIES OF FEED ADDITIVES AND PREMIXTURES

8.1 Feed additive shall be allocated to one or more of the following categories, depending on its functions and properties, namely

i. Technological additives, any substance added to feed for a technological purpose;

ii. Sensory additives, any substance, the addition of which to feed improves or changes the organoleptic properties of the feed, or the visual characteristics of the food derived from animals;
iii. Nutritional additive, any substance added to feed to fulfil specific requirement for optimal growth and performance.
iv. Zootechnical additives, any substance used to affect favourably the performance of animals, health or used to affect favourably the environment.
v. Coccidiostats and histomonostats.

8.2 The feed additives with one or more of the functional groups categorised as per third schedule of GOI notification as per **Annexure-XXIX.**

8.3 Where necessary as a result of technological progress or scientific development, additional feed additive categories and functional groups may be approved.

9. SUSPENSION OF APPROVAL

In case, the establishment change or cease their activities or no longer fulfill the conditions applicable to their activity, then the approval can be temporarily suspended.

The competent authority shall temporarily suspend the approval of an establishment for one, more or all of its activities, where it is shown that the establishment no longer fulfils the conditions applicable to those activities. Such suspension shall last until the establishment again meets those conditions, where such conditions are not met last in one year.

10. REVOCATION OF APPROVAL

The competent authority shall revoke the approval of an establishment, for one or more of its activities, where:

a. the establishment ceases one or more of its activities;

b. it is shown that the establishment has not fulfilled the conditions applicable to its activities, for a period of one year;

c. it identifies serious deficiencies or has had to stop production at an establishment repeatedly and the feed business operator is still not able to provide adequate guarantees regarding future production.

11. AMENDMENTS TO APPROVAL OF AN ESTABLISHMENT

Upon request, the competent authority shall amend the approval of an establishment, where it has demonstrated its capacity to develop activities which are additional to those for which it was first approved.

12. GENERAL REQUIREMENTS

a. The approved establishment shall establish, document, implement and maintain a management system that ensures HACCP principles are applied and implementation of HACCP at all stages of process and production.

b. Identification and traceability

i. Identify and record the product by suitable means throughout the production;

ii. Maintain a register that contains the names and addresses of manufacturers of incoming materials, additives. Incoming materials shall be verified by the Quality Control personnel.

c. The establishment shall be continually adapted in line with regulatory developments of importing country.
d. The structure of the management system of the establishment shall be specific to the organization of the operator and should include policies, requirements and process documents that reflect commitment to safety of the product.
e. The management of the establishment shall ensure that all activities carried out by them that could impact on the quality and safety of the product are consistently defined, implemented and maintained at all levels in the organization.
f. The establishment shall include quality procedures to ensure that the product consistently conforms to the authorization of the feed additive and the specification of the premixture thereof.
g. Each establishment shall perform and record the evaluation of risks associated with processes within its operations and subsequently defines controls to be applied to those based on HACCP principles/FAMI-QS.
h. Effective change control and investigative procedures shall be in place to manage product history and deviations from planned procedure.
i. The establishment shall maintain procedures to handle a threat to product quality and safety. These include, complaints, product recall, and audit findings.
j. Every raw material procured by the establishment shall be evaluated to assess any potential hazard associated with it; this shall be carried out according to HACCP principles.
k. There shall be a check that these feed additives and premixtures are being produced in compliance with the requirements of this document.
l. Verification of incoming materials
   i. Each batch entering the establishment shall be uniquely registered by means of a batch number, full name of product, date of receipt and quantity received. Any damage shall be reported and documented
   ii. If the incoming material is delivered in bulk, a receipt and storage procedure must be in place. If silos are emptied, this shall be recorded and cleaning must be evaluated.
   iii. Incoming materials should be checked and formally approved prior to use according to written procedures. Samples of these materials should be retained. Where appropriate, a retained sample shall be available for at least the shelf life of the material, either at the suppliers or the operators.
   iv. Handling of incoming product should be in accordance with its status, for example, a received product which is deemed unfit for use must be identified as such and segregated from those products released for use. In the same light, perishable materials should be treated as appropriate to ensure their wholesomeness before use.
   v. If incoming materials are rejected and thus not incorporated for any reason related to product quality and safety, their disposal, destination, or return to supplier shall be recorded.
m. Quality Control
   i. Where appropriate, a qualified person responsible for quality control must be designated.
   ii. Establishment must, as part of a quality control system, have access to a laboratory with adequate staff and equipment.

iii. A quality control plan must be drawn up in writing and implemented, to include, in particular, checks on the critical points in the manufacturing process, sampling procedure and frequencies, method of analysis and their frequency, compliance with the specifications and the destination in the event of non-compliance from processed material to final product.
iv. Documentation relating to the raw material used in final products must be kept by manufacturer in order to ensure traceability. Such documentation must be available to the competent authority for a period for the use to which product are placed on the market.
v. In addition, sample of ingredient and of each batch of product manufactured and placed on the market or of each specific portion of production must be taken in sufficient quantity using a procedure pre-established by manufacturer and be retained, in order to ensure traceability.
vi. The sample must be sealed and labelled for easy identification;
vii. They must be stored under conditions which prevent any abnormal change in the composition of the sample or any adulteration.

n. Production:
i. A qualified person responsible for production must be designated.
ii. Establishment must be ensure that the different stage of production are carried out according to pre-established written procedure and instructions aimed at defining, checking and mastering the critical point in the manufacturing process.
iii. Technical or organizational measures must be in place to avoid or minimize, as necessary, any cross contamination and error. There must be sufficient and appropriate means of carrying out checks in the course of manufacture.
iv. The presence of prohibited undesirable substance and other contaminant in relation to human or animal health shall be monitored and appropriate control strategies to minimize the risk shall be put in place.
v. Waste and materials not suitable as feed should be isolated and identified. Any such material containing hazardous shall be disposed of an appropriate way.
vi. The establishment shall plan and carry out production under controlled conditions, where access for non-authorized personnel can be prevented.
vii. A retention sample of adequate size shall be taken of each batch and held, as a minimum, for a time equivalent to the defined shelf life of the product. The samples must be sealed and labelled, stored in a manner that should prevent abnormal change, and kept at the disposal of the competent authorities for a period appropriate to the use

o. Labelling and packaging of feed additives and premixtures
i. The availability of information that describes the characteristics of the finished product.
ii. Each product shall have a unique name or code.
iii. Each package shall be labelled by a unique identifier (which can be a combination of codes) in order that the batch to which it belongs can subsequently be identified and traced.
iv. All finished product should be inspected prior to dispatch, in accordance with written procedures of the establishment, to ensure it meets specification.
v. Where products are packaged, care shall be taken to avoid contamination and cross-contamination during the packaging process, and to ensure that packaged products are correctly identified and labelled as per **Annexure-XXVI**.

vi. No person shall export a feed additive or a premixture of additives unless its packaging or container is labelled under the responsibility of a producer, packer, importer, seller or distributor and bears the following information, in a conspicuous clearly legible and indelible manner, in at least the national language or languages of the Importing Country in which it is to be exported.

p. Preservation of product

i. The processed feed additives or premixtures shall be separated from raw material in order to avoid any cross contamination.

ii. Feed additives or premixtures shall be stored and transported in suitable containers. They shall be stored in places designated, adapted and maintained in order to ensure good storage condition, to which only person authorized by the establishment have access.

iii. Feed additive/ or premixtures shall be stored and transported in such a way as to be easily identifiable, in order to avoid cross contamination and prevent deterioration.

iv. Containers and equipment used for transport, storage, conveying, handling and weighing shall be kept clean.

v. Any spoilage shall be minimized and kept under control to reduce pest invasion.

vi. Where appropriate, temperature shall be kept as low as possible to avoid condensation and spoilage.

q. Transport

i. Transportation of raw material and finished products are critical points in the process. Impurities that are hazardous to humans or animals may get in contact with the final product. Measures must be taken to ensure that the transportation of raw material and finished products is adequate in order to minimize the risk of contamination.

ii. Transport of packaged goods feed additives or pre-mixtures should not be transported, even if sealed, with goods that compromise the safety of the raw material or the finished product.

iii. The package for the raw material or the finished product should provide adequate protection against deterioration or contamination that may occur during transportation.

iv. Transport of bulk products

- The operator shall ensure that the transporter of bulk products has sufficient knowledge about handling feed additives and pre-mixtures.
- Valid information that enables container traceability about the product to be loaded must be given by the establishment to the transporters. The transporters can then define the suitable container to provide the best protection.

r. Control of non-conforming products

The establishment shall establish a documented procedure for dealing with products which do not comply with intended requirements. Responsibility for review and disposal of the non-conforming product shall also be defined.

t. Complaint handling system

i. Establishment shall implement a system for registering and processing complaints.

ii. The establishment shall put in place, system for the prompt recall of products in the distribution network. They shall define by means of written procedures, the destination of any recalled products, and before such

product are put back into circulation they must undergo a quality-control reassessment.

iii. Establishment have a formalized documented complaint handling procedure and the corrective actions carried out in a timely and effective manner, with consideration given to the frequency and seriousness of complaints that ensure to avoid recurrence and implement on going improvements.

13. INFRASTRUCTURE REQUIREMENTS

13.1 Building and facilities

a. Design and construct all buildings and facilities for manufacture, packaging and storage according to its intended use in a manner that maintenance and cleaning shall be facilitated.
b. Sufficient building and working space shall be provided to allow orderly storage of equipment and materials.
c. Adequate ventilation; controllable humidity and temperature setting;
d. Construct floors, walls, ceilings and windows of smooth, easily cleanable surfaces.
e. Adequate lighting and hygienic design of equipment shall be provided.
f. The lay-out, design, construction and size of the facilities and equipment shall be such as to minimize the risk of error and to avoid contamination, cross-contamination and any generally adverse effects on the safety and quality of the feeds.
g. Where necessary, ceilings and overhead fixtures must be designed, constructed and finished to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable microorganisms and the shedding of particles that can affect the safety and quality of product.
h. Design and construct adequate drainage and waste disposal systems.
i. Ventilation systems and devices shall be sufficient in number and capacity to prevent grease or condensation from collecting on walls and ceiling. If necessary to keep rooms free of excessive steam and condensation, mechanical ventilation of sufficient capacity shall be provided.
j. If necessary, heating, cooling or air-conditioning systems shall be designed and installed so that air-intake or exhaust vents do not cause contamination of products, equipment or utensils.
k. Lighting must be of sufficient intensity. Hygienic conditions are maintained throughout the production and storage areas, as well as where equipment and utensils are cleaned, in hand-washing areas and toilets.
l. Water used in manufacture shall be of suitable quality. It should be ensured that drainage lines and sewage systems are watertight and of sufficient capacity. Drainage facilities must be adequate for the purpose intended; they must be designed and constructed to avoid the risk of contamination.

13.2. Equipment

a. Manufacturing equipment should be located, designed, constructed and maintained to suit the manufacture of the products concerned.
b. The equipment must be designed to facilitate manual or cleaning in Place (CIP) and/or disinfection by having surfaces that are smooth, free of sharp angles, corners, crevices or smooth welds.
c. Where applicable, equipment must be placed away from walls to allow easy access for cleaning and to prevent pest infestation.

13.3 Personnel Hygiene Facilities

Ensure that personnel hygiene facilities are suitably designated, located and maintained. They should include:
a) Adequate changing and washing facilities;
b) Adequate number of toilets;
c) Adequate facilities for hand washing and drying;
d) A constant supply of potable water.

13.4. Maintenance, monitoring and cleaning

i. The establishment shall maintain a documented program for manufacturing operations and records shall be kept for the work carried out.
ii. The operator shall establish processes to ensure that monitoring can be carried out in a manner consistent with documented procedures.
iii. Ensure that all inside and outside areas, buildings, facilities and equipment are kept clean and in good state to function as intended and to prevent contamination.
iv. Cleaning and / or disinfection should remove dirt and residues which may be a source of contamination.
v. Cleaning can be carried out by e.g. physical methods like scrubbing and vacuum cleaning and chemical methods using alkaline or acidic agents and methods without the use of water.
vi. Where appropriate disinfection may be necessary after cleaning.

13.5 Cleaning programme

A written cleaning programme shall be available with the establishment and specify the following items. Where appropriate consult experts to draw up the program.

a) Areas, facilities and equipment to be cleaned

b) Method and frequency of cleaning

- establish a schedule

c) Agents used

- use and store according to the manufacturer's instruction
  - ensure clear labelling of the containers
  - separately store from raw materials and finished products
  - apply properly so as not to contaminate raw materials and finished products

d) Responsibilities for the tasks

e) Inspection and evaluation

- perform periodic checks and verify the procedure for suitability and effectiveness

f) Training of the personnel

g) Record shall be maintained of all cleaning, inspections and evaluation

13.6 Pest control-

Suitable pest control measures shall be adopted to eradicate pests inside the premises.

a. A schedule shall be implemented with areas, facilities and equipment to be inspected including frequency as well as details of pesticides, fumigation agents or traps used as well as responsibilities for the tasks.
b. Pesticides, fumigation agents or traps used shall be approved by the Local Competent Authority for the purpose concerned, clearly marked and separately stored from raw materials and finished products and applied properly to avoid contamination of raw materials and finished products.
c. The positions of traps and bait stations shall be mapped.
d. The HACCP plan shall consider the risk of contamination due to infestation or use of pesticides.
e. Windows and other openings must, where necessary, be proofed against pests. Doors must be close-fitting and proofed against pests when closed.

13.7 Waste disposal-

Waste and materials not suitable should be isolated and identified. Any such materials containing hazardous levels of veterinary drugs, contaminants or other hazards shall be disposed off in an appropriate way and not to be used. The establishment shall:

a. Identify waste clearly and dispose in a manner which avoids contamination of raw materials and finished products;
b. Store waste in closed or covered containers at defined waste accumulating areas;
c. Clean waste accumulating areas regularly;
d. Waste containers should be clearly marked and designated for that purpose only;
e. Sewage, waste and rainwater shall be disposed of according to state/central Pollution Control Board Regulations and in a manner which ensures that equipment and the safety and quality of product is not affected.

Use of Logo- "Q" Mark along with approval number shall be mandatory and use as a-logo on each package of export.

14. QUALITY CONTROL

The operator shall plan and carry out production and service provision under controlled conditions. Production areas shall be controlled so that access for non-authorised personnel can be prevented.

Controlled conditions should include, as applicable:

14.1 The availability of information that describes the characteristics of the finished product.

i. Each product shall have a written specification, which is amended when any change takes place.
ii. Each product shall have a unique name or code.
iii. Details of packaging and labelling shall be available.
iv. Each package shall be labelled by a unique identifier (which can be a combination of codes) in order that the batch to which it belongs can subsequently be identified and traced.

v. All finished product should be inspected prior to dispatch, in accordance with written procedures, to ensure it meets specification. A retention sample adequate size shall be taken of each batch and held, as a minimum, for a time equivalent to the defined shelf life of the product. The samples must be sealed and labelled, stored in a manner that prevent abnormal change, and kept at the disposal of the authorities for a period appropriate to the use. For more detailed information on possible sampling procedures see the "Guidance on sampling" (**Annexure-XXX**).

vi. If products are rejected and not put into circulation for any reason related to product quality and safety, their disposal, destination, or return to supplier shall be recorded.

14.2 The availability of work instructions:

i. The different stages of production shall be carried out according to written procedures aimed at defining, controlling and monitoring the critical points in the manufacturing process. These include procedures surrounding the precautions necessary to avoid cross-contamination and errors.

ii. Records shall be kept which confirm that procedures are followed and/or identify any deviation from them. Procedures shall be subject to regular critical appraisal to ensure that they continue to be effective.

14.3 Rules governing packaging:

i. Where products are packaged, care shall be taken to avoid contamination during the packaging process, and to ensure that packaged products are correctly identified and labelled in compliance with the provisions of relevant regulations.

ii. Packaging shall be appropriate to product type, with the objective being to maintain contents for their intended shelf life. Packaging shall be considered under HACCP analysis.

iii. Pallets shall be serviceable, clean and dry. All pallets which are returned shall be inspected and if necessary cleaned before re-use.

14.4 Rules controlling storage:

i. Finished product shall be clearly identified and stored in clean dry conditions. Access to these materials should be restricted to authorised personnel only.

ii. Incoming materials, active substances, carrier substances, products which meet the specifications – and those which do not – shall be stored in suitable places designed, adapted and maintained, in order to ensure appropriate storage conditions which manage the risks of contamination and the presence of harmful organisms. Packed materials shall be stored in appropriate packaging.

iii. Materials should be stored in a manner which enables easy identification, avoids cross-contamination and prevents deterioration. A stock rotation system should be in place.

iv. The storage environment should be set up in a manner which minimises the risk of damage to packaging and spillage of material.

14.5 Rules concerning loading and delivery:

i. Products shall be delivered with the protection of animal and human health as prime considerations.
ii. Containers and equipment used for internal transport, storage, conveying handling and weighing shall be kept clean. Cleaning procedures should consider such containers and equipment.
iii. A final inspection shall take place to ensure delivery of correct product.

14.6 The sampling plan

Proper quality control measures/sampling plan shall be established by the operator, documented and implemented to ensure the wholesomeness of the products processed. The sampling plan is given in **Annexure-XXX.**

14.7 Risk assessment

a. The manufacturer should provide compelling evidence that he conducted a throughout assessment risk analysis of its product. The risk assessment analysis should demonstrate that risk is under control and allow us to identify Critical Control Points (CCPs). The finished product shall be tested as per requirement of importing country contractual term between buyer and seller.

The following basic risks need to be considered in a HACCP study by the establishment:

1. Biological risks
2. Chemical risks
3. Physical risks

i. Biological risk

Contamination with microorganisms:

Potential critical control points are the control of the microorganisms documented in the establishment specification, e.g. salmonella, campylobacter etc.

The raw materials and finished products shall be tested. Chemical risk

a. Contamination with undesirable substances originating from raw materials as per requirement of importing Country's/contractual term between buyers & sellers.
b. Contamination with impurities, originating from the downstream process.

i. Physical risks

a. Contamination with foreign materials (particles, pest infestation, tools etc.)

b. Particle size of the carrier. This is a generic risk which applies to most other processes as well potential critical control points are filters, sieves, metal detectors as well as maintenance and packaging procedures.

15. RECORDS

Proper records shall be maintained by the establishment at all stages of production, storage and transportation Feed, additives and premixture and should be made available to the EIA/EIC officials for verification. The processor shall maintain the following basic record.

i. Raw material receiving and evaluation records.
ii. Personnel records of technical and non-technical persons.
iii. Traceability record pertaining to the nature and quantity of the additives produced, the respective dates of manufacture and, where appropriate, the number of the batch or of the specific portion of production,
iv. Cleaning and sanitation records
v. Environment control record.
vi. Calibration record
vii. CCP monitoring record
viii. Quality control record
ix. Hazards control record.
x. Packing/packaging material records
xi. Corrective action and verification records
xii. Pest control records
xiii. Waste disposal records
xiv. Training record

16. OFFICIAL CONTROL BY THE COMPETENT AUTHORITY

Strict confidentiality shall be maintained in all the official control visits and the establishment should not be given prior information about the visit. For proper official control, a three-tier surveillance system will be followed as per details given below:

16.1Monitoring Visits

16.2Supervisory Visits

16.3Corporate Visits.

16.1Monitoring Visits

i. EIA officials shall carry out periodic monitoring of the establishment to ensure that all the approved facilities are being maintained by the establishment as per the regulatory requirements and those specified by the EU/importing countries are being complied with and the products processed in the establishment conform to specification.

ii. Monitoring shall be done by an officer of the level of Assistant Director / Technical Officer and each officer shall normally be assigned to units as per discretion of the controlling officer.

iii. The monitoring officials shall verify the own checks system adopted by the unit at all stages of production starting from raw material reception to final dispatch.

16.1.1 Frequency of monitoring the establishment:

On initial approval of units, monitoring visits shall be carried out **once in three months**. If the performance of the unit is satisfactory for a year and in the absence of any foreign rejection/complaint, the frequency of monitoring shall be reduced to **once in six months**

After satisfactory performance for further one year on the basis of surveillance visits and in the absence of foreign rejection/complaint, the frequency of monitoring shall be reduced to once **in a year**.

In case, at any stage, non-satisfactory performance on account of any major deficiency is observed during monitoring, the monitoring frequency shall be increased to once in a month/**once in three months, as decided by the Competent Authority**.

Again its performance shall be reviewed after **one year**. If the performance of the unit during one year is found satisfactory and if there is no foreign rejection/complaint during the period, the frequency of monitoring shall be reduced to once **in three months.**

Further review of frequency of monitoring shall be done every year.

16.1.2 Areas of monitoring

The monitoring shall broadly focus on: -

i. Facility checks: to ensure that all the approved facilities are being maintained by the unit. This also includes verification of sanitary and hygienic conditions prevalent at all sections of the unit.
ii. Verification of HACCP Implementation
iii. Verification of testing and lab practices
iv. Verification of records
v. Details of samples drawn shall be given as finished product, water (if used), swabs (hand and equipment).

16.2 Supervisory visit

Supervisory visit shall be carried out by an officer of the level of Deputy Director and above from the concerned Agency having adequate experience in. For the Supervisory visit EIA may take the assistance of outside experts having enough of experience in the relevant field. The frequency of supervisory visits shall be once in a year. The Supervisory visit shall be conducted for

i. Checking the documentation and compliance of the requirements of a) GOI Notifications b) EU Directives (in case of EU approved units) and, other Non- EU Directives/requirements.
ii. Quality of monitoring carried out by the monitoring officers.

16.3 Corporate Audit

Audit of each EIA under the corporate audit mechanism of EIC will be carried out at the frequency of once in a year. The main objective of the corporate audit is to ensure uniform implementation of the rules and regulations issued by the Competent Authority and shall comprise:-

i. Examination of records of processor maintained by the EIA like reports of visits, lab reports, approval/renewal of approval etc.

ii. Visit by the audit team to at least 5% of the approved establishments.
iii. The audit team shall comprise of at least 2 officers which may be drawn from outside the EIA /or If required, experts from outside can also be included in the corporate audit team.

17. ACTIONS TO BE TAKEN IN CASE OF DEFICIENCIES OBSERVED.

a. In case of failure (HACCP compliance, testing, Non closure of repeated Non Confirmatory NC) observed by the monitoring officer, the processor shall be advised in writing to take appropriate corrective action, which shall be verified by the monitoring official in the subsequent visit.

b. In case of 2nd failure for the above, a show - cause notice to be issued by the In-charge of EIA to the establishment, for which the unit has to submit a reply within seven working days along with a stock position by the unit till the receipt of notice. Meanwhile, the production of the establishment would be suspended from the date of the issuance of the letter by the Competent Authority or I/C of the Agency to the approved establishment.

No production is allowed during that period. However, stock in hand may be allowed for export, after due consideration with the written permission of the C.A.

s. In case of major deficiencies observed during the visits, the explanation of the processor may be called with time frame for rectification. Further, any one or more of the following actions may be taken depending on nature of deficiencies, with approval of the Director, EIC.

18. CERTIFICATES

18.1 Certificate of approval shall be issued by EIC only after granting full approval to the establishment as per the prescribed format. The certificate under normal circumstances shall be valid for a period of two years**.**

18.2 Withdrawal of the certificate – If the Competent Authority confirms/ decides the withdrawal of the approval due to any violation, the Certificate of approval has to be withdrawn and the name of the processing establishment will be removed from the official website of EIC as well as EIC recommends its withdrawal from third country establishment list of EC.

18.3 Certificate for Export (CFE)

All the consignments of feed additives and premixtures meant for export shall be accompanied by a Certificate for Export (CFE). The approved processing units shall issue a Certificate for Export (validity for which is 45 days from the date of issue) for every export consignment.

Blank CFE books to be issued, on request by the processing unit only after the approval of Deputy Director In-charge of the scheme/ officers in-charge and after the previous CFEs issued have been accounted for and paid for. However, exporters may have up to 5 sets remaining so as not to cause any operational problems

Blank Certificate books shall be obtained from EIAs at a cost of Rs.20- per certificate. Each certificate will consist of original (in white) intended for Indian Customs; duplicate (in pink) to be forwarded to the nearest office of EIA and the last two copies (in green and blue) for the use of the establishment. EIAs shall

maintain proper records of issuance of blank CFEs and their utilization by the establishment.

The responsibility for the maintenance and proper utilization of the CFEs issued to them lies with the approved establishment. They shall issue CFEs only for those consignment that are processed in their approved establishment and have undergone all the quality checks/ tests specified. The establishment is liable for penal action for the misuse of CFEs issued to them.

Only persons authorized by the establishment shall be allowed to sign the CFEs and the list of persons authorized to sign CFEs shall be made available to the concerned EIA.

If the CFE is expired then the same can be revalidated up to another 15 days and the monitoring fee will not be charged again, if there is no upward revision in FOB value. However, no refund will be given in case of downward revision in FOB value. Further establishment has to submit the original of the cancelled CFE to EIA concerned along with other three copies (full set).

18.4Every **approved establishment shall submit a monthly Statement on Certificates for Export (CFE) issued by them** along with the pink copy of every CFE issued along with the related production code, product, packing type and invoice copy shall be attached to the monthly statement. In case any pink copy of the CFE has already been submitted to EIA for any other purpose, this may be indicated in the remarks column.

Note-If no CFE was issued during the preceding month, a “Nil” statement shall be sent to the concerned EIA office. If the approved establishment is not submitting the statements even after 30 days, further CFEs shall not be issued to them by the concerned EIA. Moreover, a show-cause notice may be issued to the concerned establishment as to why the production and export may not be suspended by the Competent Authority.

18.5Health Certificate:

18.5.1 For EU:

In-Process Quality Control (IPQC) health certificate applicable only for approved establishment. All consignment of feed additives or premixtures exported to the EU are required to be accompanied by a numbered original health certificate duly completed, signed and dated(**Annexure XVIII**).

Note- if health certificate is lost in transit or otherwise, the establishment may request for issuance of a duplicate health certificate by submitting an indemnity bond in a non-judicial stamp paper stating clearly that if found later, the same will not be reused for any further export but shall be surrendered to EIA for further action.

i. The health certificate shall be issued only for feed additives or premixtures by the establishment approved and monitored by the EIA.
ii. The processor/exporter shall request for health certificate from the controlling office/sub-office of EIA in the prescribed format along with

- The pink copy of Certificate for Export (Validity for which 45 days from date of issue) relating to consignment issued by the approved processor.
- Fee as applicable

- Analysis report of the finished product (batch wise) for all parameters as per importing country requirement/national standard/ contractual specification/ buyers parameters from EIA laboratory or EIC approved laboratory.
- Invoice and packing list

iii. Each health certificate shall bear the name, designation and signature of the authorized official person and official stamp of EIC in a colour different from that of endorsements. The colour of signature of officer issuing health certificate shall be different. The signature shall be in blue or red on the original certificate.

iv. The language of health certificate shall be of destination port/country. However, the entries to be made in English.

v. Reference number of health certificate: two Certificates issued from India shall not bear same number. Each sub-office shall give serial number of each health certificate issued prefixed Agency/sub-office codes
Ex. Financial year 2013-14, the certificate No. for EIA Delhi EIA/DEL/FAPM/2013-14/0001

vii. Health certificate shall be valid for a maximum period 45 days.

viii. If the consignment is not shipped within the period of validity of the certificate, the exporter shall be permitted to present the certificate for revalidation. In such case, the validity shall be extended for a further period of 45 days.

18.5.2For Non-EU countries:

Either the Consignment Wise Inspection (CWI) or In-Process Quality Control (IPQC) shall be applicable.

19. PROCEDURE FOR CONSIGNMENT WISE INSPECTION

19.1 Application for inspection

19.1.1 The exporter seeking approval shall submit their application for inspection in the prescribed format given at **Annexure- XX** in triplicate to the concerned EIA in their region.

19.1.2 Application shall be accompanied with a copy of the technical specification and of export contract and other details.

19.1.3 The application shall be accompanied with inspection fee as applicable in the form of demand draft/cheque drawn in favour of EIA concerned.

19.1.4 The application shall be given not less than the two days before the inspection is to be carried out if the premises is situated at the same station as office of EIA; and not less than 5 days before the inspection is to be carried out for premises which are not situated at the same station, where the EIA is concerned.

19.2 Inspection

19.2.1 The inspection shall be carried out by the concerned EIA either at the port of shipment or at the premises of the packer or any other premises, which may be registered with any regulatory authority, where the consignment is offered by the exporter subjected to adequate facilities for the inspection including drawing, preparation and sealing of the samples being provided by the exporter.

19.2.2 In addition to this, the agency shall have the right to reassess the quality of the consignment at any place of storage, in transit or at the port before the actual shipment.

19.3 Sampling

19.3.1 For the purpose of testing of consignment with reference to the standard specifications of importing country, sample in duplicate shall be drawn from each lot offered for inspection by the designated EIA officer.

19.3.2 The samples drawn shall be sealed in presence of exporter so as that unauthorised opening is detectable. Both samples shall be given an identification pack carrying the following information:

- Date of sampling
- Lot size with batch number
- Sample weight
- Name and designation of the sampling officer

19.3.3 One sample shall be given to the exporter, while the second sample shall be sent to EIA laboratory for testing as per the specifications of importing country. The exporter's sample will be analysed only in case of dispute.

19.4 Testing

19.4.1 Lab sample shall be brought by EIA official and handed over to EIA laboratory/ EIC approved lab or sent by courier with due acknowledgement in case the inspection is done by EIA sub-office but shall in no case be left with the exporter.

19.4.2 Lab samples shall be tested for all parameters prescribed in the schedule of notification/contractual/international specification as per the method of analysis referred in *Codex Alimentarius* Commission/AOAC or any other internationally recognised method.

19.4.3 Testing charges will be borne by processor/exporter on actual basis.

19.4.4 In case the sample conforms to the prescribed specifications, the EIA shall issue health certificate as per the format prescribed in **Annexure-XXI**. The health certificate will be valid for a period of 45 days.

19.4.5 If the sample drawn is found not conforming to the prescribed specification, the consignment will be rejected for export and the rejection report will be issued as per the prescribed format given in **Annexure-XXII**.

20. FEE STRUCTURE

Sl. No.	Activity	Fee (Rs.)
1	Application for approval / renewal of approval of establishment	5000/- + service tax as applicable
2.	Application for approval of additional activity/facility	5000/- service tax as applicable
3.	Application for grant of permission/renewal to process/pack for Merchant Exporter	2000/- + service tax as applicable
4.	IPQC system of approval for EU/Non EU	@ 0.2% of FOB value of exports or Rs. 2000/- whichever is higher + service tax as applicable
5.	Consignment wise inspection Non-EU	@ 0.4% of FOB value of exports or Rs. 2000/- whichever is higher + service tax as applicable
6.	Issue of Health Certificate	500/- + service tax as applicable
7.	Issuance of corrigendum or addendum or clarification to Health Certificate or duplicate certificate	500/- + service tax as applicable
8.	Drawing of sample on request of the processor	2000/- + service tax as applicable
9.	Certificate for Export (CFE) blanks	20/- per set

21. PROCEDURE TO BE FOLLOWED FOR COMPLAINTS RECEIVED FROM IMPORTING COUNTRIES (EU and Non EU)

General

When a complaint is received from the importing country or a consignment of feed additives and premixtures is detained or specific control measures are imposed by the importing countries on food safety grounds such as product contamination with micro-organisms, enzymes, toxins etc., or with residues (antibiotic, pesticides, heavy metals like cadmium, mercury etc.), the competent authority (EIC/EIA) will follow the procedure as given below. Immediately on receipt of information regarding rejection of a cargo by overseas health authorities in any importing country the exporter concerned will inform the concerned EIA of the same (in case of a merchant exporter, a copy of the communication will also be sent to the manufacturer/ processor).

21.1 Complaint shall be immediately referred to the concerned EIA by EIC. EIC may simultaneously seek complete details from the complainant, if needed.

21.2 The processing unit shall be immediately placed 'on alert' by the concerned EIA which will mean

- Frequency of monitoring visit will be increased to four visits per month.

- Next 10 consecutive consignments will be verified by an EIA officer and only after clearance from EIA based on satisfactory test results will the consignments be allowed for export to EU. However, if the consignment fails for any of the parameters tested, the consignment may be retested code-wise on request from the exporter/manufacturer and only those codes which fail on

retest will not be allowed for expor*t.* Frequency of inspection and testing by EIA for non-EU consignments will be one in four till such time 10 consecutive consignments to EU or 5 to non-EU are cleared.

-The cost of the testing of the consignments meant for EU and non-EU shall be borne by the processor,

-The increased monitoring frequency (i.e. four visits per months) shall be discontinued if all the four monitoring visit reports and test reports are found satisfactory.

- For any unsatisfactory performance the increased frequency will be continued till such time, two consecutive satisfactory performances are achieved.

Note: Charges @ Rs.2000/- and service tax per visit for the additional monitoring visits will have to be borne by the processor. Cost of testing of 10 consignments for EU as well as those for Non-EU, and retesting if any*,* will also be borne by processor. However, deputation charges will not be levied in case consignments are inspected during monitoring visits.

21.3 In case of rejection due to residues, instead of the above procedure (other than placing the unit on alert), three consecutive day codes will be tested with specific reference to the residue for which the earlier consignment was rejected in the importing country. There will be no additional monitoring visit. A composite sample each from three different codes as close as possible to the code(s) of the rejected consignment shall be tested for the specific contaminant at EIA lab, or any EIC approved labs. As far as possible samples from same type of product shall be drawn. If any of the day codes fails to meet the requirements, 5 more day codes shall be tested again for residual parameters including the specific contaminant(s) in two different approved labs. The codes which fail will not be permitted for export.

Note: In such cases, the concerned exporter/processor will bear the cost of testing only as there will be no additional monitoring.

21.4 In case of any complaint received against a non EU approved unit due to failure on account of micro-organisms, enzymes, toxins etc., next 10 consecutive consignments will be tested by EIA prior to the shipment.

21.5 EIA shall collect complete information from the processor as given below

i. Full particulars of the consignment such as product name, quantity, code/grade list along with attested copies of related documents such as purchase order/letter of credit, certificate for export, health certificate, bill of lading, test reports etc. and also source of raw materials used for processing & export. (Details regarding prices need not furnished by the exporter/processor).

ii. Details of whereabouts of the consignment.

iii. The particulars of feed additives and premixtures held in stock by the processor.

iv. If the processor has got his consignment subjected to a confirmatory test in the country where it was detained or got it surveyed by an independent surveyor in the country where it was detained, copies of such test/survey reports shall be made available to the competent authority for examination.

21.6 EIA shall arrange an immediate visit (within a week) to the processing establishment for;

i. Collection of information, in case the same has not been received.

ii. Assessment of the processing establishment to determine the cause of contamination. Assessment of the processing establishment shall be carried out by a team of officers comprising officials from EIA/EIC/others as may be decided by the competent authority. During the assessment the following will be checked:

i. The current level of GMP, plant sanitation and personnel hygiene in the processing and primary processing units of the processor.

ii. HACCP implementation

In addition, Sanitation & Hygiene control samples, raw material samples and in-process samples may be drawn as applicable and tested in EIA laboratory for assessing the general hygienic condition of the unit and to determine if the specific contaminant is present. In case of rejection due to residues, the assessment of processing unit will be done in relation to the specific contaminant to determine its cause. This will include audit of the HACCP implementation including raw material control with the specific purpose of assessment in relation to the cause of rejection. During assessment, it may be necessary to assess GMP and personal hygiene with specific reference to the cause of rejection. It may not be necessary to have a fresh assessment related to infrastructure facilities and other aspects of HACCP. Sanitation and hygiene control samples, etc. need only to be tested in relation to the specific cause of rejection.

21.7 The processor shall carry out an investigation and the causes/sources of the contamination determined by the processor and the action taken by the processor to prevent recurrence of the contamination to be examined.

21.8 Based on the assessment, the team shall prepare a detailed report and submit to the Head Office of the EIA. This report shall contain the following information:

i. Details of checks/controls for the specific contaminant on raw materials from different sources and subsequent follow-up action planned and carried out by the processor.

ii. Disinfection operations which are normally carried out in the unit to sanitise equipment/tools used in processing and in handling raw material following GMP.

iii. Systems established in the unit to ensure hygienic conditions in various phases of processing feed additives and premixtures

iv. Periodic checks and other controls affected by the unit after reported product contamination with scope to guarantee the hygienic condition of workers.

v. Adequacy or otherwise of checks, laboratory testing and other controls on raw materials, in-process and finished products

vi. Whether or not the processing establishment is capable of producing safe feed additives and premixtures.

vii. Whether HACCP is in place as per plan

viii. Findings on the possible reasons for complaint.

In case of rejection due to residues the assessment report will only relate to those of above checks which specifically relate to cause of rejection.

The Head office of EIA shall communicate the deficiencies, if any, observed during the assessment, to the processor in writing for remedial action.

21.9 Dealing with returned consignments

21.9.1 If the consignment has been brought back to India, it shall be stored in an approved storage. The processor shall inform the details of storage where these consignments are stored to the concerned EIA office, who in turn shall inform EIC also.

21.9.2 On receiving the above intimation the following actions shall be taken:

i. The local office of EIA shall arrange to get the consignment inspected/tested. One composite sample each from every production code shall be tested for the specific contaminant at two different laboratories. One sample shall be tested at EIA lab and the other sample at EIC approved lab. For this purpose EIC approved lab shall be other than the lab, which has already tested the same consignment prior to shipment, and found the results satisfactory. The results of tests shall be communicated to the Head Office of the EIA, testing fee, as applicable, shall be charged to the processor.
ii. If all the samples tested from the brought back consignment show negative results for the contaminant, the concerned EIA In-charge may take decision to release the consignment for export.

Note: Export Inspection Council where considered necessary may inform results to MOC&I as well as EC/importing country.

iii. If any of the samples tested from the consignment brought back on account of food safety complaint shows positive results, the processor shall reprocess or destroy the consignment in a manner acceptable to the In-charge of EIA concerned.
iv. The schedule of reprocessing shall be furnished to the local Office of EIA by the processor for arranging supervision of reprocessing.
v. The processor shall offer the reprocessed consignment for inspection by EIA.
vi. EIA shall inspect the reprocessed products code wise for all parameters as per the sampling plan annexed*.*
vii. The fee for EIA supervision with regard to reprocessing shall be Rs.2000/- per day. Inspection Fee at the rate of 0.4% of the F.O.B. value of the consignment shall be charged for the reprocessed consignment for export*.* Testing fee shall be charged as per prescribed rates.

Note: As no reprocessing is possible in case of rejection due to residues, supervisory fees will not be applicable.

viii. If the reprocessed products are found export worthy on inspection, the lots shall be allowed for export to countries other than the country or union of countries where it had been detained prior to its reprocessing.

Note: In the case of a sample from the returned consignment testing positive for residues, the codes testing positive will not be permitted for exports.

21.10 If the following points are satisfactory:

i. The consignment if brought back, on account of the complaint and tested for the contaminant is found free of the contamination/ defects as evidenced by test reports.
ii. The assessment report indicates that the processing establishment has been maintaining proper hygienic conditions and implementing HACCP.

iii. The periodical monitoring conducted by EIA during the past three months indicates satisfactory hygienic conditions in the unit.
iv. Samples tested during the assessment visit passes.

EIAs shall put up the case with relevant papers/reports to the Director (I&Q/C) with a recommendation for taking up the matter with the foreign health authority for revoking their specific control measures/rapid alert. On consideration, EIC will make the necessary recommendation to the foreign health authority.

The concerned EIA shall reduce the number of monitoring visits to once in a month, provided at least one month has elapsed since 'On alert' was imposed by EIA on the unit and at least 4 weekly monitoring visits have been carried out. It may be noted that the unit will continue to be 'On alert' even if recommendation to foreign health authority as above is made and revocation of 'On alert' would be considered only after 10 consecutive consignments have passed and monitoring/supervisory visits during the period are satisfactory. Revocation of 'On alert' would be done with the approval of the Director (I&Q/C).

However in case of rejection due to Residues the 'On Alert' on the unit will be lifted with approval of Director, EIC once three day codes have been tested and passed by the concerned EIA and all the above requirements are satisfactory.

21.11 However, if any of the above points are unsatisfactory, i.e.

a. The consignment, if brought back, is on testing found to be contaminated /defective;

b. The assessment report indicates unsatisfactory hygienic conditions in the unit;

c. Samples drawn during assessment visit fail;

i. Production and export to all countries shall be stopped till causes of contamination are properly identified and corrective actions taken to prevent recurrence.

ii. Processor has to show cause within 10 days why the approval granted to the establishment may not be withdrawn in the light of the complaint and the findings.

21.11.1 Once the processor informs the EIA that corrective actions have been carried out, verification, of the corrective actions, will be done by a Deputy Director level officer. The processor may be allowed to resume production and export only if the competent authority is satisfied about the rectification of the deficiencies after verification, and with the approval of the Director (I&Q/C).

21.11.2 If the Competent Authority is not satisfied with the reply of the processor as above, or with the corrective action taken, and verified as above, the approval granted to the establishment may be withdrawn.

21.11.3 After resumption of production, an officer, not below the rank of Technical Officer shall be deputed to such units for a minimum period of 10 days extendable up to 30 days to continuously strictly monitor the enforcement of various standards relating to quality control, food hygiene and food safety. The cost of such deputation of EIA officers shall be charged to the units at the rate of Rs.2000/- per day (if working is more than 1 shift, all shifts should be covered at random).

Note: Superintendence as described above will be waived off in case of rejections due to residues, if the unit can prove that the rejection is not due to a cause identified in the processing unit.

21.11.4 In such cases, after resumption of production, the next 10 consecutive consignments for EU and one in four for Non-EU till such time 10 consecutive consignments are cleared shall be got tested and cleared by the concerned EIA. The testing of non-EU consignments shall be done till 10 EU consignments are cleared or total of 5 non-EU consignments are cleared, whichever is earlier. Cost of testing shall be borne by the processor. Only after a clearance from the said EIA, based on satisfactory test results, the consignment produced by that establishment shall be allowed for export.

Note: In case of rejection due to Residues, three day codes shall be tested.

If any of the day codes fails to meet the requirements, five more day codes shall be tested again for residual parameters including the specific contaminant(s) in two different approved labs. The codes found positive will not be permitted for export

21.11.4 In case of any complaint received against a non-EU approved unit due to failure of microbiological factors, after resumption of production, next 10 consecutive consignments will be tested by the EIA prior to shipment. Fees for such instances shall be charged as per clause 21.

21.11.5 The unit shall be taken off from the 'ON ALERT' list only after monitoring and testing of consignments are found satisfactory. The above modified complaint handling procedure, with the following changes shall also be applicable to complaints received on account of quality defects such as Spoilage and other defects.

22. APPEAL

Any person aggrieved by:

i. Decision of the competent authority not to accord approval
ii. Decision of the competent authority to withdraw the approval
iii. Decision of the competent authority not to consider renewal of approval
iv. Refusal of the competent authority to issue health certificate may prefer an appeal within 10 (ten) days of receipt of such communication to an appellate authority appointed from time to time by the Government of India.

The appeal may be sent to EIC for forwarding the same to the Chairman, Appellate Authority

i. At least two-thirds of the total membership of the Appellate Authority shall consist of non-officials.

ii. The quorum for any meeting of the Appellate Authority shall be three.

iii. The appeal shall be disposed of within 30 days of its receipt.

iv. The non-official members would be eligible for TA/DA as admissible to them from time to time for attending the meetings of the Appellate Authority. The expenditure on this account will be borne by the Export Inspection Council.

23. POWER TO RELAX

In case any situation arises, which is not covered by the executive instructions, EIAs may make a suitable recommendation to EIC for decision by Director (I&Q/C)

ANNEXURE-I

(APPLICATION FORM FOR APPROVALOF ESTABLISHMENT)

From
……..
…….
……..
…….

To
The Joint Director In-charge
Export Inspection Agency- Mumbai/Kolkata/Kochi/Delhi/Chennai

Subject: Application for approval of establishment for export of feed additives/ or premixtures in accordance with Notification No. S.O 3523 (E) dated 28th November, 2013

Sir,

Please carry out the assessment of our plant as required under the Feed additives and Pre-mixture under the purview of Notification No. –S.O 3523 (E) dated 28th November, 2013

We furnish below the information regarding the facilities existing in our establishment.

We undertake that our plant meets the requirements stipulated in feed additives and pre-mixture Notification No. –S.O 3523 (E) dated 28th November, 2013

Please find enclosed application fee Demand Draft No……Dated……..

1.	Name establishment :
	Address:
	Postal Code:
	Tel No: Fax No:
	Email:
	Website:
2.	Contact person (for all correspondence with EIA)
	(a) Name of contact person

	(b) Position (c) Address (street, number, post code, city, and country) (d) Telephone (e) Fax (f) E-mail (if available)	
3.	Scope of approval (Please indicate clearly)	
4.	Trade name (if appropriate):	
5.	Category(ies) and functional group(s) of additives/ or premixture:	
6.	**Conditions of use**	
6.1	Use in complete feedingstuff	
6.1.1	Animal species or category	
6.1.3	Minimum dose (if appropriate): mg or Units of activity or colony forming units (CFU) or ml/kg of complete feedingstuffs with a moisture content of 12 %	
6.1.4	Maximum dose (if appropriate): mg or Units of activity or CFU or ml/kg of complete feedingstuffs with moisture content of 12 %	
6.2	Use in water	
6.2.1	Minimum dose (if appropriate): mg or Units of activity or CFU or ml/l of water	
6.2.2	Maximum dose (if appropriate): mg or Units of activity or CFU or ml/l of water	
6.3	Special conditions of use (if appropriate)	
6.3.1	Animal species or category:	
6.3.2	Maximum age	
6.3.3	Minimum dose (if appropriate): mg or Units of activity or CFU/kg of complementary feedingstuffs with moisture content of 12 %	
6.3.4	Maximum dose (if appropriate): mg or Units of activity or CFU/kg of complementary feedingstuffs with moisture content of 12 %	
6.3.5	Conditions or restrictions for use (if any):	
6.3.6	Specific conditions or restrictions for handling (if any):	
6.3.7	Maximum residue limit (if appropriate):	
6.3.8	animal species or category:	
6.3.9	Target tissues of products:	
6.3.10	Maximum residue in tissues or products (µg/kg):	
6.3.11	Withdrawal period:	

7.	**General**	
7.1	Is the processing plant owned or leased by the applicant	
7.2	If leased, name of the plant owner & address	
7.3	Approval requested for export to (Countries)	
7.4	Scope of approval, name of product(s)	
7.5	Additional activities, if any in the same premises	
7.6	Annual production during the previous year	
7.7	Total export during the last Financial year, Destination(Countries) Quantity, FOB value in Rupees in Lakhs	
7.8	Whether year round production or seasonal	
7.9	Give number of working hours and shifts per day	

7.10	Give number of working days per week	
8.	**Information on structure of the establishment**	
8.1	Products requiring approval–(include description of the activity and the substances used which require approval).	
8.2	Is the establishment also approved by the other agency and if so for what?	
8.3	When was the last inspection by any agency and were there any non-conformities relating to feed hygiene? (note what these were and whether they have been rectified)	
8.4	Are any additives unauthorised for use in the EU (including medicines/specified substances) being used in premixtures? (list any found and note whether they are for export and to which country)	
8.5	Typical quantities brought and sold of each product.	
9.	**Feed Safety Management Systems**	
9.1	Does the establishment have written feed safety management systems (FSMS) in place based on HACCP?	
9.2	What hazards have been identified in developing the FSMSs and are any missing?	
9.3	What CCPs have been identified and what methodology was used to determine CCPs? Are the CCPs appropriate?	
9.4	Have critical limits been set for all CCPs and what evidence is there to show the critical limit will ensure the safety of product?	
9.5	What monitoring procedures are used to identify if CCPs are under control?	
9.6	What is the procedure(s) for corrective actions?	
9.7	Are management records commensurate with the nature and size of the businesses to demonstrate the effective application of the measures set out above?	
9.8	Have any changes occurred to the product range, process or distribution process, which should have prompted review of the feed safety management systems? When was the last review and what prompted it?	
10.	**Facilities & Equipment**	
11.1	Are processing, storage facilities, equipment, containers, crates, vehicles and their immediate surroundings kept clean?	
10.2	Are effective pest control programmes implemented? Is there evidence of uncontrolled pest activity on site?	
10.3	Does design, construction of the facilities and equipment permit: a) Adequate cleaning b) Minimize the risk of cross contamination of products?	
10.4	Are all scales and metering devices used in the manufacture of feed additives appropriate for the range of weights or volumes to be measured and tested for accuracy regularly?	
10.5	Have the facilities/equipment used for mixing and or manufacturing operations undergone regular testing for a) homogeneity of mixing b) Carry-over in-line with written procedures?	
10.6	Do facilities have adequate lighting (natural/artificial)?	
10.7	Are drainage facilities adequate to avoid contamination?	
10.8	Is water used for manufacture suitable for animals and are conduits inert in nature?	
10.9	Do arrangements for the removal of waste and rainwater ensure that product is not spoiled and is dust controlled to prevent pests?	
10.10	Are windows and openings proofed against pests?	
10.11	Are ceilings and overhead fixtures designed to prevent the accumulation of dirt,	

	condensation, the growth of moulds and shedding of particles into product?	
11.	**Personnel**	
11.1	Is an organisation chart listing qualifications and responsibilities of all supervisory staff available?	
11.2	Is all supervisory staff clearly informed in writing of their duties, responsibilities and powers regarding the production of feed?	
11.3	**Production**	
11.4	Who is the designated person responsible for production – are they suitably qualified?	
11.5	Are all stages of production carried out to pre-established written procedures?	
11.6	Are technical or organisational measures taken to avoid/minimise cross contamination during manufacturing? What checks are carried out to ensure arrangements work during manufacturing?	
11.7	What steps are taken to minimize the risk of prohibited and undesirable substances entering in to product and how this is monitored?	
11.8	What procedures are in place to isolate and identify waste? Are procedures in place to safely dispose of such materials?	
11.9	What system of tracing products and materials used in them is employed?	
12.	**Quality Control**	
12.1	Who is the designated person responsible for quality control – are they suitably qualified?	
12.2	Does the establishment has access to a laboratory with adequate staff and equipment?	
12.3	What checks on critical points in the manufacturing process are carried out? (include: sampling procedures and frequencies, methods of analysis and their frequency, compliance with the specification and the destination in event of the non-compliance from processed material)	
12.4	a) Are documents relating to ingredients kept for the life of the final product? b) Are final samples kept of each batch of product produced, adequately labelled and properly stored?	
12.5	Can traceability of individual batches to final customers be demonstrated including where product is not held on-site?	
13.	**Storage and Transport**	
13.1	Is finished product kept separate from raw materials?	
13.2	Is product kept in suitable storage conditions to which only persons authorised by the FeBE have access?	
13.3	Is product easily identified in store and when transported so as to avoid cross contamination and deterioration?	
13.4	Are containers and equipment used for transport, storage, handling and weighing of product clean?	
13.5	Where appropriate, are temperatures kept low to avoid condensation /spoilage – particularly in storage areas?	
13.6	From a visual examination does labelling of products appear to comply?	
13.7	**Any other relevant information (use additional sheets if necessary)**	

Yours faithfully,

Signature

Place: Name

Date: Designation

Checklist of enclosures:

1. Prescribed fee in the form of Demand Draft
2. HACCP Manual (Including organization chart of the establishment, standard operating procedures (SOPs), process flow chart (s) with product description and manufacturing details in each step).
3. Attested copy of potability certificate of water (EC directive No.98/83/EEC dated 3.11.1998 used for process/manufacture or attested copy of water conforming to IS 4251.
4. Location and layout plan of the establishment (site plan and building plan in A-4 size), showing all infrastructure and equipment facilities.
5. Layout showing process/product flow, personnel flow, water flow (indicating serially numbered water taps) and effluent flow on A4 size paper separately in evidence of meeting food safety requirements.
6. Certified copy of the identity of the establishment
7. Certified copy of lease deed, if applicable
8. Bio-data of the technical and quality personnel with attested copies of degree certificate(s), experience certificate(s) and appointment letter/certificate of employment from the establishment
9. Guarantee and undertaking
10. Attested/Certified copy of consent letter issued by Pollution Control Board concerned.
11. Attested copy of the order allotting importer exporter code (IEC) number.
12. List of raw material used in processing
13. Material safety data sheet

Note:

a) The application must be in duplicate,

b) In case where a non-EU approved establishment submits application for the approval to process feed additives and premixtures for export to EU countries, the documents, which were submitted earlier, need not be submitted again, if there is no change.

Annexure- I-A

Undertaking

(*To be submitted in duplicate on company's letter head along with application for approval of processing establishments.)*

Date:

To
Export Inspection Agency-
……..
……..
……..

Sub: Application for approval

Sir,

With reference to our application ref. No. ---------Dated ----------, we hereby undertake the following in respect of the processing of feed additivesor premixtures in our establishment.

We handle, process, store and transport feed additives (……) or premixtures under proper hygienic conditions so as to meet the health requirements laid down by the Government of India/Importing Countries.

HACCP system has been established and implemented by us.

We are doing risk analysis for biological, physical and chemicals, where applicable, in accordance with the requirements of the importing country.

Yours faithfully,

Signature of Authorised Signatory
Name:
Designation:
Date:

Annexure-1-B

Guarantee

(*To be submitted in duplicate on company's letter head along with application for approval of processing establishments to the concerned EIA*)

To

The Export Inspection Agency
……
……
……

Sub: Guarantee

Sir,

We hereby guarantee the following:
HACCP/FAMI-QS system has been established and implemented by us.
We will not obtain Health Certificates for our export consignments from authorities other than the Export Inspection Agency…….

We will not use raw materials, semi-processed or processed products coming from an unapproved establishment. We shall provide to the Competent Authority and its representatives free access, at all times, to all parts of the establishment and to the records pertaining to production/quality of products being processed by us.

If the results of checks carried out by us or any information at the disposal of our personnel reveal the risk of health or suggest that such a risk might exist, we shall inform you immediately and take corrective actions under your official supervision.

We shall not carry out activities other than those for which we have been specifically approved without prior approval by you. We will not store the raw material/finished product in the other establishments without prior permission from the concerned EIA. We will not misuse the CFEs issued to us and will maintain proper records of the same. We are aware that approval granted to our establishment for processing of …… may be withdrawn by you in case any of the above guarantees are violated by us.

Signature

Head of Production (Name & Designation)

Date :
Place:

Counter Signature
Chief Executive Officer (Name & Designation)

ANNEXURE-II

ASSESSMENT REPORT FOR ESTABLISHMENT

Name of the establishment				
Address	Address: District: State: Country: India Ph. Fax: Email:			
Address of registered office	Address: District: State: Country: India Ph. Fax: Email:			
Scope(s) of assessment				
Date of assessment				
Opening meeting location and date				
Closing meeting location and date				
Name of IDP members	Designation	organization	Opening meeting (Sign)	Closing meeting (Sign)
Name of IDP members				
Name of representative(s) of establishment	Designation	organization	Opening meeting (Sign)	Closing meeting (Sign)

1	**General information**	
1.1	Name of the Chief Executive (MD/GM/proprietor)	
1.2	Is the processing plant owned or leased by the applicant	
1.3	If the leased, name of the plant owner and address	
1.4	Approval requested for export to (countries)	

1.5	Scope of approval, Name(s) of the product(s)	
1.6	Number of working hours and shift per day	
1.7	Number of working days per week	
2	**Infrastructure**	
2.1	Does the building suitable for the purpose to minimize risks.	
2.2	Does the building durable to minimize maintenance and feed safety risks.	
2.3	Are the building well maintained by a preventive maintenance program.	
2.4	Are necessary utilities are available?	
2.5	What is the quality of potable water or other water	
2.6	Steam	
2.7	Pressured air	
2.8	Heating system	
2.9	Extraction units	
2.10	Other relevant utility system	
2.11	Are waste materials are properly identified to avoid mix-up with production materials.	
2.12	Is the waste handled properly to avoid risks for workers or environment, both internally and externally?	
3.	**General documentation requirements**	
3.1	Is a management system exists.	
3.2	The quality manual is o In place o Approved and signed by responsible person (s) o Dated and updated	
3.3	Is a quality and safety policy exists.	
3.4	Have Management System (MS) include the operator's intention to meet obligations the produce and market safe products.	
3.5	Is the MS includes the operator's responsibility to its customers.	
3.6	Is the MS manual readily available to relevant staff?	
3.7	Is the document control system traceable?	
3.8	Are the specifications on raw materials and finished products exist	
3.9	Is the label system in place meets legislative requirements?	
3.10	Are the master formulae exist on all products.	
3.11	Have controlled operating instructions and batch process records for each product exist.	
3.12	Are the Standard Operating Procedures (SOPs) available?	

4.	**Management Responsibility**	
4.1	Is the management shows commitment to quality and feed safety	
4.2	Is the evidence of commitment documented?	
5.	**Quality and safety policy**	
5.1	Is the quality and safety policy specifies the objectives.	
5.2	Are the requirements appropriate to the business goals?	
5.3	Is the scope of the HACCP program defined?	
5.4	Is the HACCP scope communicated to all involved persons?	
6.	**Resource management**	
6.1	**Provision of resources**	
6.2	That the equipment suits its purpose.	
6.3	The design is appropriate.	
6.4	The staffs are sufficient and skilled to comply with expected tasks and requirements.	
6.5	Appropriate persons have adequate responsibilities to comply with external requirements.	
6.6	An organisational chart exists and updated.	
6.7	Job descriptions are available and updated.	
7.	**Human resources**	
7.1	Are qualifications of employees documented	
7.2	Necessary disciplines are available like o Feed safety o HACCP competencies o Hygienic knowledge o Quality competencies o Health and safety o Environment	
7.3	Are training files documented and maintained	
8.	**Work environment**	
8.1	Product conformity is maintained by adequate work environment, like	
8.2	Ventilation	
8.3	Humidity control	
8.4	Temperature control	
8.5	Lighting	
8.6	Hygienic design	
9.	**HACCP Program**	
9.1	A HACCP program is developed and maintained.	

9.2	A multidisciplinary HACCP team is announced.	
9.3	A competent team leader is appointed.	
9.5	Adequate training of the HACCP team members is supplied.	
9.6	An adequate prerequisite quality program exists.	
9.7	A HACCP analysis is performed and documented.	
	• The Critical Control Points (CCPs) are identified.	
	• Critical limits are specified.	
	• Monitoring is provided.	
	• A deviation procedure is established and implemented.	
	• Verification procedures are established and implemented.	
	• Possible biological, physical and chemical hazards are considered.	
	• All procedures and records are archived.	
10.	**Handling of incoming materials**	
10.1	New suppliers are covered by an approval process.	
10.2	Approved suppliers are documented, reviewed, re-evaluated and the documentation is up-to-date.	
10.3	The review is done periodically at a predetermined interval.	
10.4	Purchased incoming material has an agreed specification.	
10.5.	Specifications comply with feed safety topics and legislative requirements,	
11.	**Verification of incoming materials**	
11.1	A written procedure on handling of incoming materials exists.	
11.2	Incoming materials are registered uniquely and include:	
	• Supplier's name and lot/batch number	
	• Operator's lot/batch number	
	• Name of material	
	• Quantity and date of receipt	
	• Possible expiry date.	
11.3	Materials are inspected before, during and after unloading.	
11.4	The inspection includes contamination, pest infestation and documentation of findings.	
11.5	Non-conformities are recorded.	
11.6	Records of inspection results are documented and archived.	
11.7	Records of supplier guarantees and other relevant supplier documentation kept.	

11.9	Incoming materials are released before use.	
11.10	Documentation is maintained in case a product is returned to the supplier.	
12.	**Quality Control and Production**	
12.1	Production areas are accessible to authorized personnel only.	
12.2	Production is run according to formal production planning.	
12.3	The production plan is distributed to relevant persons.	
12.4	Production records are kept prove compliance with master formula.	
12.5	Cross-contamination is prevented or controlled.	
12.6	Each product has a specification, unique name and/or code.	
12.7	Each product has a predefined label.	
12.8	Finished products are clearly marked and identified.	
12.9	Each product has a predefined packaging instruction.	
12.10	The packaging process is controlled to avoid contamination and mix-up.	
12.11	Deliveries are inspected prior to dispatch.	
12.12	This inspection is documented	
12.13	Non-conforming products are segregated and stored in a manner to prevent failures.	
12.14	Storage facilities are adequate to the purpose.	
12.15	Storage facilities are operated in a manner to prevent failures during handling	
12.16	Storage facilities are suitable to the purpose, e.g. cleanliness, ventilation, dry, and temperature controlled	
13.	**Identification and traceability**	
13.1	A traceability system is in place, including tracing back from the final product through quality control data and batch records to the raw materials used and the suppliers.	
13.2	Deliveries can be traced to customers, including customer name, date, batch and amount.	
14.	**Preservation of product**	
14.1	A stability program is defined and on-going.	
14.2	Product environment is controlled during storage to preserve conformance with quality and safety requirements.	
15.	**Transport**	
15.1	Transporters are controlled, evaluated and meet expected quality and safety requirements.	
15.2	Procedures are in place to check for the previous load carried by bulk haulers.	

15.3	n case the previous load present a risk to the operator's product, perform a check that the bulk transporters provide cleaning certificates for the cargo compartments and discharge equipment.	
15.4	A final inspection takes place before shipping and the result is documented.	
16.	**Control of monitoring and measuring devices**	
16.1	Maintenance work does not interfere with product safety.	
16.2	A formal calibration system is in place.	
16.3	This includes items to be calibrated.	
16.5	Appropriate calibration intervals are defined.	
16.6	Calibration results are documented.	
16.7	A formal preventive maintenance system exists.	
16.8	Appropriate maintenance intervals are defined.	
16.9	Maintenance work is documented.	
17.	**Cleaning**	
17.1	A formal cleaning program exists, covering	
	• Daily house-keeping	
	• Periodic deep cleaning	
	• Cleaning after maintenance	
17.2	The program defines responsibility.	
17.3	Post evaluation is covered. Cleaning records are filled-in currently.	
17.4	Procedures on cleaning of equipment exist, and support hygiene and feed safety.	
17.5	Employees are trained in cleaning procedures and the training is documented	
18.	**Pest control**	
18.1	A formal (documented) preventive pest control system is in place	
18.2	The responsibility: In-house or contracted	
18.3	Ensure that relevant preventive measures are taken, for Rodents Insects, flying and crawling, birds etc	
18.4	Have ensured a map or schematics of preventive measures showing the locations exist and updated.	
18.5	Are the pest control activities documented?	
18.6	Are applied pesticides/chemicals suitable for the purpose (Product Data Sheet)	
18.7	Are ensured legality of the pesticide/chemicals	
18.8	Is the plant maintained reasonably clear of infestation.	

19	**Internal audits**	
19.3	Is an audit system in place?	
19.4	Are the internal audits carried out?	
19.5	Is a scheduled audit program in place?	
19.6	Are the auditors suitably trained?	
19.7	Are the audits done reported and documented.	
19.8	Is the audits contain a define scope.	
19.9	Are the feed safety issues included in scope?	
19.10	Are identified non-conformities reported?	
19.11	Is a formal follow-up reported?	
19.12	Have verified corrected non-conformities.	
20.	**Complaint handling system**	
20.1	A formal customer complaint handling system exists.	
20.2	The complaints are evaluated according to:	
	• Cause	
	• Seriousness	
	• Customer	
	• Environmental health and safety risks	
	• Other relevant topics	
20.3	The complaint topics are used to prevent reoccurrence.	
20.4	The related corrective actions are carried through.	
20.5	From a visual examination of does labelling of products appear to comply?	
	Sample(s) Taken:	
	Overall Comments/Actions Required (use additional sheets if necessary)	

ANNEXURE-III

EXPORT INSPECTION AGENCY – ……..

NON-CONFORMITY REPORT (NCR)
For surveillance visits

Name of the establishment:

Approval No:

Nature of inspection:

Date of Visit:

Name and Designation of EIA officer(s)

Name and Designation of the representative of the establishment

1. Earlier ***NCR*** pending for rectification

2. Details of deficiency/non-conformity observed along with the details of the major NCR

3. Comments / Agreed action:

---

i. Acknowledgement of report copy

ii. Deficiencies/non-conformities have been fully explained and understood by the establishment

iii. Confirmation of agreed or proposed corrective actions to be made to EIA within (7/15/30 etc.) days

Signature : …..……..	Signature:
Name: …….	Name:
Designation: ……	Designation:
(EIC/EIA officer)	Representative of the establishment

Note: It is advised that a copy of this report be pasted by the establishment in the establishment inspection register for necessary follow up action and future reference.

Annexure –IV
FORMAT FOR APPLICATION FOR RENEWAL/EXTENSION OF APPROVAL

To
The Joint Director-In-charge,
Export Inspection Agency-
Mumbai/Kolkata/Kochi/Delhi/Chennai

Sir,

It is to inform you that our establishment is approved under the Export of feed additive(s)/ or pre-mixture under (Quality Control, Inspection and Monitoring) Rules 2013, vide your letter no. …. ……. dated……. as granted approval is getting expiry of……We furnish the following details for renewal of the approval along with application fee of Rs. 5,000 through demand draft/cheque no.-…… dated…….. and request you to do the needful at the earliest for renewal of approval.

1. Approval no
2. Volume of Export during the last one year
3. Annual production during the last one year
4. Fee paid to EIA during the last one year
5. No. of complaints from importing country during last one year (attach details).
6. Recognition during past one year from any Government bodies.
7. Details of change in management, if any
8. Name of Head of the Organization
9. Water potability certificate no. (Attach copy)
10. PCB consent for operation number & its validity
11. Copy of HACCP manual if revised
12. No. of chemist/technologist
13. Layout changes in past one year
14. Sectional facilities/equipment in past one year

- Raw materials procurement facilities
- Processing
- Packaging
- Storage
- Transportation
- On floor and lab. Facilities

15. Scope of extension if any:
16. Any other relevant information

It is hereby certified that the aforesaid information is true to the best of my knowledge.

Thanking you

Yours faithfully

Signature of the Head of the Organization
Along with seal of the Company

ANNEXURE-V

EXPORT INSPECTION AGENCY – ……

MONITORING REPORT

Date of Visit :
Name of the Processing Establishment :
Approval No. :
Product being processed at the time of visit :

Sl. No.		Observations/suggestions
General		
1.	Name and Designation of Monitoring officer(s) last visited	
2.	Whether defects pointed out earlier have been rectified by the establishment	
3.	Mention deficiencies that are not rectified	
4.	Whether any time frame given for rectification	
5.	Results of samples tested in the previous visit	
6.	Action taken in case of failure of test results	
Facility Checks *(Record observations on the maintenance of infrastructure facilities and sanitary / hygienic conditions at each section mentioned below)*		
1	Premises	
2.	Raw material receiving and inspection area.	
3.	Workers entry points, Change room, toilet	
4.	Production section	
5.	Storage site	
6.	Equipment	
7.	Lights and ventilations	
8.	Floor, walls and roof	
9.	Drainage	
10.	Effluent treatment plant	
HACCP Implementation of the Establishment		
1	Whether the identified CCPs monitored properly and recorded?	
2	Whether all control measures are in place?	
3	Whether appropriate corrective actions as stipulated in the HACCP plan taken in case of deviation from Critical limits?	
4	Whether the monitoring and corrective actions, if any, recorded and verified at laid down frequency by the responsible person(s)?	
5	Whether validation is being done regularly?	
Own Check system (give details on the following controls exercised by establishment)		
1.	Raw material purchasing details	
2.	Product controls	
3.	Process controls	
4.	Quality management system	
5.	Pest control	
6.	Personal hygiene	
Verification of records		
1.	Traceability records	
2.	Process control records	

3.	Storage and transportation records	
4.	Calibrations records	
5.	Sanitary and hygiene records	
6.	Raw material test reports	
7.	Environment control record	
Details of samples drawn during monitoring		
1.	Finished product for biological, physical and chemical analysis	
Any other relevant information		
Recommendation		

- Overall Rating – Satisfactory / Unsatisfactory

- Deficiency reported to the establishment
(As per Non Conformity report)

Remarks of the Controlling Officer

Signature :
Name :
Designation:
Date & Place:

Signature :
Name :
Designation:
Date & Place:

ANNEXURE- VI
SUPERVISORY VISIT REPORT

EXPORT INSPECTION AGENCY –……

1. Date of visit:
2. Approval No. :
3. Name of the Processing Establishment:
4. Product being processed at the time of visit:
5. Assessment of Establishment

S.No,	Area	Satisfactory	Details of deficiencies, if any/Remarks
1.	Surroundings area		
2.	Receiving of raw material		
3.	Hygiene condition		
4.	Processing sections hygiene		
5.	Personal hygiene		
6.	Change Room and facilities		
7.	Processing controls		
8.	Water/Chemical/Additives		
10.	Rodent/Vermin Control		
11.	Effluent Treatment		
12.	Own Checks/HACCP system		
13.	Maintenance of records		
14.	Packaging/Storage/Transportation		
15.	Inspection and Testing		
16.	Any other relevant information i) Quality of the monitoring ii)Area of focus in which detailed assessment was done		

6. MVs since last SV:

Sl. No.	Date	MO	Satisfactory / Unsatisfactory	Lab. Results	Deficiencies observed	Action by Processor

7. Results of Water:

8. Recommendations:

Overall Rating – Satisfactory /Unsatisfactory
NCR

Signature:

Name:

Designation:

Date: Place:

Remarks of the Agency In-charge

Signature:

Name and Designation:

Date and Place:

Note: MV= Monitoring Visit, SV=–supervisory Visit, MO= Monitoring Officer, NCR= Non-Conformance Report

ANNEXURE- VII

CORPORATE AUDIT REPORT

EXPORT INSPECTION COUNCIL, New Delhi
(MINISTRY OF COMMERCE)
GOVERNMENT OF INDIA

1.	Auditee	
2.	Dates of Audit	
3.	Activity under Audit	
4.	Scope of Audit	
5.	Audit Team	
6.	Audit Schedule	
(i)	Opening Meeting	
(ii)	Closing Meeting	
7.	Observations	
8.	Non Conformities	
9.	Any other Remarks	

7. OBSERVATION FORM

S. No.	Element	Observation	Reference
1			
2.			
3.			
4.			

8. NON-CONFORMITY REPORT (NCR)

S. No.	Non-Conformity observed	Doc. Ref	Type of NC Major/Minor
1.			
2.			
3.			
4.			

9. General Observations

1.	
2.	
3.	
4	
5.	
6.	

Team Leader Auditor

Proposed Corrective actions

Probable Date of Completion

Auditee

NC cleared/downgraded/statuesque

Auditor Team Leader

Annexure-VIII
EXPORT INSPECTION AGENCY_____

SUGGESTIONS FOR IMPROVEMENT

Name of the establishment:

Address:

Approval No. :

Nature of inspection:

Date of Visit:

Name and Designation of EIA officer(s):

Name and Designation of the representative of the establishment:

1.

2.

3.

4.

5.

Agreed action by the processor:
Signature: ……..

Name: ……
Designation: ……

Signature:
Name:
Designation:
(EIC / EIA officer) Representative
of the establishment

ANNEXURE-IX
(On the letter head)
INDEMNITY BOND

We solemnly declare that the Certificate for Export (blank) with Serial No: ..... Book No : .....issued to us by Export Inspection Agency ..... has been lost/ misplaced without having been utilised for export of goods and the said certificate ,if traced latter, will not be utilised for export of any consignment, but will be surrendered to the Export Inspection Agency..... for cancellation.

We further declare that we are fully liable for any action in the event of the misuse of such certificate either by us or on account of us and we agree to keep the Export Inspection Agency indemnified in case of misuse or illegal use of such certificate.

Witnesses

1.

2.

Signature:

Place:
Date:

Name and Designation
Seal of the Company:

ANNEXURE- X

EXPORT INSPECTION AGENCY…….....

Monthly report of supervisory/monitoring visits to the EU/Non EU approved feed additives/or premixture establishments for the month of.....

Sl.no	**Action taken**	EU		Non-EU	
		Supervisory	Monitoring	Supervisory	Monitoring
1.	Number of visits planned				
2.	Number of visits actually conducted				
3.	Number of units which are satisfactory based on the visits				
4.	Number of units which are unsatisfactory based on the visits				
5.	Reasons for short fall, if any in supervisory /monitoring visits				
6.	Action taken in case of each unsatisfactory unit				
7.	Details of verification of corrective action taken by the processing units reported unsatisfactory in the earlier statements.				
8	Any other information				

Place:

Date:

Signature:

Name:

Designation:

ANNEXURE XI

EXPORT INSPECTION AGENCY.....
(CHANGES IN THE LIST OF APPROVED UNITS (EU AND NON- EU) AS ON.....)

SL.NO	AP.NO	NAME AND ADDRESS OF ESTABLISHMNET	ADDRESS OF REGISTERED OFFICE	EU OR NON -EU	DATE OFINTIAL APPROVAL	VALID OF APPROVAL UP TO

ANNEXURE – XII
APPLICATION TO PROCESS FEED ADDITIVES OR PREMIXTURES FOR EXPORT BY MERCHANT EXPORTER

(To be typed on company letterhead)

To
The Joint Director-
Export Inspection Agency- _____

Sub: Request for permission to process feed additives or premixtures for export by merchant exporter.
Ref.: Approval Number of the establishment _____

Sir,

We request that permission may kindly be granted to us to process feed additives or premixtures

1) Name and Address of
the merchant exporter(s)

2) Countries to which exports:
Are proposed to be made

3) Production capacity of the unit:
as fixed by EIC/EIA

We hereby state that we, as approved processor, shall be responsible for the quality and safety of the feed additives/ or premixtures processed and packed by us for export by the merchant exporter(s). We also undertake to comply with the directions that may be given in this regard by EIC/EIA and assure that the production capacity fixed by EIA for our establishment will not be exceeded at any time.
We also assure you that feed additives/ or premixtures for export by the merchant exporter(s), for which Certificate for Exports are to be issued by us, will only be processed in our approved unit under our control and the products will not be taken out of our control or stored in unauthorised/un-approved places by the merchant exporter(s).
We also undertake that we shall be responsible and liable for any act of omission or commission by the merchant exporter(s) in respect of any quality issue or in respect of any trade related issues including cheating.

Yours faithfully,

Signature:

Name:
Designation:
Company Seal:

Place:
Date:
Encl:
1. Certified true copy of the agreement entered into between the processor and the merchant exporter(s)
2. Declaration from merchant exporter(s) stating that he will abide by the rules and regulations laid down by EIC/EIA.

ANNEXURE – XIII

LETTER OF PERMISSION TO PROCESS FEED ADDITIVES OR PREMIXTURES FOR MERCHANT EXPORTER

EXPORT INSPECTION AGENCY
(MINISTRY OF COMMERCE AND INDUSTRY)
GOVERNMENT OF INDIA

No. EIA/ Date:

Dear Sir,

Sub: Permission to process and pack feed additives or premixtures for merchant exporter: M/s. (*Name and address of merchant exporter*)
Ref: Your letter dated _____

With reference to your letter cited above, you are informed that you are permitted to process and pack feed additives/ or premixtures for export by merchant exporter: M/s. (*Name and address of merchant exporter*), to any country including EU/Non EU countries, subject to the following conditions:

1. The export packages must bear the name, address and approval number of the approved processing establishment and also the name and address of the merchant exporter;
2. The approved processor (M/s. (Name and address of approved processor), with processor Code No.) shall be responsible for the quality and safety of the feed additives or premixtures processed by it for export by the merchant exporter;
3. The approved processor shall ensure that the consignments of feed additives or premixtures processed by it for export by the merchant exporter are not taken out of its control or stored in unauthorised/unapproved premises by the merchant exporter before the actual shipment for export; and
4. The approved processor shall maintain proper records showing the details of feed additives or premixtures processed by it for the merchant exporter and such records shall be made available to the monitoring officials of the EIC/EIA for verification.
5. The validity of the permission granted by EIA for processing and packing feed additives or premixtures of merchant exporter shall be co-terminus with the validity of the approval of the establishment/validity of the agreement entered between the processor and the merchant exporter, WHICHEVER IS EARLIER.

Please acknowledge receipt.

Yours faithfully,

Agency In-Charge

Copy to
(1) The Joint Director, EIC, New Delhi-110001.
(2) The Officer In-charge, EIA-_____, SO: _____.

ANNEXURE XIV
LETTER OF WITHDRAWAL OF PERMISSION TO PROCESS AND PACK FEED ADDITIVE OR PREMIXTURES FOR EXPORT BY MERCHANT EXPORTER

EXPORT INSPECTION AGENCY – _____
(MINISTRY OF COMMERCE AND INDUSTRY)
GOVERNMENT OF INDIA

No. EIA/ Date:

To,

Sub: Withdrawal of permission to process and pack feed additives or premixtures for export by merchant exporter.

Ref: (1) Your letter No. dated:
(2) Our letter No. EIA/ dated:

Dear Sir,

In pursuance of your request cited above, the permission given to you to process and pack feed additives or premixtures for the following merchant exporter(s) is hereby withdrawn:

Name and Address of Merchant Exporter
}
}

Yours faithfully,

Agency In-Charge

Copy to
(1) The Joint Director, EIC, New Delhi-110001.
(2) The Officer In-charge, EIA-_____, SO: _____.

ANNEXURE XV
STATUS REPORT ON FEED ADDITIVE OR PREMIXTURE ESTABLISHMENT, WHICH HAD COMPLAINT FROM IMPORTING COUNTRY.
EXPORT INSPECTION AGENCY----------
As on…… (Date)

1.	Name and Address of the establishment :	
2.	Approval No. :	
3.	**Details of Complaints**:	
	(a) Nature of complaint	
	(b) RASFF Notification	
	(c) Product	
	(d) Health Certificate No.	
	(e) Complaint Country	
4.	**Date of placing the unit' On Alert'** :	
5.	**Current Status and Location of the consignment** in question	
	(a) Whether the consignment has been brought back to India	
	(b) If brought back, details of tests	
	• Test results by EIA	
	• Test results by other lab	
	• Action taken, if any	
	(c) If not brought back, status of the consignment	
6.	**Assessment of the establishment**	
	a) Date of assessment	
	b) Composition of assessment team	
	c) Outcome of the Assessment	
	Whether the unit meets the conditions specified in GOI Notification/other requirements	
	Implementation of HACCP	
	Routine testing by the unit	
	Traceability and the source of raw material used for the consignment in question.	
	Corrective action suggested/implemented, if any.	
	Whether the consignment has been tested prior to shipment for the contaminant(s)_ in question (if so, give details)	
	Test results of samples drawn during assessment (with details like number of samples, test methods, name of the Lab etc.	
7.	**Current status of Sanitation/Hygiene of the unit(after placing the unit ' on alert')**	
	No. of Monitoring Visits (MV) conducted	
	No. of Satisfactory MVRs including Lab reports	
	No. of unsatisfactory reports with details of non-compliance	
8.	**Details of consignment inspection tested (with details of testing method, Lab etc**	
	No. of consignments tested	
	No. of consignments passed	
	No. of consignments failed	
	Reason for failure/other remarks	
9.	**Present status:**	
	Date of recommendations to EIC to send recommendation to the foreign health authority	
	Change in Frequency of Monitoring (F.M.), if any	

	Date of recommendation to EIC to lift 'on alert'	
	Date of Revocation of 'on alert' and EIC reference	
10	Action pending	

Signature
(Name and designation)

ANNEXURE XVI

DETAILS OF SAMPLES FAILED DURING MONITORING OF EU APPROVED FEED ADDITIVE UNIT FOR THE MONTH-------

Export Inspection Agency-------

S.NO.	Name of the unit with Ap.no.	Products from which samples drawn	Date of sampling	Name of the lab	Parameters failed	test results	Test methods /detection level	Specified levels	Actions taken

ANNEXURE- XVII

Request letter from the establishment for health certificate

(To be typed on the letterhead of the approved establishment/processor)

Ref: Date:

To,
The Joint Director
Export Inspection Agency_____

Sub: Request for issue of Health Certificate Export of feed additives or premixtures as per the requirement of the importing country.

Ref: 1) Our approval number_____
2) Certificate for Export No._____ dated _____ Export to _____ (Country)

Sir,

In connection with the above subject, we hereby submit details of the information required by the importing country for the purpose of Health Certificate for Export of feed additives or premixtures. Further, we request you to issue the attestation required by the importing country for the consignment under reference, for which the relevant declaration / health attestation dated from our establishment is also enclosed.

It is hereby certified that the information furnished is true and correct to the best of my knowledge & belief and the feed additives or premixtures meant for export, as detailed in the Certificate for Export cited under reference, are free from any hazardous substances and fit for animal consumption.
Please debit the prescribed fee from our deposit account maintained at EIA and issue the Health Certificate for the consignment.

Yours faithfully,
(Authorized signatory)

Encl:
1. The health certificate prescribed by the importing country, duly filled.
2. Certificate for export (pink copy) No. dated_____
3. Copy of Invoice, No:
4. Certificate of analysis No_____dated_____

ANNEXURE XVIII

EU Health Certificate Worksheet

Applicant (Company Name)		Mail Certificate to	
Applicant Number		Contact	
Customer Ref		Company	
Contact		Street	
E-Mail Address		City	
Telephone		State	
Fax		Zip	
☐ Faxed Certificate*		Additional Certified Copies*	

*additional charges apply

I.1 Consignor Name Address Tel.N°			I.2 Certificate reference number		I.2.a
			I.3 Central Competent Authority AMS		
			I.4 Local competent Authority		
I.5 Consignee Name Address Postal code Tel.N°			I.6		
I.7 Country of origin	ISO code	I.8 Region of origin Code	I.9 Country of destination	ISO code	I.10
I.11 Place of origin Name Approval number Address			I.12		
I.13 Place of loading			I.14 Date of departure		
I.15 Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification: Documentation reference:			I.16 Entry BIP in EU I.17		
I.18 Description of commodity			I.19 Commodity code (HS code)		
			I.20 Quantity (Net/Gross Weight)		
I.21 Temperature of product Ambient ☐ Chilled ☐ Frozen ☐			I.22 Number of packages		
I.23 Identification of container/Seal number			I.24 Type of packaging		
I.25 Commodities certified for: Human consumption ☐					
I.26 For transit through EU to 3rd country ☐ 3rd country ISO code			I.27 For import or admission into EU ☐		
I.28 Identification of the commodities Species (Scientific name) Approval number of establishment manufacturing plant Number of packages Net weight Batch number					

Note- Fit for animal consumption

ANNEXURE – XIX
Health Certificate Format to Non-EU

Country of destination	:	
Reference number of the health certification	:	
Exporting country	:	INDIA
Responsible Ministry	:	Ministry of Commerce & Industry, Government of India
Certifying Department	:	Export Inspection Council of India, New Delhi
I.IDENTIFICATION OF FEED ADDITIVE OR PREMIXTURE		
Name of additive or premixture	:	
Nature of packaging	:	
Number of packages	:	
Net Weight	:	
II. ORIGIN OF FEED ADDITIVE OR PREMIXTURE		
Address and Approval No. of the approved establishment(s)	:	
III. DESTINATION OF FEED ADDITIVE OR PREMIXTURE		
The FEED ADDITIVE OR PREMIXTURE will be sent from	:	
By the following means of transport	:	
Number of the Seal (*)		
Name and address of consignor		
Name and address of consignee		
IV. ATTESTATION :		
The undersigned is authorised Officer to issue Health certificate for additive or premixture described above: (a) Come from plants approved by the competent authority (b) Have undergone all precautions to avoid recontamination after treatment		

Date:

Place : Signature

Stamp (X) Name and Designation of EIA official

The certificate is valid for 45 days from the date of issue.

(*) Optional

(-----) Delete as appropriate

(X) The signature and the stamp must be in a colour different to that of the printing

Note- Fit for animal consumption

Annexure XX

Application for Consignment Wise Inspection (CWI)

Exporter's Name Address 1		Invoice No. Date 10	Exporter's Ref. 11
		Buyer's Order No. & Date 12	
		To 13 The (Name & Address of the Inspection Authority)	
Manufacture's Name & Address 2			
		Please inspect the consignment and issue a Certificate for export under the ..... Act. A crossed cheque for Rs. ..... drawn on ..... is enclosed as inspection fee. Please debit our Account Pass Book No. ..... enclosed	
Details of the Manufacture's Seal, if any 3			
		Date	Signature of Exporter
Inspection required on 4	Weekly Holiday 5	Address where consignment is to be inspected 14	
Vessel/Flight No. 6	Port of Loading 7		
Probable Date of Loading 8	Date of Sealing Flight 9		

Marks & Nos 15	No.& Kind of Pkgs 16	Description of Goods 17	Quantity as declared 18	FOB Value (in Rs.) 19

Technical requirements including specifications/approved samples with its characteristics as stipulated in the export contact 20

Other Revelavent Information 21

Declarations: Certified that the goods mentioned above have been manufactured/ produced to satisfy the requirements stipulated by ..... authorities and consignment conforms to the relevant specification.

Certified that the goods have been offered previously for inspection vide intimation no. ..... Dated ..... and the defects as pointed out earlier have been duly rectified.

Certified that no additional technical or quality requirement other than mentioned above have been stipulated by the overseas buyer

Signature & Date

Annexure XXI
Health Certificate for Consignment Wise Inspection (CWI)

Book No. ..... SNo. .....

HEALTH CERTIFICATE
TO WHOMSOEVER IT MAY CONCERN

1. Details about the Product
   Name and Address of Exporter :
   Name and Address of Manufacturer :
   Description of Product :
   Lot No / Batch No. :
   Invoice No. and Date :
   Quantity :
   No and Kind of Packages :
   Manufacturing Date :
   Date of Expiry :
   Date & Place of Inspection :
   Mode of Sealing :

SPECIMEN COPY

2. Destination of the Product
   The Product is to be despatched
   From ..... (Place of Despatch)
   To..... (Country & Place of Destination)
   By the following means of transport
   .....
   Name and address of consignor:
   Name and address of consignee:

THIS IS TO CERTIFY THAT THE GOODS MENTIONED ABOVE COMPLY WITH THE HYGIENE STANDARDS AND ARE NOT HAZARDOUS TO HUMAN HEALTH

Place of issue **Signature of authorised officer**

Date of issue **Name**

Office Seal **Designation**

Annexure XXII
CERTIFICATE OF REJECTION

EXPORT INSPECTION AGENCY _____

NO. EIA/

To
M / S._____
_____
_____

Sub : Pre shipment Inspection of _____
Ref : Your Intimation No. _____dated _____

Dear Sir,

With reference to your above mentioned intimation for inspection, this is to inform you that the consignment of _____ was inspected and it was not found conforming to the specification recognized under Feed additive and premixtures Export (Quality Control, Inspection and Monitoring) VideNo. S.O 3523 (E) dated 28th November, 2013. It is, therefore, regretted that the certificate of export worthiness cannot be issued due to the following reasons.

Reason (s) for rejection
1)
2)
3)
4)
5)

Yours faithfully,

For Export Inspection Agency,

Annexure-XXIII

Terms and definitions

The following terms and definitions are used in this guide and associated annexures:

a. 'Act' means the Export (Quality Control and Inspection) Act, 1963 (22 of 1963);

b. 'Agency' means the Export Inspection Agency established under sub section (1) of section 7 of the Export (Quality Control and Inspection) Act, 1963 (22 of 1963);

c. 'Appellate Authority' means Director of Inspection and Quality Control;

d. 'Central Competent Authority' means the Council through its Director;

e. 'Certificate' means certificate issued under sub-section (3) of section 7 of the Act stating that the commodity conforms to the conditions regarding quality control and inspection;

f. 'Competent Authority' means Agency established under section 7 of the Export (Quality Control and Inspection) Act, 1963 (22 of 1963) for approval, monitoring, inspection or certification intended for export;

g. 'Complete feedingstuffs' means mixtures of feeding stuffs which, by reason of their composition, are sufficient for a daily ration;

h. 'Compound feedingstuffs' means mixtures of feed materials, whether or not containing additives, for oral animal feeding in the form of complete or complementary feedingstuffs;

i. 'Council' means the Export Inspection Council established under section 3 of the Act;

j. 'Country of Despatch' means India;

k. 'Country of Destination' means the country to which goods are dispatched from India;

l. 'Daily ration' means the average total quantity of feedingstuffs, calculated on a moisture content of 12 %, required daily by an animal of a given species, age category and yield, to satisfy all its needs;

m. 'Director' means Director of Inspection and Quality Control appointed by the GOI under section 4 of the Act;

n. 'Establishment' means any premises where feed additives or premixtures or ingredients are prepared, processed, packaged or stored at unit of a feed businesses;

o. 'Feedingstuffs' means products of vegetable or animal origin in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, used singly or in mixtures, whether or not containing additives, for oral animal feeding.

p. 'Microorganism' means: colony-forming microorganisms.

q. 'Premixtures' means mixtures of feed additives or mixture of one or more feed additives with feed materials or water used as carriers, not intended for direct feeding to animals;

r. 'Complementary feeding stuffs' means mixtures of feeding stuffs which have a high content of certain substances but which, by reason of their composition, are sufficient for a daily ration only if used in combination with other feeding stuffs;

s. ‘Veterinary medicinal product’ means (a) any substance or combination of substances presented as having properties for treating or preventing disease in animals; or (b) any substance or combination of substances which may be used in or administered to animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis;

t. ‘Animals’ means animals belonging to species normally nourished and kept or consumed by man as well as animals living freely in the wild in cases where they are nourished with feeding stuffs;

u. ‘Antimicrobials’ means substances produced either synthetically or naturally, used to kill or inhibit the growth of micro-organisms including bacteria, viruses or fungi, or parasites, in particular protozoa;

v. ‘Antibiotics’ means antimicrobials produced by, or derived from, a micro-organism, which destroys or inhibits the growth of other micro-organisms;

w. ‘Coccidiostats and histomonostats’ means substances intended to kill or inhibit protozoa;

x. ‘Maximum residual limit’ means the maximum concentration of residue from the use of an additive in animal nutrition which may be accepted by the community as being legally permitted or recognized as acceptable in or on a food;

ANNEXURE-XXIV

Technical Definition

a. **Applicant:** An individual or firm authorized to act on behalf of an operator such as by executing commercial transactions without ever taking legal responsibility of the product and the way it is supplied and provided into the feed chain.

b. **Technical personnel:** Persons who have skills, permission and purpose as specified by job descriptions, process descriptions or management.

c. **Batch:** unit of production from a single plant using uniform production parameters or a number of such units, when produced in continuous order and stored together. It consists of an identifiable quantity of product and is determined to have common characteristics, such as origin, variety, type of packing, packer, consignor or labelling.

d. **Calibration:** The demonstration that a particular instrument or device produces results within specified limits by comparison with those produced by a reference or traceable standard over an appropriate range of measurements.

e. **Contamination:** The undesired introduction of impurities of a chemical or microbiological nature or of foreign matter, into or onto a raw material, intermediate, feed additive or premixture during production, sampling, packaging or repackaging, storage or transport.

f. **Corrective Action:** Action to eliminate the cause of a detected non-conformity or other undesirable situation. Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

g. **Cross-Contamination:** Contamination of a material or product with another material or product.

h. **Feed additives:** Substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the following functions:

1. Favourably affect the characteristics of feed;
2. Favourably affect the characteristics of animal products;
3. Favourably affect the colour of ornamental fish and birds;
4. Satisfy the nutritional needs of animals;
5. Favourably affect the environmental consequences of animal production;
6. Favourably affect animal production, performance or welfare, particularly by affecting the gastro- intestinal flora or digestibility of feeding stuffs; or
7. Have a coccidiostatic or histomonostatic effect.

i. **Feed business:** Any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing or distribution of feed additives and premixtures.

j. **Feed business operator:** The natural or legal person responsible for ensuring that the requirements of law are met within the feed business under their control.

k. **Feed hygiene:** The measures and conditions necessary to control hazards and to ensure fitness for animal consumption of a feed additive or a premixture, taking into account its intended use.

l. **Feed material:** Various products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof. Organic or inorganic substances, whether or not containing additives,

which are intended for use in oral animal feeding either directly as such, or after processing, in the preparation of compound feeding stuffs or as carriers of premixtures.

m. **Feed safety**: High level of assurance that the feed (feeding stuff, feed additive, or premixture) will neither cause harm to the farm animals when prepared or consumed according to the intended use, or to the final consumer. Throughout the Code, the word 'safety' is taken to have the same meaning as "feed safety".

n. **Flow diagram:** A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item.

o. **HACCP (Hazard Analysis and Critical Control Point):** A system which identifies, evaluates, and controls hazards to feed safety. *(Codex Alimentarius and modified)*

p. **Hazard analysis:** The process of collecting and evaluating information on hazards, and conditions leading to their presence, to decide which are significant for feed safety and therefore shall be addressed in the HACCP plan.

q. **Hazard:** Biological, chemical or physical agent in the feed chain with the potential to cause an adverse health effect for animals or consumers.

r. **Homogeneity:** The degree to which a property or a constituent is uniformly distributed throughout a quantity of material.

s. **Incoming material:** A general term used to denote raw materials delivered at the beginning of the production chain (e.g. reagents, solvents, processing aids, feed materials, feed additives etc).

t. **Intermediate:** Any material which has been processed by the operator before the final product is obtained.

u. **Manufacture/production:** All operations encompassing receipt of materials, processing, packaging, repackaging, labelling, relabeling, quality control, storage, and distribution of feed additives and premixtures and related controls.

v. **Operator:** Feed additives, premixture business operator.

w. **Plan:** To establish the objectives and processes necessary to deliver results in accordance with the operator's policies regarding quality and safety.

x. **Premixtures:** Mixtures of feed additives or mixtures of one or more feed additives with feed materials or water used as carriers, not intended to direct feeding to animals.

y. **Preventive Action:** Action to eliminate the cause of a potential non-conformity or other undesirable potential situation. Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence.

z. **Procedure:** Operations to be performed, precautions to be taken and measures to be applied directly or indirectly related to the manufacturing of a material, feed additive or premixture.

aa. **Processing aids:** Any things intentionally used in the processing of feeding stuffs or feed materials to fulfil a technological purpose during treatment or processing which may result in the unintentional but technological unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not have any adverse effect on animal health,

human health or the environment and do not have any technological effects on the finished feed.

bb. **Quality:** Degree to which a set of inherent characteristics fulfils requirements. (ISO 9000:2005)

cc. **Raw material:** Any material which enters the manufacturing process of the feed additive and/or premixture.

dd. **Recall:** Any measure aimed at achieving the return of a dangerous product that has already been supplied or made available to consumers by the operator.

ee. **Record:** Written document containing actual data.

ff. **Reworking:** Any appropriate manipulation step in order to ensure a feed additive or premixture will conform to specifications.

gg. **Risk:** A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard.

hh. **Shelf life:** A defined time period for which a product fully complies with it is specification if stored appropriately.

ii. **Should:** Means “must” and the activities, descriptions or specifications accompanied by the word “should” are intended to be mandatory, unless the manufacturer is able to demonstrate that the activity, description or specification is inapplicable or can be replaced by an alternative which must be demonstrated to provide at least an equivalent level of quality and safety assurance.

jj. **Sign / signature:** Confirmation of an authorised person in writing or by electronic means with controlled access.

kk. **Specification:** A list of tests, references to analytical procedures, and appropriate acceptance criteria that are numerical limits, ranges, or other criteria for the test described. It establishes the set of criteria to which a material shall conform to be considered acceptable for its intended use. Compliance to specification means that the material, when tested according to the listed analytical procedures, meets the listed acceptance criteria.

ll. **Sufficient:** —Adequate.

mm. **Stages of production, processing and distribution**: Any stage, including import, from and including the primary production of a food, up to and including its storage, transport, sale or supply to the final consumer and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale and supply of feed additives or premixtures.

nn. **Traceability:** The ability to trace and follow a food, feed, food producing animal or substance intended to be, or expected to be incorporated into a food or feed through all stages of production, processing and distribution.

oo. **Verification:** Application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine compliance with a requirement.

pp. **Where appropriate:** where necessary.

qq. **Written documents:** Paper printed documents. These may be substituted by electronic, photographic, or other data processing systems provided that the data will be appropriately stored during the anticipated period of storage (archive) and can be made readily available in a legible form.

ANNEXURE XXV

General Conditions of Use

a. The quantity of additives that also exists in the natural state in certain feed materials shall be calculated so that the total of the elements added and the elements present naturally does not exceed the maximum level provided for in the approval / permission.

b. Mixing of additives shall be permitted only in premixtures and feeding stuffs where there is physico-chemical and biological compatibility between the components of the mixture in relation to the effects desired.

c. Supplementary feeding stuffs, diluted as specified, may not contain levels of the additives which exceed those fixed for complete feeding stuffs.

d. In the case of premixtures containing silage additives; the words ‘of silage additives’ must clearly be added on the label after ‘PREMIXTURE’.

ANNEXURE-XXVI

Labeling and packaging of feed additives and premixtures

1. The packaging or container of a feed additive or a premixture of additives for export shall be labelled by packer or producer with all the desired information as per importing country requirement and international standards, in a conspicuous, clearly legible and indelible manner, in English and if desired, in the language of destined country.
2. The labeling information shall include the following:
   (a) The specific name given to the additives upon approval, preceded by the name of the functional group as mentioned in the approval;
   (b) The name and the address or registered office of the registered or approved establishment and the exporter;
   (c) The net weight or, in the case of liquid additives and premixtures, either the net volume or the net weight;
   (d) Where appropriate, the approval number assigned by the EIA to the establishment;
   (e) Directions for use, and any safety recommendations regarding the use and, where applicable, the specific requirements mentioned in the approval, including animal species and categories for which the additive or premixture of additives is intended;
   (f) The identification number;
   (g)The batch reference number and date of manufacture in the format 'DD/MM/YY'.
3. For flavouring compounds, the list of additives may be replaced by the words 'mixture of flavouring compounds'. This shall not apply to flavouring compounds subject to a quantitative limitation when used in feed and drinking water.
4. Moreover, in the case of premixtures, the word 'PREMIXTURE' (in capital letters) must appear clearly on the label, and the carrier substance must be declared and, where water is used as a carrier, the moisture content of the premixture shall be declared. Only one minimum storage life may be indicated in respect of each premixture as a whole; such minimum storage life shall be determined on the basis of the minimum storage life of each of its components.
5. Additives and premixtures shall be exported only in closed packages or closed containers which must be closed in such a way that the fastener is damaged on opening and cannot be re-used.
6. In addition to the information specified in "2" above, packaging or container of certain feed additives and for premixtures belonging to a functional group shall bear specific information on the labels as follows:

(1) Zoo technical additives, Coccidiostats and histomonostats:

   a) the expiry date of the guarantee or the storage life from the date of manufacture,
   b) the directions for use, and
   c) the concentration;

(2) Enzymes, in addition to the abovementioned indications:

   a) the specific name of the active component or components in accordance with their enzyme activities, in conformity with the authorisation given,
   b) the International Union of Biochemistry identification number, and

c) instead of concentration: units of activity (units of activity per gram or units of activity per millilitre);

(3) Micro-organisms:

a) The expiry date of the guarantee or the storage life from the date of manufacture,
b) The directions for use,
c) The strain identification number, and
d) The number of colony-forming units per gram;

(4) Nutritional additives:

a) The active-substance level, and
b) The expiry date of the guarantee of that level or storage life from the date of manufacture;

(5) Technological and sensory additives with the exception of flavouring compounds: the active substance level;

(6) Flavouring compounds: the incorporation rate in premixtures.

ANNEXURE-XXVII

DOCUMENTATION ON SUMMARY OF INFORMATION REQUIRED ON ADDITIVE AND PREMIXTURE

Requirements	**Additives**		**Premixtures**	
	PSS	**Label**	**PSS**	**Label**
Reference to PSS	N/A	M	N/A	M
Name and Address	M	M	M	M
Company Approval No	M	M	M	M
Product Identification	M	M	M	M
Commercial or Brand Name	V	V	V	V
Product Classification	M	V	M	M
Additive Functional Group	M	V	M	V
Product Specification (additives)	M	V	M	V
Product Specification (carriers)	N/A	N/A	M	V
Directions for use (general)	M	V	M	M
Contra-indications and warnings	M	M	M	M
Withdrawal periods	M	M	M	M
Product Physical Characteristics	V	N/A	V	N/A
Manufacturing Date	N/A	M	N/A	M
Expiry Dates	Indicate Shelf Life	M	Indicate Shelf Life	M
Net Weight	V	M	V	M
Bar Codes	N/A	V	N/A	V
Packaging description	V	N/A	V	N/A

KEY
M = Mandatory
V = Voluntary
N/A = Not Applicable
PSS = Product Specification Sheet

ANNEXURE- XXVIII

Categories of Additives and Premixtures

1. Approval of establishment: An establishment wishing to exercise one or more of the activities stated below must receive approval from Agency for each of its activities.

(1) Manufacturing / handling of additives listed below:

(a)	Antibiotics	all additives in the group
(b)	Coccidiostats and other medicinal substances	all additives in the group
(c)	Growth promoters	all additives in the group
(d)	Vitamins, provitamins and chemically well-defined substances having a similar effect	all additives in the group
(e)	Trace elements	all additives in the group
(f)	Enzymes	all additives in the group
(g)	Micro-organisms	all additives in the group
(h)	Carotenoids and xanthophyll	all additives in the group
(i)	Substances with antioxidant effects	only those with a fixed maximum content
(j)	Proteins obtained from microorganisms belonging to the group of bacteria, yeasts, algae, lower fungi	all additives in the group (except for sub-group 1.2.1)
(k)	Co-products of the manufacture of amino acids by fermentation	all additives in the group
(l)	Amino acids and their salts	all additives in the group
(m)	Hydroxy analogues of amino acids	all additives in the group

(2) Manufacturing / handling of premixtures prepared from type of additives listed below:

(a)	Antibiotics	all additives in the group
(b)	Coccidiostats and other medicinal substances	all additives in the group
(c)	Growth promoters	all additives in the group
(d)	Vitamins, provitamins and chemically well-defined substances having a similar effect	A and D
(e)	Trace elements	Cu and Se

2. Approval of establishment: An establishment wishing to exercise one or more of the activities stated below must be registered by Agency for each activity.

(1) Manufacturing / handling of additives for which a prescribed maximum level is set and which are not included in list 1. (1) above

(2) Manufacturing / handling of premixtures prepared from type of additives listed below:

(a)	Vitamins, provitamins and chemically well-defined substances having a similar action	all additives in the group except for vitamins A and D
(b)	Trace elements	all additives in the group except for Cu and Se
(c)	Carotenoids and xanthophyll	all additives in the group
(d)	Enzymes	all additives in the group
(e)	Micro-organisms	all additives in the group
(f)	Substances with antioxidant effects	only those with a fixed maximum content

ANNEXURE-XXIX

Functional Groups of Additives in Different Categories

1. Functional groups in Technological additives category:

(a)	preservatives:	substances or, when applicable, micro-organisms which protect feed against deterioration caused by micro-organisms or their metabolites;
(b)	antioxidants:	substances prolonging the storage life of feeding stuffs and feed materials by protecting them against deterioration caused by oxidation;
(c)	emulsifiers:	substances that make it possible to form or maintain a homogeneous mixture of two or more immiscible phases in feeding stuffs;
(d)	stabilisers:	substances which make it possible to maintain the physico-chemical state of feeding stuffs;
(e)	thickeners:	substances which increase the viscosity of feeding stuffs;
(f)	gelling agents:	substances which give a feeding stuff texture through the formation of a gel;
(g)	binders:	substances which increase the tendency of particles of feeding stuffs to adhere;
(h)	substances for control of radionucleide contamination:	substances that suppress absorption of radionuclides or promote their excretion;
(i)	anticaking agents:	substances that reduce the tendency of individual particles of a feeding stuff to adhere;
(j)	acidity regulators:	substances which adjust the pH of feeding stuffs;
(k)	silage additives:	substances, including enzymes or micro-organisms, intended to be incorporated into feed to improve the production of silage; and
(l)	denaturants:	Substances which, when used for the manufacture of processed feeding stuffs, allow the identification of the origin of specific food or feed materials.

2. Functional groups in Sensory additives category:

(a)	Colourants:	(i) Substances that add or restore colour in feeding stuffs; (ii) substances which, when fed to animals, add colours to food of animal origin; and (iii) substances which favourably affect the colour of ornamental fish or birds.
(b)	Flavouring compounds:	substances the inclusion of which in feeding stuffs increases feed smell or palatability

3. Functional groups in Nutritional additives category:
   (a) Vitamins, provitamins and chemically well-defined substances having similar effect;
   (b) Compounds of trace elements;
   (c) Amino acids, their salts and analogues; and
   (d) Urea and its derivatives.
4. Functional groups in Zoo technical additives category:
   (a) Digestibility enhancers: substances which, when fed to animals, increase the digestibility of the diet, through action on target feed materials;
   (b) Gut flora stabilisers: micro-organisms or other chemically defined substances, which, when fed to animals, have a positive effect on the gut flora;
   (c) Substances which favourably affect the environment; and
   (d) Other zootechnical additives.

ANNEXURE-XXX

GUIDANCE ON SAMPLING

The sampling procedure must be adapted for the purpose of sampling, to the type of controls intended to be applied to the samples, and to the material to be sampled. The procedure should be described in writing. All operation related to sampling should be performed with care, using proper equipment and tools. Any contamination of the sample by dust or other foreign material is liable to jeopardize the validity of the subsequent analyses.

1. Purpose of sampling

Sampling may be required for different purposes such as: acceptance of consignments, batch release testing, in-process-control, special controls, deterioration, adulteration, obtaining retention sample, etc.

2. Sampling facilities

Where possible sampling should be performed in a defined area. Sampling from large containers of storing material or bulk products can present difficulties. Whenever possible this work should be carried out within the warehouse in order to reduce the risk of contamination by dust of either the sample or the remaining material in the container, or cross-contamination.

3. Qualification of the sampler

Everyone called upon to take samples should be trained in the practical aspects of sampling and should have sufficient knowledge of the materials or products to execute the work effectively and safely. A conscientious approach, with meticulous attention to detail and cleanliness, is essential. The sampler must remain alert to any signs of contamination, deterioration or tampering.

4. Health and safety

It is the responsibility of the sampler to read the relevant health and safety information i.e. Material Safety Data Sheet before sampling the material or product. The information must include necessary safety precautions and requirements for both the sampler and the environment. The sampler must wear appropriate protective clothing for the task.

Sampling process: For the sampling of products the sampler should have at his/her disposal all the tools needed to open the packages, barrels, containers, etc. and material to re-close the packages as well as labels to indicate that a part of the contents has been removed from the package or container. Cleaning of containers due to be sampled should be performed prior to sampling if necessary. All tools and implements should be made of inert materials and kept clean. After use, or before re-use, they should be thoroughly washed, rinsed and dried. They must be stored in clean condition. The use of disposable sampling materials has distinct advantages.

1. Sampling operation and precautions

The sampling procedure should be such that any non-uniformity of the material can be detected. Signs of non-uniformity include differences in shape, size or colour of particles in crystalline, granular, or powdered solid substances, moist crusts on hygroscopic substances, deposits of solid material or stratification in liquid products. Such changes, some of which may be readily reversible, can occur during prolonged storage or exposure to extreme temperatures during transportation. Non-

homogeneous portions of the material should be sampled separately from the rest of the material that has a normal appearance. Compositing of the samples from the different portions should be avoided, since it can mask quality problems.

Labelling of samples should indicate appropriate details such as product name or identification code, batch/lot number, quantity, date of sampling, storage conditions, handling precautions, container number, etc. Labels should be applied at the time of sampling.

3. Storage and retention

The container used to store the sample should not interact with the sampled material nor allow contamination. It should also protect the sample from light, air, moisture etc. as required by the storage conditions. Any headspace should be kept to a minimum in case of any degradation through oxidation. Adequate storage conditions must be ensured for the rooms where samples are stored.

Note- The sampling of raw material and finished products may be done as prescribed "source of the statistical plans: •WHO GUIDELINE FOR SAMPLING OF PHARMACEUTICALS AND RELATED MATERIALS' as given below

A. Raw materials If the material of a consignment can be regarded as uniform the sample can be taken from any part of the consignment. If, however, the material is not physically uniform special sampling tools may be required to withdraw a cross-sectional portion of the material. In some instances, however, an attempt can be made to restore the uniformity of the material before sampling, based on information concerning the subsequent handling and manufacturing steps. Thus, a stratified liquid may be stirred, or a solid deposit in a liquid may be dissolved by gentle warming and stirring. Such interventions should not be attempted without adequate knowledge of the properties of the contents and appropriate discussions with owner of the goods.

All partially processed natural products should be treated as intrinsically non-uniform. Special procedures requiring considerable practice are used to prepare representative samples from such consignments.

A. Sampling plans for raw materials and finished products:

From a practical point it is not prudent to open all containers for sampling. The number of units depends on different assumptions following the three plans.

I. The n-plan (Assuming a uniform material from a recognized source where there is a high degree of confidence in the source)

Samples can be withdrawn from any part of the container; usually from the top layer. The n-plan is based on the formula n = □√N+1, where N is the number of sampling units in the consignment. The value of n is rounded up to the next higher integer. According to this plan samples are taken from n sampling units selected at random and these are subsequently place in separate sample containers. The control laboratory inspects the appearance of the material and tests the identity of each original sample according to the relevant specification. If the results are concordant the original samples are pooled into a final sample from which the analytical sample is prepared, the remaining part being kept as a retention sample.

II. The p-plan (Assuming a uniform material from a recognized source with the main purpose to check identity) *

The p-plan is based on the formula p = 0.4 √N, where N is the number of sampling units. According to this plan samples are taken from each of the N sampling units of the consignment and placed in separate sample containers. These original samples are visually inspected and tested for identity by a simplified method. If the results are concordant p final samples are conformed by pooling of the original samples.

III. **The r-plan (Assuming the material is non-uniform and/or from a source that is not well known)** *

The r-plan is based on the formula r = 1.5 √N, where N is the number of sampling units. Samples are taken from each of the N sampling units of the consignment and placed in separate sample containers. These original samples are transferred to the control laboratory and tested for identity. If the results are concordant r samples are randomly selected and individually subject to testing. If the results are concordant the r samples are pooled for the retention sample.

*** Source of the statistical plans**: WHO GUIDELINE FOR SAMPLING OF PHARMACEUTICALS AND RELATED MATERIALS'