EXPORT INSPECTION COUNCIL
New Delhi
EIC LABORATORY APPROVAL SCHEME- 2010

0. INTRODUCTION

0.1 The Export Inspection Council (EIC) is the official export inspection and certification body of India set up under the Export (Quality Control & Inspection) Act, 1963 to ensure sound development of India's export trade through quality control and inspection. It operates through its field organizations, Export Inspection Agencies (EIAs), set up under Section 7 of the Act, headquartered at Chennai, Delhi, Kochi, Kolkata and Mumbai, and a network of 30 sub offices including laboratories in important ports and industrial centers in India to carry out its functions.

0.2 Accordingly, EIC is operating export inspection and certification schemes for various notified commodities as well as non-notified commodities. Product testing is integral to the export inspection and certification services being rendered by EIC/EIAs and therefore, EIAs have established a network of laboratories to cater to the inflow of samples generated during the operation of its export inspection and certification systems. However, the need for independent testing facilities may arise from time to time to supplement its own laboratory network either due to shortage of capacity or absence of specific testing capability as per standards for export which are normally international standards or regulatory standards prescribed by the importing countries.

0.3 Keeping this in view, EIC has reviewed and revised its laboratory approval scheme (Issue 4) for approval of laboratories that are technically competent having implemented quality management systems as per national & international standards and perform tests as per the guidelines/ procedures stipulated in the relevant standards of various export products.

0.4 The conformity assessment under EIC Laboratory Approval Scheme is based on changing international requirements from time to time, in addition to conformity / accreditation to ISO/IEC 17025 'General requirements for the competence of Testing and Calibration laboratories' with their scope covering the products and testing facilities of the interest of EIC / EIAs.

0.5 This Review of the Scheme shall apply with immediate effect

1. SCOPE

1.1 This document lays down the guidelines for general as well as the technical criteria for approval, terms and conditions of approval, withdrawal / cancellation of approval and financial aspects of the scheme, for the applicant laboratories for the purpose of providing its services to meet the international specifications based on the assessment and need of EIC / EIAs.

1.2 The approval scheme shall apply to laboratories, which shall be functioning independently irrespective of being an in-house laboratory or linked directly or indirectly to any of the manufacturing / processing unit / organization / institution to the satisfaction of EIC for demonstrating no conflict of interest.

1.3 Approval under the Scheme shall be accorded to a laboratory for single premises only where actual testing is carried out. If the laboratory carries out testing activities in more than one premise, separate approval for each premise will have to be obtained with a clear demarcation of scope of approval. However, if the laboratory establishes field / satellite laboratories for preliminary / screening tests near / at the place of the primary production of the food and feed of animal or plant origin, the facilities can be considered as part of the central / main laboratory of the establishment, with additional scope, where conformity tests can be carried out for the presence of the particular substance(s), provided such arrangements are addressed in the Quality Manual of the Laboratory.

2. CRITERIA FOR APPROVAL

The laboratories seeking approval shall have implemented and maintained Laboratory Management System in accordance with ISO / IEC 17025:2005 'General requirements for the competence of Testing and Calibration laboratories'. The applicant laboratory shall have adequate capability and competence for testing of food safety and quality parameters as per the requirements of EIC/EIAs and importing country. The laboratory shall be considered for assessment and approval for the scope of interest to EIC/EIAs provided it is adjudged for its capability and competency as per the international requirements and notifications issued for various commodities from time to time. For the purpose of certification of products for export to European Union, the testing of the products shall be as per the European Commission regulations / guidelines.

3. PROCEDURE FOR OBTAINING APPROVAL

3.1 APPLICATION

3.1.1 Interested Laboratory shall apply to the regional EIA office in the prescribed proforma along with a copy of its Quality Manual and application fee, as prescribed from time to time. A format of application is annexed to this document. One copy of the application complete in all respect as verified by the EIA concerned shall be forwarded to EIC along with all enclosures including Quality Manual (Please refer Clause No. 3.1.3). Additionally, a soft copy (scanned)/hard copy of signed application complete in all respect along with all enclosures including Quality Manual shall be forwarded to EIC by the laboratory. The application fee is non- refundable. The Schedule of Fee is given in Clause No. 9. Application fee shall be applicable separately for each of the scope and separate annexure as per the Annex-1 should be enclosed for each of the scope given below:

Scope	Parameters covered
Biological-1	Sampling and analysis of samples of food and agriculture commodities, environment, hygiene and sanitation for microbial parameters including pathogens & Viruses for food safety and GMO status of food and agriculture commodities. This shall exclude microbial assay for drug residues / contaminants and bio-toxins.
Chemical-1	Sampling and analysis of samples of food and agriculture commodities for residues and contaminants by microbial assay and screening tests like ELISA.
Chemical-2	Sampling and analysis of samples of food and agriculture commodities of animal origin (Matrix/Product wise) for residues of prohibited and permitted pharmacologically active substances and their metabolites.
Chemical-3	Sampling and analysis of samples of food and agriculture commodities of both animal origin and plant origin (Matrix/Product wise) for residues and metabolites of prohibited and permitted pesticide residues.
Chemical-4	Sampling and analysis of samples of food and agriculture commodities of both animal origin and plant origin (Matrix/Product wise) for contaminants like heavy metals, malachite green, mycotoxins / biotoxins, Dioxin and dioxin like PCBs, etc.
Chemical-5	Sampling and analysis of samples of food and agriculture commodities for proximate composition and constituents.
Chemical-6	Sampling and analysis of samples of Minerals and ores
Physical-1	Sampling and analysis of samples of food and agriculture commodities for sensory parameters and physical characteristics like, turbidity, pH, particle size, etc.
Water-1	As per Council of European union Directive 98/83/EC
Water-2	As per IS 4251:1967 and IS 10500:2012

Note: For the purpose of requesting importing country to enlist/approve name of the laboratory for testing of specific commodity for export to that country e.g. Marine products for Japan; the laboratory shall make specific request along with supporting document for scope for testing and application fee as per Clause No. 9. The request to the importing country's authority shall be made by EIC, provided the laboratory has valid scope of approval under EIC's Laboratory Approval Scheme.

The laboratory shall ensure the followings:

(i) The scope for approval shall be supported with the validation data, as appropriate, in the prescribed format given at Annex-2. A separate validation data shall be enclosed for each matrix/product as per the scope for approval.

(ii) The scope shall not be amended/changed; however it may be reduced but shall not be appended, till on-site assessment is completed once application is submitted.

(iii) The scope for approval shall not include any test by sub-contracting. Sub-contracting is permitted with prior permission of EIC/EIAs concerned / the customer in another EIC approved laboratory with valid scope of approval only in case of failure of instrument. Sub-contracting is not permitted from the laboratory, which is not approved by EIC.

(iv) The application for approval for the specific scope shall be taken into consideration only on the scrutiny and recommendation by the EIA concerned.

Laboratories seeking approval for any of the scope mentioned above may make a written request to EIA for getting information on the scope for which the laboratory services would be required. Alternatively, relevant information can be downloaded from EIC website (www.eicindia.gov.in).

3.1.2 The application shall be signed by the proprietor, partner or the Chief Executive Officer (CEO) of the laboratory or any other person duly authorized for the purpose. The authorization shall be supported with the Board Resolution or a letter, as applicable under companies act/rules. The name and designation of the person signing the application must be recorded legibly in a space set apart for the purpose in the application form.

3.1.3 On receipt of application, along with fee as per Clause No. 9, EIA concerned shall deposit the fee and within five working days scrutiny the application for adequacy based on the needs of the EIC/EIA concerned. If necessary, EIA concerned shall seek further information from the applicant in order to facilitate processing of the application. The applicant shall submit the satisfactory relevant information within 30 days from the date of communication from EIA. If the applicant has not responded within the stipulated time, the application submitted shall be considered as closed and the applicant shall apply afresh. On receipt of the application complete in all respect as per the scheme, within three working days EIA shall inform to EIC along with its clear recommendation for assessment of the laboratory and scope for its approval.

3.1.4 On receipt of the application, laboratory quality manual along with the fee details, enclosures and recommendation from the EIA concerned, EIC shall scrutinize it further for completeness as well as adequacy of facilities with regard to list of equipments and details of personnel to meet the basic requirements, with the scope of approval applied for, of interest to EIC / EIAs. The laboratory shall have adequate infrastructure and equipment facilities and resources to perform the sampling/tests under the scope for approval, which shall be verified during the on-site assessment.

3.1.5 If necessary, EIC shall seek further information from the applicant in order to facilitate processing of the application. The applicant shall submit the satisfactory relevant information within 30 days from the date of communication from EIC. If the applicant has not responded within the stipulated time, the application submitted shall be considered as closed and the applicant shall apply afresh.

3.1.6 The application for approval shall be considered based on the testing requirements, which EIC and EIA concerned are looking for. EIC/EIA concerned reserves the right to reject an application for one or more of the following reasons:

i) The laboratory is seeking approval for the scope, which is not the need of EIC/EIAs at that time;
ii) The laboratory does not have adequate facilities for the scope applied for as given in its application;
iii) Application fee as applicable for each scope for approval and adequacy audit fee, as applicable has not been submitted;
iv) Application form is not completely filled;
v) Quality Manual has not been submitted along with the application and not addressing the scope applied for, adequately;
vi) In case of renewal of approval, performance of the laboratory is not satisfactory during its previous approval;
vii) The laboratory has not conducted at least one internal quality system audit, one technical audit covering all areas under the scope applied for.
viii) The laboratory has not done management review on yearly basis to ensure the implementation of the documented quality system.
xi) The laboratory is sub-contracting any test under the scope for approval.
ix) Any other reasons as deemed fit by EIC, without giving any reason.

3.2 ADEQUACY AUDIT/ DESK ASSESSMENT

After acceptance of the application, adequacy audit of the Quality Management System shall be conducted by Assessor/ any other person deputed by EIC based on the Quality Manual submitted by the laboratory. The laboratory shall pay adequacy audit fee to the EIA concerned as per Clause No. 9. Any deficiencies observed in the Manual shall be communicated to the applicant for taking suitable corrective actions and resubmission of the Quality Manual for review. The laboratory shall take satisfactory corrective actions within 30 days. If the applicant has not responded within the stipulated time, the application submitted shall be considered as closed and the applicant shall apply afresh. In case of amendments in the documents, copies of amendments shall be submitted for verification.

3.3 ASSESSMENT

3.3.1 EIC shall process the application for on-site assessment only after adjudging the suitability of management system by adequacy audit. A team of not less than two assessors with at least one assessor for each scope/as required including for sampling shall be deputed to ascertain compliance to the documented Management System, equipment facilities/ infrastructure, technical competence, EIC/EIAs requirements and importing countries requirements as per international norms. The laboratory shall make arrangements for travel and stay of the assessors/observers and provide the facilities required for on-site assessment as per the auditing principles. The assessor shall plan and prepare checklist for assessment of the specified field.

3.3.2 The on-site assessment shall constitute to the following steps:

a) Opening Meeting - This meeting will be conducted by the assessment team leader in which the Chief Executive Officer of the laboratory, the management representative and the technical heads of all the divisions being audited are expected to be present. During this meeting, the team leader will explain the scope and extent of the assessment as well as the proposed plan for assessment. The scope for approval shall not be changed during the opening meeting. Permission to take photocopy or photograph of documents relevant to substantiate the audit findings shall be complied with by the laboratory. The assessment schedule shall be planned to cover all the areas on sample basis in scheduled time period between 0930 hours and 1800 hours on the planned mandays. The laboratory shall ensure that necessary infrastructure facilities and documentary evidences are provided promptly to complete the assessment in scheduled time. The laboratory shall primarily be responsible for completing the assessment in scheduled time.

b) Conducting Assessment - The assessment shall be conducted as per the assessment plan agreed to during the opening meeting, and shall cover areas of the relevance to the scope of approval of the laboratory. Evaluation shall include verification of test facilities, accommodation and environment, examination of documents and records, including in-house internationally accepted method validation documents in place that shall be matrix specific for the scope applied for approval, assessment of competence of laboratory personnel in conducting laboratory analysis/ testing, performance in witness tests, documentary evidence of participation in International Proficiency testing programs for relevant analytes and matrices and compliance to its Annual Plan for participation in such programs. The testing under the scope for approval shall be in compliance to the methods of validation as per the requirements of the importing countries. E.g. for the purpose of export to European Union, testing shall be in compliance with the requirements as per the relevant Regulations, Directives and Decisions of European Commission (Please see Appendix 2). A laboratory official, conversant with the activities of the division(s) being audited, should accompany each assessor. The non-conformances (NCs) identified by the assessment team shall be briefed and submitted to the auditee for necessary corrective action(s).

c) Closing meeting - The assessment shall conclude with a closing meeting during which the assessment team shall present its findings to the laboratory. All the members present in the opening meeting should preferably be present in the closing meeting. The non-conformance reports shall be acknowledged by Management Representative or authorized signatory, as a token of acceptance and time frame for the corrective action(s) will be agreed to. No NC shall be closed either during the assessment or at the time of closing meeting.

3.3.3 Before assessment is undertaken, the applicant laboratory shall have conducted at least one internal quality system audit, one technical audit covering all areas under scope applied for and also one management review to ensure the implementation of the documented management system. The related documents of the same shall be presented to assessment team before the commencement of audit.

3.3.4 The Assessment team shall recommend for approval of the laboratory for the specific scope in case there is no major or minor NC. The scope recommended shall not include the parameters that are sub-contracted by the laboratory. The lead assessor and the corresponding technical assessor shall duly sign on the recommended scope with appropriate recommendations.

3.3.5 In case any NC, the assessment team may recommend for approval of the laboratory subject to closure. Assessor shall not carry out any verification of the closure of NC, raised during the current assessment. No NC shall be closed at the end of the assessment. The laboratory shall ensure the closure of NC(s) within stipulated time period of not more than 60 days. The minor NC closure may not require on-site verification. However, closure of major NC may require on-site

verification. In case of non-closure of the NCs within the stipulated time period, the laboratory shall have to apply a fresh after satisfying itself the closure of the NCs and ensuring compliance to the requirements.

3.3.6 The Lead Assessor shall send Assessment Report to EIC within three days after completion of the assessment of the laboratory.

3.4 ASSESSMENT FEE

The applicant laboratory shall bear assessment fee, as estimated by EIC, for the number of assessors and man-days deputed for assessment, based on the scope applied for and arrangement for travel/stay etc. as per Clause No. 9.

3.5 RESPONSIBILITIES OF APPLICANT DURING THE ASSESSMENT

The laboratory is expected to provide the following assistance to the assessment team during the visit:

a) Arrangements for stay, local guidance and travel etc.
b) A representative of laboratory to accompany the team during the assessment.
c) A suitable room where members of the team can meet and discuss during the day and at the end of the day to exchange their notes and findings.
d) Secretarial and other office assistance like photocopying, etc.
e) Free accessibility to the records, test facilities as is deemed relevant by the assessors
f) Ensuring the availability of respective lab personnel including samplers/ admin/accounts staff and availability of purchase documents, if stored at premises other than the lab.

3.6 FOLLOW UP ASSESSMENT

The laboratory shall take necessary corrective actions within the stipulated time period of not more than two months for the closure of the NC's, brought on record by the assessment team, which will have to be verified by the corresponding assessor before considering it for grant of approval. On-site verification assessment by the corresponding assessor may be required for closure of major NCs. This follow up visit, for full or partial assessment, may be carried out as above, on request and bearing applicable assessment fee and arrangements by the laboratory as per clause No.9. During the verification assessment, if the implementation of the corrective action is not found satisfactory, then the laboratory shall not be recommended for approval and the laboratory shall have to apply afresh after taking satisfactory corrective action.

3.7 GRANT OF APPROVAL

3.7.1 Based on the recommendation of the assessment team, EIC shall consider for grant of approval to the laboratory. The laboratory will be issued a Certificate of Approval annexed with the scope of approval and approval letter. The decision of the Director, EIC for granting the approval or otherwise shall be final.

3.7.2 The approval granted shall be valid for a period of two years from the date of approval and it shall be renewable for two years at a time. It shall be binding for the approved laboratory to comply with the directions/any modification in the scheme, issued by EIC from time to time. The EIC approved laboratory shall bound with the terms and conditions given under Clause No. 7.

3.8 CONSIDERATION FOR ACCREDITATION

Laboratories having NABL accreditation may have due weightage depending upon the scope of accreditation but not binding to EIC for consideration. The adequacy audit of Quality Manual may not be carried out at the time of renewal, in case it is not a new revised issue.

4. SURVEILLANCE/VERIFICATION ASSESSMENT

4.1 The approved laboratory shall be subjected to surveillance audits at least once in a year by EIC as per decision of the Director EIC to verify the continued compliance and maintenance of competency and the implementation of quality system established by the laboratory. The laboratory shall be subjected to verification audit (informed in advance /uninformed depending upon the nature of complaint) in case of any complaints in sampling, testing and test reports or any other reasons.

4.2 During the validity of approval, if the laboratory is found violating the terms and conditions of Approval, its approval is liable to be suspended and may call for verification visits, for which the laboratory is liable to pay visit charges, as set out in Schedule of Fee given in Clause No. 9.

4.3 If complaint is received from importing country (eg. RASFF- Rapid Alert System on Food and Feed) against a consignment, for presence of any hazards either microbiological or other contaminants like heavy metals, pesticide or antibiotic residues, the laboratory in which the sample has been tested and or drawn prior to

export, shall be subjected to audit trail (verification audit) by an assessor/assessment team or an officer/officers nominated by the Director, EIC. The laboratory shall pay the assessment fee as set out in Schedule of Fee given in Clause No. 9. The laboratory shall be audited for the following parameters;

a) Availability of trained manpower for conducting the tests/sampling
b) Internal quality control systems
c) Verification of related records
d) Relevant Equipment status and its records
e) Validation of the method of testing as required by the importing country
f) Method of Proficiency testing or Inter laboratory comparison
g) Participation in international proficiency testing programs (compliance to ISO/IEC 17043)
h) Witness of retesting of retained, remnant and or corresponding sample.
i) Any other as deemed fit of merit

4.3.1 Based on the finding of the verification assessment EIC shall take appropriate action including suspension / withdrawal of approval the laboratory in line with clause 8.4 of the scheme.

5. EXTENSION OF SCOPE

The approved laboratory can request EIC for extension of its scope of approval to cover additional products/matrix and test parameters of the interest to EIC/EIAs by following the procedure as given in Clause No.3. The laboratory shall apply in the prescribed format by filling in the relevant information applicable to the extension of scope along with supporting documents and application fee prescribed in Clause No. 9. In case the Quality Manual is revised, Current Quality Manual shall also be submitted for scrutiny along with adequacy audit fee prescribed in Clause No. 9.0. On-site assessment shall be conducted for the applied scope for extension as per the procedure given in Clause No. 3. Assessment fee shall be applicable as per Clause No. 9. f) **.**

5.1 The approved laboratory can request EIC for approval of additional authorized samplers/signatories. In such cases the laboratory shall follow the procedures stated in the clause 5. On-site assessment shall be conducted for the additional authorized samplers/signatories as per the procedure given in Clause No. 3. Application fee and Assessment fee shall be applicable as per Clause No. 9.

6. RENEWAL OF APPROVAL

6.1 Any approval granted automatically expires at the end of the period of its approval. The approved laboratory shall apply to EIA concerned with a copy to EIC at least four months before the date of expiry of its approval. Application for renewal of approval shall be rejected if application does not reach to EIC/EIA before four months of expiry of its current approval.

6.2 The laboratory shall submit the application for renewal of its approval as per Clause No. 3. Assessment for renewal of approval shall be carried out similar to the initial assessment.

6.3 It shall be ensured during renewal assessment that the terms and conditions for approval were not breached during the validity of approval.

6.4 In case there is a impediment in renewal of approval, the laboratory shall undertake to maintain the integrity of already received samples by providing appropriate storage conditions and return to the in its original condition so that the same can be analyzed in another laboratory. The laboratory shall not carry out either sampling and testing or receiving samples for testing for the purpose of self-monitoring / quality control by the processor / exporter or for the purpose of official control / certification for export. No test report shall be issued by the laboratory when it has no valid approval of EIC. The laboratory shall restrict itself from entertaining any sampling and/or testing for the commodities or product within the purview of the Export (Quality Control and inspection) Act, 1963, when it has no valid approval of EIC.

7. TERMS AND CONDITIONS OF APPROVAL

7.1 The approval shall be granted for a period of two years, which shall be renewable for maximum period of two years at a time subject to satisfactory performance based on periodic review/ surveillance and assessment for renewal of the laboratory by EIC. The laboratory shall apply for its renewal at least four months before expiry of approval.

7.2 The testing charges fixed by EIC shall be adhered to for testing of the products / parameters as per relevant methods under the scope of approval of the laboratory. Laboratory shall not revise the testing charges without prior concurrence of EIC.

7.3 The approved laboratory shall perform all the tests in its approved premises as per the valid scope of approval. No sub-contracting of any test is permitted (Refer clause 3.1.1 (iii)

7.4 The approved laboratory shall not make any change in the Quality Management System, which forms the basis for the grant of the approval and which prevents its compliance to the Scheme without prior approval of EIC. It shall document all changes made to the Quality Management System and make records of such changes available to EIC within a period of 10 days with a copy to the EIA concerned.

7.4.1 Any change in key personnel in relation to quality assurance, key technical functions (including authorized signatory and sampler) or senior management shall be duly intimated to EIC within a period of 10 days with a copy to the EIA concerned.

7.4.2 The approved laboratory shall inform EIC and EIA concerned, immediately about the major changes/breakdown of equipment with reasons thereof etc. effecting testing of the relevant products/compliance to this laboratory scheme. The laboratory shall not carry out sampling or accept any sample for testing, when there is breakdown of the equipment to be required for performing the test(s). The laboratory shall not carry out sampling or accept any sample for testing, without prior approval of EIC, when there is major change in the Management System, which may affect performance of the testing.

7.4.3 The approved laboratory shall inform EIC immediately about the suspension/ withdrawal of accreditation from NABL with a copy to the EIA concerned.

7.5 The following instructions shall be followed by the approved laboratory for testing the samples sent by EIC/EIAs or processor/exporter for the purpose of monitoring / certification:

7.5.1 Sample shall always be accompanied by a test request specifying the parameters, specification and purpose. Samples shall not be accepted by them if they are not accompanied by such test requests.

7.5.2 Whenever required, the approved laboratory shall draw samples only by its own trained, authorized and approved samplers. The sampler shall have the minimum qualification of graduation.

7.5.2.1 The sampler shall strictly adhere to the sampling procedure of the lab based on Executive Instructions issued by EIC for various food products from time to time/ EC regulations/Importing country requirements, and provide sampling details as per EIC requirements. The sample shall be drawn only from the complete Assortment / Batch/ shipment/ consignment/ Lot as the case may be having uniform characteristic in the form of source / production conditions / processing conditions.

7.5.2.2 The sampler shall also ensure drawl of true representative sample of complete Assortment/ Batch/ shipment/ consignment/ Lot/ source wise /Pond wise (if applicable) as the case may be.

7.5.2.3 The sampler shall endorse the relevant records of complete Assortment/ Batch/ shipment/ consignment/ Lot as the case may be, maintained at the place of sampling.

7.5.3 The laboratory shall ensure the integrity and chain of custody of sample during transportation. Further, laboratory shall ensure that the seal is intact with the details of the sealing indicated in the test request while accepting the samples / sample containers sealed by EIA officers / authorized representatives of laboratory / processor / exporter. A statement / record to this effect shall be made on receipt of sample and in the test report by the concerned laboratory.

7.5.4 The laboratory is liable to maintain confidentiality of samples and information thereof.

7.5.5 The laboratory shall carry out the tests as per the conditions stipulated in the relevant standard method approved by EIC, which has been satisfactorily validated “as fit for the purpose”, with duly calibrated equipments and use of only valid certified reference materials and /or internal standards.

7.5.6 The test report duly sealed in confidential cover unless the report is sought by any other means in the format as per the requirements of EIC (specimen format for Test Report at Annex 10) shall be sent to the officer / processor / exporter, who has sent the sample and requested the testing. The test report shall clearly indicate who has drawn the sample and the reference method including validation parameter adopted for particular test. Alternatively, However, formats stipulated in the specific guidelines / instructions shall be used.

7.5.7 The laboratory shall keep the remnants of the sample after testing for a minimum period of three months and reference sample for a period of six months in stipulated storage conditions before they are disposed off or returned to the customer. In case of samples tested for Biological parameters the sample shall be retained for reasonable period as per lab’s policy based on EIC/importing country’s requirement. The mode of disposal of sample after test shall be recorded and indicated in the test request as well.

7.5.8 The test report shall be treated as strictly confidential between the testing laboratory and EIC / EIA concerned. No information regarding the sample or its results shall be divulged to any person including the manufacturer / processor who may deliver the sample for testing on behalf of EIA

concerned. However, in case sample is submitted by the processor / exporter for testing within the scope of approval for the purpose of self monitoring or for monitoring / certification by EIAs, the details of testing shall be made available to EIC and EIA concerned. In case of failure of any samples for any parameter, it shall immediately inform to the EIC / EIA concerned as well as the processor / exporter who has submitted the sample.

7.5.9 The manufacturer/processor shall not be allowed to witness the test or to come in contact with the testing personnel without prior approval of EIC / EIA concerned. Any assistance or intervention from the manufacturer required for testing the sample shall be duly indicated by EIA in the test request and shall be reported in the test report.

7.5.10 The laboratory shall issue the test reports immediately after completion of the tests and not later than a maximum period of 7 days, excluding the time period required for testing by the relevant specification.

7.5.11 The Test report/Certificate shall include information as per the details given in EIC-approved proforma (Annex 10). Additionally the information shall be in compliance with the ISO/IEC 17025 requirements. However, formats stipulated in the specific guidelines / instructions shall be used. The laboratory shall utilize the service of authorized signatory and authorized samplers only. The authorized signatory shall be complying with the following requirements.

Authorized signatory for biological scope shall fulfill either of the following requirements: (a) Graduates in the relevant field or equivalent with five years experience in similar area out of which at least two years experience should be at supervisory level. (b)-Postgraduate/higher degree in the relevant field or equivalent with a minimum of two years supervisory level experience in the relevant scope. The testing laboratories carrying out testing of pathogens shall have a qualified microbiologist (graduate/post graduate in Microbiology with the above-mentioned experience) as the authorized signatory.

The minimum requirement for an Authorized Signatory for chemical scope shall be a Graduate in Science with chemistry as one of the subjects / Diploma in Chemical engineering / technology or equivalent from a recognized university with at least 5 years experience in relevant field, or Post-graduate in chemistry / specialization in relevant subject / Degree in Chemical engineering / technology or equivalent from a recognized university with at least 2 years experience in relevant field.

7.5.12 The laboratory shall maintain the record of observations, a copy of the test report and purchase documents for a minimum period of three years. In case of chemicals/media etc, the laboratory shall maintain purchase documents till the validity of chemical/ media etc. Original data/records to establish audit trail/data integrity shall be maintained in the lab pertaining to each activity which affects the quality of test results

7.5.13 In case of withdrawal / cancellation of approval, the laboratory shall give an undertaking to make available of the records of EIC/EIA related testing of three years.

7.5.14 The payment towards testing charges for the samples sent by EIA for testing shall be made by the office of EIA concerned, who has sent the samples and therefore, the concerned laboratory shall forward the bill, in duplicate, to them along with the test reports.

7.5.15 The approved laboratories generating Pre-export test reports with digital signatures shall send test reports directly to concerned EIA/S.O which will issue the Health Certificate and shall not provide any copy of above test report directly to the exporter/processor. Such laboratories shall submit an undertaking in ₹ 100/- Non Judicial stamp paper signed by the CEO of the laboratory with respect to above.

7.6 The approved laboratory shall participate in Proficiency Testing / Inter-Laboratory Test Comparison programmes organized by national and international bodies of repute for demonstrating technical competence of the laboratory personnel, at its own cost. The Annual proposed plan for participation in Proficiency testing programs pertaining to approved scope for the forthcoming year shall be submitted to EIC before 31st December of each year as per Annex 7A. The laboratory shall cover all the critical parameters in the relevant matrix within a period of 4 years. In case of, unsatisfactory result (Quantitative score $Z > \pm 2$) is scored, the same shall be informed to EIC immediately with appropriate root cause analysis.

7.7 The approved laboratory shall permit access to EIC/EIA officer(s)/team(s) deputed for the purposes of assessment, surveillance or investigation. It shall give access to all relevant records, documents and equipments etc. for the purpose of verifying any details.

7.8 An approved testing laboratory shall not use its approval in such a manner as to bring EIC / Government of India into disrepute/dispute and shall not make any statement relevant to its approval, which EIC may consider to be misleading.

7.8.1 The approved laboratory may make a public claim regarding its approval. However, such claim shall be strictly based on the scope of its approval. It shall discontinue claiming EIC approval and withdraw all promotional and advertising material upon expiry / suspension or cancellation of its approval. Further, the approved laboratory shall not issue any export worthy certificate/Health Certificate for the commodities under the purview of EIC

7.8.2 The approved laboratory enjoying the privilege of approval under this scheme shall furnish either a performance bank guarantee of ` One Lakh or the payment of ` One Lakh (refundable) by way of Demand Draft/ Pay order drawn in favor of Export Inspection Agency- DELHI/ MUMBAI/ KOLKATA/ CHENNAI/ KOCHI, to the concerned regional EIA, before grant of approval,. This guarantee/ payment made can be invoked only with the due approval of the Director (I&Q/C), EIC, by his nominated official for breach of any of the undertakings given.

7.8.3 The laboratory shall be issued a show cause for time bound reply and reasons furnished thereof shall be adjudged by the nominated official of EIC before any action for invocation of its bank guarantee/ payment is initiated.

7.9 A laboratory may relinquish approval by giving three months notice in writing to EIC. It shall however either complete testing of all samples pending with it or return the samples pending along with the test requests. It shall not be entitled to any refund of approval fee.

7.10 EIC may, at its discretion cancel or suspend approval, reduce its scope or direct reassessment due to changes in personnel/equipment, break-down of equipment, and/or if a complaint or any other information is received which indicates that the technical competence and integrity/ confidentiality of the laboratory is not satisfactory.

7.11 The laboratory shall not use the approval certificate/letter after its validity period is over or in case of cancellation of approval.

7.12 The approved laboratory shall submit periodic statements to EIC containing the particulars, as per the schedule given below:

(i) Number of samples declared failing/non compliant	Monthly for the entire month by first working day of the next month
(ii) Number of samples pending testing	- do -
(iii) Delay in issuance of test reports, if any & the reason thereof	- do -
(iv) Number of samples received for testing	once in six months for the period between 1st April to 30th September and 1st October to 31st March of every financial year
(v) Number of samples tested	- do -
(vi) Number of samples declared pass/compliant	- do -
(vii) Number of samples failed specifying the parameter/test and other details	- do -

Whenever there is failure of sample showing test result not conforming to the specification, a report with complete details as per Annex 9 shall be sent to EIC with a copy to regional EIAs and the customer immediately. The periodic statements of the testing shall be submitted as per Annex 9A.

7.13 The approved laboratory shall not handle any sample of the client for laboratory testing when the laboratory fails to demonstrate satisfactorily to EIC that its direct/indirect trade association has no consequence/ bearance on its test results.

8. EXPIRY/ SUSPENSION AND CANCELLATION OF APPROVAL

8.1 The approval of laboratories shall automatically expire at the end of their validity, unless renewal is sought timely by the laboratories concerned along with the prescribed fee.

8.2 The approval of laboratories shall also expire if the renewal is not agreed to by EIC without giving any reason.

8.3 The approval of laboratories may also be suspended / cancelled any time during the approval period for any and or the reasons given below:

8.3.1 If EIC feels that no useful purpose is being served by the continuation of the approval of the laboratory;

8.3.2 If the laboratory is found violating the terms and conditions of approval; and

8.3.3 If the laboratory is unable to maintain the Criteria for Approval.

8.4 EIC shall issue a show cause notice in case it intends to suspend / cancel approval of a laboratory, as per clause 8.3.2 and 8.3.3 after due investigation, if required. The concerned laboratory shall be given an opportunity to explain its view point before any action is taken against the laboratory.

8.5 The laboratory may apply a fresh not earlier than one year from the date of cancellation / withdrawal / non-renewal of approval.

8.6 The laboratory shall return the pending sample(s) in appropriate conditions to the customer for onward transmission to another approved laboratory and undertake to retain records as per requirements of Clause 7.5.13 on cancellation / withdrawal / non-renewal / expiry of approval.

8.7 If the location change/acquisition/merger/transfer/takeover of the approved laboratory happens the approved laboratory shall inform EIC immediately and the laboratory shall be reassessed by the EIC.

9. SCHEDULE OF FEE

9.1 The following shall be the fee payable by applicant / approved laboratory.

a) Application Fee: (Approval / renewal of approval for each scope) for each as specified under Clause No. 3.1.1	5000/- per scope
b) Adequacy / Desk audit of Quality Manual for initial scrutiny or verification of revised issue of Quality Manual	2500/- per adequacy audit
c) Assessment Fee / Surveillance Fee / Special visit charges	5000/-per man-day plus expenses for travel and stay of assessors at actual
d) Approval Fee (to be paid in advance on consideration for approval)	50000/-
e) Enhancement of Scope (for each as specified under Clause No. 3.1.1) f) Additional Authorized Signatory/sampler (if applied separately)	5000/- per scope 5000/-
g) Change in Name of Laboratory	2000/- (copy of legal document reflecting the change of name shall be submitted)
h) Application / Request for listing the name of laboratory by importing country (e.g. Japan for Marine products)	5000/-

9.2 The laboratory shall make these payments in the form of Demand Draft / Pay Order drawn in favor of the 'EXPORT INSPECTION AGENCY-DELHI / MUMBAI / KOLKATA / CHENNAI / KOCHI, depending upon the location of the Laboratory.

9.3 The laboratory shall pay service tax applicable from time to time for the fees specified in clause 9

10. RELAXATION IN CRITERIA

10.1 In case of need for specialized laboratory, the compliance to Criteria for Approval as per Clause No. 2 may be relaxed at the discretion of Director, EIC and laboratory may be approved based on technical competence only.

10.2 Anything not covered under this approval scheme shall be dealt on case to case basis under the provisions of EIC rules & regulations in force.

APPLICATION FOR APPROVAL / RENEWAL OF APPROVAL

(Under the EIC Laboratory Approval Scheme, 2010)

A)	General Information	
1.	Name of the Applicant Laboratory /	
2.	Address of location for which approval is sought?	
3.	Phone, Fax and e- mail	
4.	Name and Designation of Chief Executive and contact details	
5.	Name of the Laboratory representative for contacts and contact details	
6.	Address of Head office (if different from 2.)	
6.1	Phone, Fax and e- mail	
7.	Legal status and date of establishment (Please give registration number and name of the authority who granted the registration with all documentary proof).	
8.	Is the laboratory operating on a commercial basis or providing testing services free of cost?	
B)	Technical information	
9.	Scope for approval or Approved scope by EIC. Specify as per Clause No. 3.1.1 for Non-EU countries / EU countries including EU / (Name of country) (Please attach as Annex 1 and Annex 2 in the format)	
10.	Date of validity of Approval (in case of renewal of approval)	
11.	Has the laboratory implemented Quality Management System (QMS) as per guidelines of ISO/IEC 17025: latest version?	
12.	In case of application for renewal or enhancement , scope for approval, Specify as per Clause No. 3.1.1 for Non-EU countries / EU countries including EU / (Name of country) (Please attach as Annex 1 and Annex 2 in the format)	
13.	Is the QMS covers the scope for approval as required by EIC	
14.	Whether accredited by NABL as per ISO/IEC 17025?	
14.1	If yes, is the scope of accreditation covers the scope applied for EIC approval? (please attach certificate and scope of accreditation along with a separate comparison sheet)	
15.	Whether major changes in Quality Manual carried out? If yes, enclose the copy of same along with applicable fee for adequacy audit (applicable for renewal of approval / enhancement of scope / verification of NC closure)	
16.	List of equipment with laboratory (Please attach as Annex 3 in the format given)	
17.	List of Standard/ Certified reference materials (SRM/CRM) available for use: (Please attach as Annex 4 in the format given)	
18.	Internal Audit and Management Review:	
18.1	Date of last Internal Audit, its findings and corrective action taken	
18.2	Whether all requirements of ISO/ IEC 17025: 2005 covering all activities of laboratory have been audited at least once in last one year	
18.3	Date of last Management review	
19.	Manpower details	
19.1	Name and designation of the person responsible for technical operation/ Technical Manager(s).	
19.2	Name and designation of the person responsible for Quality Management Systems/ Quality Manager.	
19.3	No. of personnel	
19.3.1	Senior management	
19.3.2	Testing personnel	
19.3.3	Details of professionally qualified staff with qualification (Enclose details as per Annex 5)	
19.3.4	Authorized signatories for issuance of test reports (enclose details as per Annex 6)	
19.3.5	Authorized samplers (enclose details as per Annex 6)	

20.	Details of subcontracting, if any	
21.	Proficiency Testing: Participation in International PT programme: (Please attach as Annex 7 in the format given)	
21.2	Annual Proficiency testing plan	
22.	Total Turnover (in terms of Test reports issued for last 3 years as per the scope)	
22.1	For domestic purposes	
22.2	For exports, if any. Give details.	
23.	Name of exporters for whom products tested in the areas applied for over last one year.	
24.	Any complaints/disputes in last three years pertaining to laboratory testing activities (Please attach as Annex 8 in the format given)	
C)	DETAILS OF FEE:	
25.	Fee in the form of Demand Draft / Pay Order payable to Export Inspection Agency – Bombay / Calcutta / Cochin / Delhi / Chennai (As applicable depending upon location of the laboratory)	
25.1	Application Fee (Approval / Renewal of Approval) Rs.5000/- for each scope	
25.2	Adequacy Audit Fee `2500/-per audit	

D). DECLARATION BY THE LABORATORY:

I / We declare that

a) We have read & understood the terms and conditions of the EIC Laboratory Approval Scheme and are willing to abide by them

b) We agree to comply fully with ISO/IEC 17025: 2005 for the approval of testing laboratory.

c) We agree to comply with approval procedures, pay all costs for assessment, verification visit (if any), surveillance and reassessment irrespective of the result.

d) We agree to co-operate with the assessment team appointed by EIC for examination of all relevant documents by them and their visits to those parts of the laboratory that are part of the scope of approval.

e) We satisfy all national, regional and local regulatory requirements for operating a laboratory.

f) In case of breach of any of the terms and conditions of EIC Laboratory approval scheme, the decision to invoke action/ Bank guarantee/ payment made, by the Director (I&Q/C) EIC, is final and binding on us.

g) All information provided in this application is true to the best of our knowledge.

Date: Signature of Authorized Signatory
Place: Name
Designation
Stamp

Instructions:

1. Application with fee and quality manual (two copies) is to be submitted to the concerned EIA as per address given below:

(a) Export Inspection Agency-Mumbai, Aman Chambers-4th Floor, 113, Maharshi Karve Road, Mumbai-400 004
Phone: 91-22-23630311/23630312 Fax: 91-22-2368 3927; E mail: eia-mumbai@eicinida.gov.in

(b) Export Inspection Agency-Kolkata, World Trade Centre, 14/1B, Ezra Street, Kolkata-700 001
Phone: 91-33-22355004/22352651/22352652 Fax: 91-33-22354562; E mail: eia-kolkata@eicinida.gov.in

(c) Export Inspection Agency-Kochi, 27/1767A, Shipyard Quarters Road, Panampilly Nagar (South), Kochi-682 036
Phone: 91-484-2314645/2316946/ 2316949 Fax: 91-484-2316948; E mail: eia-kochi@eicinida.gov.in

(d) Export Inspection Agency-Delhi, Thakkar Bapa Smarak Sadan, 2nd Floor, Dr. Ambedakar Marg, (Link Road), (Behind Jhandewalan Metro Station), New Delhi – 110 055
Phone: 91-11-23626320/21/22/23/24/25/26/27 Fax: 91-11-23626328; E mail: eia-delhi@eicinida.gov.in

(e) Export Inspection Agency-Chennai, 6th Floor, CDMA Tower – II, No. 1, Gandhi Irwin Road, Egmore, Chennai-600 008
Phone: 91-44-28552841/28552842 Fax: 91-44-28552840; E mail: eia-chennai@eicinida.gov.in

2. One copy of application complete in all respect, along with laboratory quality manual (without fee) is to be submitted to:

The Director (I & QC), Export Inspection Council, (Ministry of Commerce & Industry, Government of India), 3rd Floor, ND YMCA Cultural Centre Building, 1, Jai Singh Road, New Delhi- 110001.
Tel. No.011-23365540, 23748188, 23748189m Fax: 011-23748024; E-mail: eic@eicindia.gov.in

Annex-1

FORMAT FOR SCOPE OF APPROVAL

(Name of the laboratory, address & contact details)

(SCOPE OF APPROVAL)

For export to Non-EU countries / EU countries including EU / (Country)

(Item 9 and 12 of Application)

Category / Group	Specific Tests or Parameter (Analyte)	Products, Materials or Items (Matrix)

(Page x of y)

Annex 2

FORMAT FOR VALIDATION DATA

(*to support scope of approval*)

(Name of the laboratory, address & contact details)

(SCOPE OF APPROVAL)

For export to Non-EU countries / EU countries including EU / (Country)

(Item 9 and 12 of Application)

Sl. No.	Category or Group of Substances (e.g. A1 to B3f for residues and contaminants as per EU, or Category for other tan residue and contaminants)	Specific tests (Parameter / Analyte), i.e. actual substance or test parameter like metabolites in drugs, as applicable for test	Name of Substance / Type (name of the parent compound / substance, as applicable)	Name of Group / Therapeutic Classification (name of group classification like antibiotic residues, pesticide residues, chemical elements, physical characteristics,	Target product / material / item / tissue (Matrix) like tissue, fat, kidney, offal, oil, raw milk, raw honey, etc.,	Product category / Animal species / plants products like bovine, poultry, fruits, fish, crustaceans, etc.	*MRPL / MRL / ML	Specification, standard/test method against which product tested like AOAC, BIS, in-house, etc.	**Validation protocol in place. Specify & state which criteria like 2002/657/EC, IUPAC, CODEX, etc.	Analytical Method like ELISA, Delvoset, Four Plate, LC-MS-MS, etc.Specify technique	Decision limit (LOD / CCα), as applicable, Limit of determination CCβ in case of screening tests for residues & contaminants	Detection capability (LOQ / CCβ), as applicable	Recovery / Accuracy at Detection capability, (as applicable)	Measurement of Uncertainty (±) / Claimed accuracy, (as applicable)	Range of testing (wherever applicable)	NABL Accreditation status
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17

(Page x of y)

** Minimum Required Performance Limits (MRPLs) for prohibited veterinary drugs, Maximum Residue Limits (MRLs) for veterinary medicines, Maximum Residue Levels (MRLs) for pesticides etc. and Maximum Limits (MLs) for contaminants like heavy metals etc.*

*** (Specify EU legislation) / IUPAC / CODEX / Other Equivalent method. Specify & state which criteria*

Note: - Separate Annexure to be enclosed for each scope. Approval may be limited to the scope of interest of EIC/EIA based on its need to use laboratory facilities.

Annex 3

FORMAT FOR LIST OF EQUIPMENT

(Name of the laboratory, address & contact details)

(For export to Non-EU countries / EU countries including EU / (Country)

(Item16 of Application)

S.No.	Name of equipment and date	Model/Type/year of make	Receipt date & date placed in service	Purpose / scope of the equipment	Range and accuracy	Maintenance (In house/ outside)	Date of last calibration	Due date of next calibration	Traceability	Calibrated by whom (Incase in-house, whether personnel trained/ authorized for the purpose)

(Page x of y)

Annex 4

FORMAT FOR LIST OF REFERENCE MATERIALS AVAILABLE

(Name of the laboratory, address & contact details)

(For export to Non-EU countries / EU countries including EU / (Country)

(Item 17 of Application)

S.No	Name of reference Material/strain/ culture/CRM	Source	Date of expiry/validity	Traceability

(Page x of y)

Annex 5

FORMAT FOR MANPOWER AVAILABLE

Name of the laboratory, address & contact details)

(For export to Non-EU countries / EU countries including EU / (Country)

(Item 19.3.3 of Application)

Sr. No.	Name of the official with designation (Date of Joining the Laboratory)	Academic and professional qualification	Relevant experience including training	Area of specialization in testing

(Page x of y)

Annex 6

FORMAT FOR AUTHORISED SAMPLER/SIGNATORIES FOR ISSUE OF TEST CERTIFICATES AND REPORTS

(Name of the laboratory, address & contact details)

(For export to Non-EU countries / EU countries including EU / (Country)

(Item 19.3.4 and 19.3.5 of Application)

Sl. No.	Laboratory/ Department/ Section	Name & Designation of Sampler/Signatory	Qualification with Specialization	Experience in years related to present work	Relevant Training	Authorized for which specific area of sampling/testing	Location of sampling (in case of samplers)	Specimen Signature

(Page x of y)

Annex 7

FORMAT FOR PROFICIENCY TESTING

(Name of the laboratory, address & contact details)

(For export to Non-EU countries / EU countries including EU / (Country)

(Item 21.1 of Application)

Sr. No.	Product / Matrix	Details of Test(s)	Date of Testing	Nodal Laboratory (Accreditation body / Country)	Performance in terms of Z score	Corrective action taken

(Page x of y)

Annex 7 A

FORMAT FOR ANNUAL PROPOSED PLAN FOR PROFICIENCY TESTING

(Name of the laboratory, address & contact details)

(For export to Non-EU countries / EU countries including EU / (Country)

(Item 21.2 of Application)

Sl. No.	Analytes	Matrix	Proficiency test (Program ID/Number/Round Robin No)	Start date of Proficiency Test

(Page x of y)

Annex 8

FORMAT FOR COMPLAINTS/DISPUTES IN LAST THREE YEARS

(Name of the laboratory, address & contact details)

(For export to Non-EU countries / EU countries including EU / (Country)

(Item 24 of Application)

Sr. No.	Name of the client	Nature of complaint/dispute	Whether resolved in favor of Laboratory/Client	Brief of the action taken for resolving the complaint	Latest status (if not resolved yet)

(Page x of y)

Annex 9

FORMAT FOR COMMUNICATION OF FAILURES OBSERVED DURING TESTING

(Name of the laboratory, address & contact details)

(For export to Non-EU countries / EU countries including EU / (Country) - separate sheet for each country

(Clause 7.12 of EIC Laboratory Approval Scheme)

S. No.	Sample Code /Sample No.	Date of receipt	Date of completion of test	Name of the exporter and approval number	Name of Importing country	Type of product	Test Certificate No.	Invoice No. /Purchase order No. (if sample covered under pre export testing)*	Production code	Reasons for analysis if other than pre export*	Parameters tested	Reported Results (concentrations in µ/ kg inclusive of correction factor/recovery factor) [failures to be reported in bold]	Method of Analysis	Results communicated to EIA

* where ever applicable

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Annex 9A

FORMAT FOR SUBMITTING PERIODIC STATEMENTS DETAILS OF SAMPLES TESTED AND RESULTS

(SEPARTE SHEET FOR RESIDUES AND OTHER PARAMETERS AS PER SCOPE)

(Name of the laboratory, address & contact details)

(For export to Non-EU countries / EU countries including EU / (Country), - separate sheet for each country

(Clause 7.12 of EIC Laboratory Approval Scheme)

Period of statement	Total number of samples	Analyte group as listed in Annex I to Council Directive 96/23/EC	Substance	Analyte (and number of non-compliants)	Matrix / Species	method used (Screening /Confirmatory)	Validation data				Number of samples in the RMP/NRCP for the laboratory Other residue samples taken outside the RMP/NRCP (e.g. private samples) should be listed in brackets [ ]			No of non-compliant samples under RMP [non-RMP]	Concentration found (µg/kg) in case of non-compliant results	Details of Intimation to EIAs / MPEDA, in case of non-compliant results
							LOD (µg/kg)	LOQ (µg/kg)	CC alpha (µg/kg)	CC beta (µg/kg)	Foreseen to be tested	Received in lab	Actually tested			

LOD–Limit of Detection; LOQ–Limit of Quantification; CCalpha-decision limit; CCbeta–detection capability (see pt 1.1., Annex to Commission Decision 2002/657/EC)

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Annex 10

'Specimen' FORMAT OF TEST REPORT

(Name of the laboratory, address & contact details)

(For export to Non-EU countries / EU countries including EU / (Country)

(Clause 7.5.6 of EIC Laboratory Approval Scheme)

(On letter head of Laboratory with complete details of location where tests carried out)

Test Report No.: (to be mentioned on every page for identification purpose with date)

Name & address of Processor/Exporter & Approval No:

Invoice order/purchase order no.:

Date of sampling:
Date of sample receipt:
Condition of Sample (at the time of receipt):

Details of sample:
Type & Nature of Product:
Type of Packing
No. of M/Cs (serial no. if any)
Code covered in the consignment.
Grade covered in the consignment (if applicable)
Registration number of Aquaculture pond/Farm(if applicable):
No. of Cases selected for sampling:
Sampled Cases Seal No. (if any):
Sampled by (by authorized sampler for certification purpose and not by the exporter or processor):
Consignment intended for export to (Name of country) (if applicable):

Result of Analysis

Date of start of analysis: Date of completion of analysis:

Test results

Sl. No.	Parameter tested for	*Unit of measurement	**Results with corrected recovery along with level of recovery	Limit of determination / quantification: LOQ / CCα / CCβ, as applicable (e.g. LOQ in case of pesticides, CCβ,for Screening test, CCα for drugs & contaminants, etc)	LOD, as applicable	***MRL/ MRPL / ML/ Limits	Analytical Method (e.g. ELISA, Delvoset, Four Plate, TLC, HPLC, LC-MS-MS, etc.)	Specification, standard/test method against which product tested like AOAC, BIS, in-house, etc.	Validation protocol (e.g. specify like 2002/657/EC, IUPAC, CODEX, etc.

* Specify the unit of measurement as µg/Kg, mg/Kg, cfu /ml etc. to avoid any confusion and use the same unit of measurement in all parameters.

** Results reported must be inclusive of recovery correction/correction factor. Result may be expressed as x ± U in case of reporting substances; wherein x is result and U is expanded uncertainty, as per method validation

*** *Minimum Required Performance Limits (MRPLs) for prohibited veterinary drugs, Maximum Residue Limits (MRLs) for veterinary medicines, Maximum Residue Levels (MRLs) for pesticides and Maximum Limits (MLs) for contaminants like heavy metals, etc.*

The format shall also include the additional information stipulated under specific requirements.

Remarks, if any

Annex 11

'Specimen' FORMAT FOR PERFORMANCE BANK GUARANTEE

(Clause 7.8.2 of EIC Laboratory Approval Scheme, on the non-judicial bond of minimum `100/-)

Guarantee No. _____ dated _____

To

(addressed to the Export Inspection Agency concerned)

Performance Bank guarantee in favor of the Export Inspection Agency - _____, (Ministry of Commerce & Industry, Government of India), (Address of Agency), (hereinafter called the said "EIA").

Whereas _____ (name & address of the laboratory) (hereinafter called the said "Laboratory") has been directed to furnish security of ` 1,00,000/-(Rupees one lakh only) (hereinafter called the said "Guarantee")in connection with approval of the laboratory by Export Inspection Council, _____, (Ministry of Commerce & Industry, Government of India), New Delhi, (hereinafter called the said "EIC") under the EIC Laboratory Approval Scheme for the purpose of certification of commodities or monitoring of establishments for export by EIA.

We _____ (Name and address of bank) (hereinafter called the said "Guarantor") in consideration thereof, do hereby undertake to bind ourselves to pay the _____(name and address of the EIA concerned) any amount subject to maximum of the said Guarantee on demand from the said EIC and also to keep Government of India indemnified to the extent of the said amount against any loss or damage caused to or suffered would be caused to or suffered by the Government by reason of any breach by the said Laboratory, of any of the terms or conditions contained in the EIC Laboratory Approval Scheme.

We the said Guarantor further agrees that the guarantee herein contained shall remain in full force and effect for two and half years from the date of issue of this guarantee.

We the said Guarantor finally undertake not to revoke this guarantee during the currency without the previous consent of the said EIC in writing.

We, the said Guarantor, further agree that the said Guarantee herein contained shall remain in full force and effect during the period that would be taken for the performance of the said Laboratory and that it shall continue to be enforceable till all the dues of the Government under or by virtue of the said Guarantee have been fully paid under its claims stratified or discharge or till EIC certifies that the terms and conditions of the said Guarantee have been fully and properly carried out by the said Laboratory and accordingly discharge this Guarantee.

Notwithstanding any thing mentioned herein above our liability under this guarantee is limited to Rs.1,00,000/- (Rupees one lakh only) and this guarantee will be valid for a period of two and half years from the date of issue i.e up to _____ (date of expiry). If a written claim or demand in writings is not served on us on or before _____ (date of expiry) (which includes claim period of six months) we shall be relieved and discharged from all the liability under this guarantee.

We, the said Guarantor, further agree with the government that the government shall have be fullest liberty without consent or/and without affecting in any manner our obligation hereunder to vary any of the terms and conditions of the said Guarantee or to extend time of performance by the said Laboratory from time to time to postpone for any time or from time to time any of the powers exercisable by the Government against that the said Laboratory and to forbear or enforce any of the terms and conditions relating to said Guarantee and we shall not be relieved from our liability by reason of any such variation or extension being granted to the said Laboratory or for any forbearance, act or omission on the part of the Government or any indulgence by the Government to the said Laboratory or by any such matter or thing whatsoever which under the law relating to sureties would, but for this provision have effect of so relieving us.

This Guarantee will not be discharged due to the change in the constitution of the Bank or the Laboratory

This guarantee is non-transferable.

IN WITNESS WHEREOF we _____ (Name and address of bank) hereunto affix our hand and seal on the _____ (date of issue).

Dated the _____ day of _____

For _____ (Name of the bank)

Authorized Signatory

(Page x of y)

Appendix 1

Glossary

1. Accuracy: Closeness of agreement between a test result and the true, or the accepted reference value. When applied to a set of test results, it involves a combination of random error (estimated as precision) and a common systematic error (trueness or bias) (ISO 5725-1).
2. Analyte: The chemical species of which the concentration (or mass) is to be determined. For the purposes of these guidelines: a Veterinary medicinal Product/ pesticide or a metabolite, breakdown product or derivative/ element etc.
3. Analytical sample: Sometimes referred to as a "test portion", or "test sample". A sample prepared from the laboratory sample and from which "test portions" or "analytical portions" are taken (ISO 78/2, 1982). See also Directive 2002/63/EC.
4. Analytical portion: Sometimes referred to as "test portion". The quantity of material (usually homogenized) taken from the analytical sample, and on which the analysis/test is performed (ISO 78/2, 1982,). See also Directive 2002/63/EC.
5. AQC: Analytical quality control. Measurement and recording requirements intended to demonstrate the performance of the analytical method in routine practice. The data supplement those generated at method validation. AQC data may be used to validate the extension of methods to new analytes, new matrices and new levels. Synonymous with the terms internal quality control (IQC) and performance verification. Concurrent AQC data are those generated during analysis of the batch in which the particular sample is included.
6. Batch (analysis): For extraction, clean-up and similar processes, a batch is a series of samples dealt with by an analyst (or team of analysts) in parallel, usually in one day, and should incorporate at least one recovery determination. For the determination system, a batch is a series undertaken without a significant time break and which incorporates all relevant calibration determinations (also referred to as an "analysis sequence", a "chromatography sequence", etc.). With formats such as 96-well plates, a plate or group of plates may form a batch. A determination batch may incorporate more than one extraction batch. This document does not refer to "batch" in the IUPAC or Codex sense, which relates to manufacturing or agricultural production batches.
7. Bias: Also referred to as "accuracy" .The difference between the mean measured value and the true value, i.e. the total systematic error.
8. Blank:
   (i) Material (a sample, or a portion or extract of a sample) known not to contain detectable levels of the analyte(s) sought. Also known as a matrix blank
   (ii) A complete analysis conducted using the solvents and reagents only; in the absence of any sample (water may be substituted for the sample, to make the analysis realistic). Also known as a reagent blank or procedural blank
9. Bracketing calibration: Organization of a batch of determinations such that the detection system is calibrated immediately before and after the analysis of the samples, for example, calibrant 1, calibrant 2, sample 1.....sample *n*, calibrant 1, calibrant 2.
10. Calibration: Determination of the relationship between the observed signal (response produced by the detection system) from the target analyte in the sample extract and known quantities of the analyte prepared as standard solutions. In the present document, calibration does not refer to calibration of weighing and volumetric equipment, mass calibration of mass spectrometers, and so on.
11. Calibration standard: A solution (or other dilution) of the analyte (and internal standard, if used) used for calibration of the determination system. May be prepared from a working standard and may be matrix-matched.
12. Certified reference material: (CRM)-See reference material
13. Comminuting: The process of reducing a solid sample to small fragments
14. Confirmation: The process of generating sufficient evidence to ensure that a result for a specific sample is valid. Analytes must be identified correctly in order to be quantified. The identity and quantity of residues should be confirmed. It is impossible to confirm the complete absence of residues. Adoption of a "reporting limit" at the LCL avoids the unjustifiably high cost of confirming the presence, or absence, of residues at unnecessarily low levels. The nature and extent of confirmation required for a positive result depends upon importance of the result and the frequency with which similar residues are found. Assays based on colorimetric, ELISA, TLC or ECD tend to demand confirmation, because of their lack of specificity. Mass spectrometric techniques are often the most practical and least equivocal approach to confirmation. AQC procedures for confirmation should be rigorous.
15. Contamination: Unintended introduction of the analyte into a sample, extract, internal standard solution etc., by any route and at any stage during sampling or analysis.
16. Determination/detection system: any system used to detect and determine the concentration or mass of the analyte. For example, GC-FPD, LCMS/ MS, LC with post-column dramatization, ELISA, TLC with bioassay.
17. False negative: A result wrongly indicating that the analyte concentration does not exceed a specified value.
18. False positive: A result wrongly indicating that the analyte concentration exceeds a specified value.
19. Interference: A positive or negative response produced by a compound(s) other than the analyte, contributing to the response measured for the analyte, or making integration of the analyte response less certain or accurate. Interference is also loosely referred to as "chemical noise" (as distinct from electronic noise, "flame noise", etc.). Matrix effects are a subtle form of interference. Some forms of interference may be minimized by greater selectivity of the detector. If interference cannot be eliminated or compensated, its effects may be acceptable if there is no significant impact on accuracy (bias) or precision.
20. Internal quality control: (IQC)-see AQC
21. Internal reproducibility: see reproducibility
22. Internal standard: A chemical added, in known quantity, at a specified stage in analysis to facilitate determination of the identity and/or quantity of the analyte. The analyte concentration is deduced from its response relative to that produced by the internal standard. The internal standard should have similar physico-chemical characteristics to those of the analyte. Isotopic ally labeled analytes form ideal internal standards, where available. For all other types of internal standard, the relative responses must be calibrated for each batch of analyses. Standard addition could be regarded as a special form of ideal internal standardization.
23. Laboratory sample: The sample sent to and received by the laboratory.

24. LCL: Lowest calibrated level. The lowest concentration (or mass) of analyte with which the determination system is successfully calibrated, throughout the analysis batch. See also "reporting limit".
25. Level: In this document, refers to concentration (e.g. mg/kg, µg/ml) or quantity (e.g. ng, pg).
26. Limit of detection: The minimum concentration or mass of the analyte that can be detected with acceptable certainty, though not quantifiable with acceptable precision. Various definitions are used but, for convenience, it is often the quantity of analyte that generates a response 3 times greater than the noise level of the detection system. Definitions based on standard deviation of blank values can be difficult to apply in chromatographic analysis. With most methods and determination systems, the limit of detection has no fixed value. The term is usually restricted to the response of the detection system but, in principle, it should be applied to the complete analytical method.
27. LOD: Limit of determination (see LOQ below).
28. LOQ: Limit of quantitation (quantification) (also known as limit of determination, LOD). The minimum concentration or mass of the analyte that can be quantified with acceptable accuracy and precision. Should apply to the complete analytical method. Variously defined but must be a value greater than the limit of detection. With most methods and determination systems, the LOQ has no fixed value. LOQ is preferable to LOD because it avoids possible confusion with "limit of detection". However, in legislation MRLs that are set at the limit of quantification/ determination are referred to as "LOD MRLs", not "LOQ MRLs".
29. Matrix blank: See blank.
30. Matrix effect: An influence of one or more undetected components from the sample on the measurement of the analyte concentration or mass. The response of some determination systems (e.g. GC, LC-MS, ELISA) to certain analytes may be affected by the presence of co-extractives from the sample (matrix). Partition in headspace analyses and SPME is also frequently affected by components present in the samples. These matrix effects derive from various physical and chemical processes and may be difficult or impossible to eliminate. They may be observed as increased or decreased detector responses, compared with those produced by simple solvent solutions of the analyte. The presence, or absence, of such effects may be demonstrated by comparing the response produced from the analyte in a simple solvent solution with that obtained from the same quantity of analyte in the presence of the sample or sample extract. Matrix effects tend to be variable and unpredictable in occurrence, although certain techniques and systems (e.g. HPLC-UV, isotope dilution) are inherently less likely to be influenced. More reliable calibration may be obtained with matrix-matched calibration when it is necessary to use techniques or equipment that is potentially prone to the effects.
31. Matrix-matched calibration: may compensate for matrix effects but does not eliminate the underlying cause. Because the underlying cause remains, the intensity of effect may differ from one matrix or sample to another, and also according to the "concentration" of matrix. Isotope dilution or standard addition may be used where matrix effects are sample dependent. Matrix-matched calibration intended to compensate for matrix effects and acceptable interference, if present. The matrix blank (see "blank") should be prepared as for analysis of samples. In practice, the pesticide is added to a blank extract (or a blank sample for headspace analysis) of a matrix similar to that analyzed. The blank matrix used may differ from that of the samples if it is shown to compensate for the effects. However, for determination of residues approaching or exceeding the MRL, the same matrix (or standard addition) should be used.
32. Method: A sequence of analytical procedures, from receipt of a sample through to the calculation of results.
33. Method development: The process of design and preliminary assessment of the characteristics of a method, including ruggedness.
34. Method validation: The process of characterizing the performance to be expected of a method in terms of its scope, specificity, accuracy (bias), sensitivity, repeatability and reproducibility. Some information on all characteristics, except reproducibility, should be established prior to the analysis of samples, whereas data on reproducibility and extensions of scope may be produced from AQC, during the analysis of samples. Wherever possible, the assessment of accuracy (bias) should involve analysis of certified reference materials, participation in proficiency tests, or other interlaboratory comparisons.
35. MRL: Maximum residue level. In the Directives that list MRLs for pesticide/commodity combinations, an asterisk indicates that the MRL* is set at or about the LOQ.
36. MS/MS: Tandem mass spectrometry, here taken to include MSn. An MS procedure in which ions of a selected mass to charge ratio (*m/z*) from the primary ionization process are isolated, fragmented usually by collision, and the product ions separated (MS/MS or MS2). In ion-trap mass spectrometers, the procedure may be carried out repetitively on a sequence of product ions (MSn), although this is not usually practical with low-level residues.
37. Performance verification: see analytical quality control (AQC)
38. Procedural blank: See blank.
39. Procedural standard: A calibration standard of a derivative, degradation product, etc., of the analyte which is generated from a precursor, as part of the analytical method. Procedural standards are often employed in cases where the derivative, degradation product, etc., is not available as a "pure" standard. The term is not applied to transient species generated in the detector, e.g. fragments in mass spectrometry. However, it is applicable to the products of post-column reactions generated prior to detection in HPLC.
40. Reagent blank: See blank.
41. Recovery: (of analyte through an analytical method) the proportion of analyte remaining at the point of the Final determination, following its addition (usually to a blank sample) immediately prior to extraction. Usually expressed as a percentage. Routine recovery refers to the determination(s) performed with the analysis of each batch of samples.
42. Reference material: Material characterized with respect to its notionally homogeneous content of analyte. Certified reference materials (CRMs) are normally characterized in a number of laboratories, for concentration and homogeneity of distribution of analyte. In-house reference materials are characterized in the owner's laboratory and the measurement accuracy (bias) may be unknown.
43. "Pure": Standard A relatively pure sample of the solid/liquid analyte (or internal standard), of known purity. Usually >90% purity, except for certain technical pesticides.
44. Repeatability: The precision (standard deviation) of measurement of an analyte (usually obtained from recovery or analysis of reference materials), obtained using the same method on the same sample(s) in a single laboratory over a short period of time, during which differences in the materials and equipment

used and/or the analysts involved will not occur. May also be defined as the value below which the absolute difference between two single test results on identical material, obtained under the above conditions, may be Expected to lie with a specified probability (e.g. 95%).

45. Reporting limit or reporting level: The lowest level at which residues will be reported as absolute numbers. It may represent the practical LOQ, or it may be above that level to limit costs. It must not be lower than the corresponding LCL. For EU monitoring purposes where samples for surveys are analyzed over a 12-month period, the same reporting limit should be achievable throughout the whole year.
46. Representative Analyte: An analyte used to assess probable analytical performance in respect of other analytes notionally sought in the analysis. Acceptable data for a representative analyte are assumed to show that performance is satisfactory for the represented analytes. Representative Analytes must include those for which the worst performance is expected.
47. Representative matrix: Sample material or an extract of a commodity used as an indicator of method performance, or for matrix-matched calibration, in the analysis of broadly similar commodities. Similarity is usually determined according to the content of water, acids, sugars, lipids, secondary plant metabolites, etc., physical characteristics, or matrix effects. Represented analyte Analytes notionally sought but for which no concurrent quality control data are generated. Quality control data obtained from representative analytes are assumed to show whether or not analytical performance is acceptable for these analytes. Relative responses must be reasonably consistent to ensure that calibration is meaningful. Accuracy (recovery bias) is assumed to be no worse than that of the worst-case representative analyte(s). Represented matrix Sample material or an extract of a commodity sufficiently similar to the representative matrix that analytical quality control data (or matrix-matched calibration) generated from the latter can be considered valid for the former. Where potentially unacceptable residues are detected, method performance data should be generated from the represented matrix.
48. Reproducibility: The precision (standard deviation) of measurement of an analyte (usually by means of recovery or analysis of reference materials), obtained using the same method in a number of laboratories, by different analysts, or over a period in which differences in the materials and equipment will occur. Internal reproducibility is that produced in a single laboratory under these conditions. May also be defined as the value below which the absolute difference between two single test results on identical material, obtained under the above conditions, may be expected to lie with a specified probability (e.g. 95%).
49. Response: The absolute or relative signal output from the detector when presented with the analyte.
50. RSD: Relative standard deviation (coefficient of variation).
51. Sample: A general term with many meanings but, in these guidelines, refers to laboratory sample, test sample, test portion, or an aliquot of extract.
52. Sample preparation: The first of two processes which may be required to convert the laboratory sample into the test sample. The removal of parts that are not to be analyzed, if required.
53. Sample processing: The second of two processes which may be required to convert the laboratory sample into a test sample. The process of homogenization, comminuting, mixing, etc., if required.
54. SD: Standard deviation.
55. Selectivity: The ability of the extraction, the clean-up, the derivatisation, the separation system and (especially) the detector to discriminate between the analyte and other compounds. GC-ECD is a selective determination system providing no specificity.
56. S/N: Signal-to-noise ratio.
57. Specificity: The ability of the detector (supported by the selectivity of the extraction, clean-up, derivatisation or separation, if necessary) to provide signals that effectively identify the analyte. GC-MS with EI is a fairly non-selective determination system capable of high specificity. High resolution mass MS and MSn can be both highly selective and highly specific.
58. Spike or spiking: Addition of analyte for the purposes of recovery determination or standard addition.
59. Standard: A general term which may refer to a “pure” standard, stock standard, working standard, or calibration standard.
60. Stock standard: The most concentrated solution (or solid dilution, etc.) of the “pure” standard or internal standard, from which aliquots are used to prepare working standards or calibration standards.
61. Test portion: Also referred to as the “analytical portion”. A representative sub-sample of the test sample, i.e. the portion which is to be analyzed.
62. Test sample: Also referred to as the “analytical sample”. The laboratory sample after removal of any parts that are not to be analyzed, e.g. bones, adhering soil. It may or may not be comminuted and mixed before withdrawing test portions. See also Directive 2002/63/EC.
63. Trueness: The measure of trueness is normally expressed as ‘biases. The closeness of agreement between the average value obtained from a series of test results (i.e. the mean recovery) an accepted reference or true value (ISO 5725-1).
64. Uncertainty: (of measurement) A range around the reported result within which the true value can be expected to lie with a specified probability (confidence level, usually 95%). Uncertainty data should encompass trueness (bias) and reproducibility.
65. Unit: (sample) a single fruit, vegetable, animal, cereal grain, can, etc. For example, an apple, a T-bone steak, a grain of wheat, a can of tomato soup.
66. Validation: sees method validation
67. Violative residue: A residue which exceeds the MRL or is unlawful for any other reason.
68. Working standard: A general term used to describe dilutions produced from the stock standard, which are used, for example, to spike for recovery determination or to prepare calibration standards.

Reference Document for Definition: - METHOD VALIDATION AND QUALITY CONTROL PROCEDURES FOR PESTICIDE RESIDUES ANALYSIS IN FOOD AND FEED, Document No. SANTE 11945/2015.

Appendix 2
Requirements for export to EU

The samples from EIA approved establishments for export to EU shall be tested as per EU legislations for all purpose i.e. for approval by EIA, self-monitoring by establishment, monitoring by EIAs, certification by EIAs.

Commission Decision 2002/657/EC shall be applicable for analysis of residues and contaminants. Commission Decision 2002/657/EC provides rules for the analytical methods to be used in the testing of official samples drawn pursuant to Article 15(1), second sentence, of Directive 96/23/EC, which specifies common criteria for the interpretation of analytical results of official control laboratories for such samples. This Decision shall not apply to substances for which more specific rules have been laid down in other Community legislation like Document No. SANTE 11945/2015, Commission Regulation (EC) No 333/2007 (subsequent amendments), Commission Regulation (EC) No 401/2006(subsequent amendments), Commission Regulation (EC) No 1881/2006, Commission Regulation (EC) No 2073/2005 Commission Regulation (EC) No 589/2014 etc. in line with the Document No. SANCO/0895/2007. The laboratory shall ensure sample integrity in line with requirements of clause 2.6 and 2.9 of the Annex to Commission Decision 98/179/EC. The latest specific rules shall be applicable as per the Community legislations. The latest specific rules can be downloaded from EuRLEX website (**eur-lex**.europa.eu/homepage.html)

Formats:-

1. **Application Format (Word Doc)**
2. **Annexes Formats (Word Doc)**
3. **Assessment Formats (Word Doc)**