



National Accreditation Board for Testing and Calibration Laboratories (NABL)

Procedure for Integrated Assessment & Additional Requirements of Regulatory Body(ies) For Testing Laboratories

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AMENDMENT SHEET

| S. No. | Page No. | Clause No. | Date of Amendment | Amendment | Reasons | Signature QA Team | Signature CEO |
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| 1 | 3 | 1.4 | 21.12.2018 | Inclusion of policy as highlighted | Regulatory Body requirement | -Sd- | -Sd- |
| 2 | 6, 17, 29 | 2.3, 3.31, 6.10 | | 'NABL' is added as NABL/EIC, NABL/APEDA & NABL/FSSAI as highlighted | NABL requirements | | |
| 3 | 5 | 1.23 | 24.06.2019 | Inclusion under general requirements as highlighted | Internal review | -Sd- | -Sd- |
| 3 | 6 | 1.29 | | Inclusion of policy requirements as highlighted | Regulatory Body requirement | | |
| 4 | 6 | 1.30 | | Unidirectional structured testing facility for microbiological analysis | | | |
| 5 | 22 | 3.47 | | Time period for remnants of the sample and reference sample | APEDA additional requirement | | |
| 6 | 34 & 35 | 6.15,6.16, 6.17,6.18 & 6.19 | | As highlighted | FSSAI additional requirements | | |
| 7 | 5 | 1.21 | | 02-May-2020 | Accreditation decision making | | |
| 8 | 6, 9, 13, 21, 22, 25, 28, 30, 32, 36 | 1.27, 1.28, 2.5, 2.8, 2.34, 3.39, 3.42, 3.61, 4.13, 5.17, 5.39, 6.23, | 02-May-2020 | Rearrangement in the text related to the Proposed personnel responsible for authorizing the results | | -Sd- | -Sd- |
| 9 | 6 | 1.31 | | Document name corrected | Aligned with NABL 133 | | |
| 10 | | | | | | | |

CONTENTS

| S. No. | Title | Page No. |
|--------|---|----------|
| 1. | Procedure for Integrated Assessment of Testing Laboratories to obtain Recognition/ Approval from Regulatory Body(ies) | 3 |
| 2. | Additional Requirements of Export Inspection Council (EIC) | 7 |
| 3. | Additional Requirements of Agricultural and Processed Food Products Export Development Authority (APEDA) | 16 |
| 4. | Additional Requirements of Other commodity Board (s) | 26 |
| 5. | Additional Requirements of Indian Oilseeds and Produce Export Promotion Council (IOPEPC) | 28 |
| 6. | Additional requirements for Food Safety and Standard Authority of India (FSSAI) | 32 |

1. Procedure for Integrated Assessment of Testing Laboratories to obtain Recognition / Approval from Regulatory Body (ies)

- 1.1. This document describes specific requirements of assessment that a testing laboratory, seeking recognition / approval from Export Inspection council (EIC), APEDA, FSSAI and other commodity boards, has to meet, in parallel to the accreditation in accordance with of ISO/IEC 17025 by NABL.
- 1.2. The application for integrated Accreditation/Recognition/ Approval scheme for the specific scope shall be taken into consideration only on the scrutiny by NABL and evaluation of competence and compliance through integrated assessment approach by NABL /EIC / APEDA /FSSAI, grant of accreditation by NABL and parallel recognition from concerned regulatory Body (ies) based on the decision of NABL. Relevant information may be downloaded from NABL website (www.nabl-india.org)
- 1.3. Application fee and Assessment charges will be paid to NABL only. All other charges including the Annual Accreditation fee/ Membership fee/ Approval fee as applicable shall be payable to the respective regulatory body (ies).
- 1.4. Laboratory seeking approval from regulatory Body with NABL accreditation through integrated assessment approach, shall apply to NABL Office in the prescribed application form (NABL 154) for all the parameters under applied commodity/ product group as specified by the respective Regulatory Body (ies), along with a copy of its Quality manual/ Management System document, enclosures, and application fee, as prescribed from time to time or through Online National Laboratory Portal. Application with partial scope for product/ matrix shall not be accepted and Approval/ Recognition shall not be granted for the partial scope to the laboratories.
- 1.5. On receipt of the application, laboratory quality manual/ Management System document along with the fee details and other requisite enclosures, NABL shall scrutinize the same for its completeness as well as adequacy of facilities with regard to list of equipments and details of personnel to meet the basic requirements, with the applied scope of interest to NABL, EIC, FSSAI and APEDA for accreditation/ approval.
- 1.6. The application shall be signed by the proprietor, partner or the Chief Executive Officer (CEO) of the Laboratory or any person duly authorized for this 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 apart for the purpose in the application form.
- 1.7. NABL shall process the application for Pre-assessment (which is optional) only after adjudging the suitability of management system by adequacy audit. Lead assessor shall be deputed to

ascertain compliance to the documented Management System, equipment facilities/ infrastructure, concerned Regulatory Body's requirements and importing countries requirements as per international norms.

- 1.8. The assessment team shall be nominated by NABL for on-site witness audit of the laboratory pertaining to verification for the methods of sampling and analysis. The team so nominated shall conduct assessment; follow up assessments, if needed as well as surveillance of the laboratory.
- 1.9. The composition of assessment team would be selected from NABL empanelled assessors/ experts, one or more representative depending upon the scope from concerned regulatory body for testing laboratories; the team shall be independent and impartial conforming to requirements of Accreditation/Recognition/ Approval.
- 1.10. The constitution of assessment team shall be shared with the regulatory body (ies) before approval to avoid potential conflict of interest, if any.
- 1.11. The duration of assessment shall be normally of 5 days depending upon the scope applied.
- 1.12. The assessment team will be based on the scope applied. The assessment team will cover compliance to ISO/IEC 17025, importing countries' requirements, sampling and relevant additional requirement of concerned Regulatory Body (ies).
- 1.13. The integrated assessment conducted shall cover areas of the relevance to the scope of Accreditation /Recognition/ Approval of the laboratory. Assessment shall include verification of test facilities, accommodation and environment, examination of documents and records, in house internationally accepted method validation documents in place, that shall be matrix specific for the scope applied for Accreditation /Recognition/ Approval, 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.
- 1.14. The assessment team shall recommend for Accreditation /Recognition/ Approval of the laboratory for the specific scope in case there is no major or minor NC. The Lead assessor and the corresponding technical assessor shall duly sign on the recommended scope with appropriate recommendation.
- 1.15. In case of any NC, the assessment team may recommend for Accreditation /Recognition/ Approval of the laboratory subject to closure of those said NCs. No NC shall be closed at the time of assessment.
- 1.16. The Laboratory shall take necessary Corrective actions within the stipulated time period of not more than 30 days for the closure of NCs, brought out on record by the assessment team. The

minor NC closure may not require on-site verification; however, closure of major NC may require on-site verification.

- 1.17. The follow up visit, for full or partial assessment, may be carried out on request. Laboratory shall bear the applicable assessment charges and make arrangements of accommodation and travel for the assessment team. During the verification assessment, if the implementation of the corrective action is not found satisfactory, then the laboratory shall not be recommended for Accreditation/ Recognition/Approval and the laboratory shall have to apply afresh after taking satisfactory corrective action.
- 1.18. In case of Non closure of the non conformities within stipulated time period, action shall be taken as per NABL 216.
- 1.19. On receipt of corrective action report, NABL shall review the actions taken along with the objective evidence that the actions taken are sufficient and effective and obtain comments of the team members regarding the closure of Non-Conformities. If the actions taken by the laboratory are insufficient, further information shall be sought.
- 1.20. A representative from the concerned regulatory body(ies) will be the part of the accreditation committee or the assessment report will be shared for comments with the concerned regulatory body (ies) prior to decision making
- 1.21. After approval from the **CEO**, NABL, Accreditation certificate with the scope of accreditation shall be issued by NABL. The scope of recognition/Approval (Annexure B) shall be issued by NABL with name & logo of concerned Regulatory Body (ies)
- 1.22. The Accreditation /Recognition/ Approval granted shall be valid for a period two year from the date of approval and it shall be renewable after two years at a time. Validity of the laboratory Accreditation /Recognition/ Approval shall be specified on the recognition/ Accreditation certificate.
- 1.23. During the validity of approval/ recognition, if the laboratory is found violating the terms and conditions of Approval/ recognition, its approval/ recognition is liable to be suspended and may call for verification visits, for which the laboratory is liable to pay visit charges. If complaint is received from importing country (e.g. RASFF- Rapid Alert System on Food and Feed) against a consignment, 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, or by any other means (regulatory body or any other sources) shall be subjected to audit trail (verification audit-informed in advance/ uninformed depending upon the nature of complaint) by a joint assessment team comprising of officer/ assessors from the concerned regulatory body (ies) or commodity boards and NABL immediately. The expenditure

incurring for the verification assessment shall be borne by the laboratory. Such verification assessment shall also be conducted in case of any other complaints in sampling, testing and test reports or any other reasons as deemed fit.

- 1.24. The accredited/ approved/ recognized laboratory shall be subject to on-site surveillance once in a year by NABL to verify the continued compliance, competency and the implementation of quality system established by the laboratory. The on-site surveillance assessment will be less comprehensive than reassessment.
- 1.25. Annual on-site surveillance shall be carried out by the assessment team nominated by NABL including representative of Concerned Body (ies) and shall be carried out in same manner as in initial assessment.
- 1.26. Any Accredited/Approved laboratory automatically expires at the end of the period of its Accreditation /Recognition/ Approval. The Lab shall apply to NABL at least six months before the date of expiry of its Accreditation /Recognition/ Approval.
- 1.27. The approved laboratory can request NABL for extension of its scope of approval to cover additional product/matrix and parameter/ **personnel responsible for authorizing the results/ sampler.** The Laboratory shall apply in the prescribed format by filling in the relevant information applicable for the extension of the scope along with supporting documents and application.
- 1.28. For qualification & experience requirements for **personnel responsible for authorizing the results,** please refer NABL 165 “NABL’s Policies for Accreditation as per ISO/IEC 17025:2017”.
- 1.29. If recognition by a regulatory body/ commodity board is denied for a particular commodity/ product group, the laboratory shall apply afresh for the complete set of parameters under that particular commodity by submitting the applicable fee as defined in NABL 100.
Note: This clause can be superseded by Regulatory body (ies) / Commodity board requirements which may state otherwise.
- 1.30. Laboratory seeking recognition through integrated assessment shall have unidirectional structured testing facility for microbiological analysis as per the regulatory body’s requirement.
Note: Already Accredited laboratories are required to comply with this requirement by 30.06.2020.
- 1.31. **All the test reports issued by the laboratory for the scope under Integrated Assessment shall bear NABL symbol in line with NABL 133 ‘Policy for Use of NABL Symbol and / or Claim of Accreditation by Accredited Conformity Assessment Bodies (CAB) & NABL Accredited CAB Combined ILAC MRA Mark’.**
Note 1: NABL will maintain the validity of the accreditation cycle for the laboratory as per its own defined procedure. The concerned regulatory body (ies) will align the validity of its recognition/ approval with NABL Accreditation cycle. In the event that the Recognition/ Approval of the Regulatory Body (ies) is

getting expired before that of NABL, then the Laboratory will approach the concerned Regulatory Body (ies) for extension of validity.

Note 2: *In addition to the above-mentioned procedure & requirements, other NABL requirements as defined in relevant NABL documents such as NABL 131, 132, 133, 134,142, 165, 201 & 216 to deal with, shall also be applicable*

| | | | | |
|--|--|----------------|-------------------------|-------------------|
| National Accreditation Board for Testing and Calibration Laboratories | | | | |
| Doc. No.: NABL 127 | Procedure for Integrated Assessment & Additional; Requirements of Regulatory Body (ies) for Testing Laboratories | | | |
| Issue No.: 01 | Issue Date: 19-Nov-2018 | Amend. No.: 03 | Amend Date: 02-May-2020 | Page No.: 7 of 36 |

2. Additional Requirements of Export Inspection Council (EIC)

- 2.1. This document describes specific requirements of Export Inspection council (EIC), which, a testing laboratory has to comply in conjunction with the requirements of ISO/IEC 17025.
- 2.2. The laboratories seeking approval shall have implemented and maintained laboratory management system in accordance with ISO/IEC 17025; 'General requirements for competence of testing and Calibration Laboratories' and adequate capability and competence for testing of Food safety and quality parameters as per the requirements of EIC and importing countries. The approval for the scope of interest to EIC is granted, provided, it is adjudged for its capabilities 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.
- 2.3. The application for approval shall be considered based on the testing requirement, which EIC is looking for. NABL/ EIC concerned reserves the right to reject an application for one or more of the following reasons:
 - 2.3.1. The Laboratory is seeking approval for the scope, which is not the need of EIC at that time.
 - 2.3.2. The Laboratory does not have adequate facilities for the scope for approval and adequate audit fee, as applicable has not been submitted.
 - 2.3.3. The laboratory is subcontracting any test under the scope for approval.
 - 2.3.4. Any other reason as deemed fit by NABL/ EIC, without giving any reason.
 - 2.3.5. The scope covered shall not include any test by sub-contracting. Sub-contracting is permitted with prior permission of EIC, to another EIC approved laboratory with valid scope of approval only in case of failure of instrument. Subcontracting is not permitted from the laboratory, which is not approved by Regulatory Body.
 - 2.3.6. The approved laboratory shall participate in all the Proficiency Testing Programmes conducted by accredited Export Inspection Laboratories as per ISO/IEC 17043.
 - 2.3.7. Evaluation of samplers for authorization for sampling to assess the technical competence in a specific area shall also be conducted during the assessment. The sampler shall have the minimum qualification of graduation.
- 2.4. 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.

- 2.5. The approved laboratory can request NABL for approval of additional personnel responsible for authorizing the results/ samplers. In such cases an onsite assessment shall be conducted for the additional authorized samplers/signatories as per the procedure.
- 2.6. Based on the finding of the verification assessment, NABL along with EIC shall take appropriate action including suspension / withdrawal of approval of the laboratory as per NABL 216 document.
- 2.7. 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.
- 2.8. Any change in key personnel in relation to quality assurance, key technical functions (including personnel responsible for authorizing the results and samplers) or senior management shall be duly intimated to EIC/NABL within a period of 15 days.
- 2.9. The approved laboratory shall inform NABL/ EIC, 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.
- 2.10. 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:
 - 2.10.1. Sample shall always be accompanied by a test request specifying the parameter, specification and purpose. Samples shall be not be accepted by them if they are not accompanied by such test requests.
 - 2.10.2. Whenever required, the approved laboratory shall draw samples only by its own trained, authorized and approved samplers. The Approved samplers shall have the minimum qualification of graduation with minimum sampling experience.
 - 2.10.3. The samplers 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.

2.10.4. The samplers 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.

2.10.5. 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 representative of laboratory / processor / exporter. A statement / report to this effect shall be made on receipt of sample and in the test report by the concerned laboratory.

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

2.12. 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.

2.13. 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.

2.14. 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.

2.15. 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 for testing by the relevant specification.

2.16. The laboratory shall only utilize the service of authorized signatory (ies) and authorized sampler(s) complying with the requirements of NABL/ EIC.

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

- 2.18. The approved laboratories generating Pre export test reports with digital signatures shall issue 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 signed by the CEO of the laboratory with respect to above.
- 2.19. 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/NABL before 31st December of each year as per Appendix 4. 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.
- 2.20. The approved laboratory shall permit access to EIC/EIA officer (s) / team (s) deputed for the purpose of any assessment, surveillance or investigation. It shall give access to all relevant records, documents and equipments etc. for the purpose of verifying any details.
- 2.21. 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.
- 2.22. A laboratory may relinquish approval by giving three months notice in writing to both NABL and EIC. It shall however wither complete testing of all samples pending with it or return the samples pending along with the test requests.
- 2.23. NABL/EIC may, at its discretion, cancel or suspend approval, reduce its scope or direct re assessment due to change in personnel/ equipment, breakdown 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.
- 2.24. An approved testing 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 materials 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.
- 2.25. The approved laboratory shall submit periodic statements to EIC containing the particulars, as per the schedule given below in prescribed format (Appendix 1).

Appendix 1

| | | |
|-------|--|---|
| (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 - |

- 2.26. Whenever there is failure of sample showing test result not conforming to the specification, a report with complete details as per Appendix-3 along with test report 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 Appendix 2.
- 2.27. 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/ bearing on its test result
- 2.28. The approval of laboratories may also be suspended / cancelled any time during the approval period for any kind and or the reasons given below:
- 2.28.1. If EIC feels that no useful purpose is being served by the continuation of the approval of the laboratory.
- 2.28.2. If the laboratory is found violating the terms and conditions of the approval; and
- 2.28.3. If the laboratory is unable to maintain the criteria for approval.
- 2.29. The Laboratory may apply a fresh not earlier than six months from the date of cancellation / withdrawal / non renewal of approval.
- 2.30. The laboratory shall return the pending sample (s) in appropriate conditions to the customer for onward transmission to another laboratory and undertake to retain records as per requirements stated above on cancellation/ withdrawal / non renewal/ expiry of approval.
- 2.31. The approved laboratory shall issue the test report in format given in Appendix 5.

- 2.32. Approval under the Scheme shall be accorded to a laboratory for single premise 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/Management system document of the Laboratory.
- 2.33. The testing charges for the products and parameters shall be applicable as fixed by EIC from time to time. However, in case the testing charges are not fixed by EIC, then mutually agreed charges shall be applied. No testing charges shall be applicable for the samples submitted by EIC/EIAs for the purpose of ILC (Inter laboratory comparison), proficiency testing, reference sample testing / verification due to complaints, if any, etc.
- 2.34. For qualification & experience requirements for personnel responsible for authorizing the results, please refer NABL 165 “NABL’s Policies for Accreditation as per ISO/IEC 17025:2017”

Appendix 2

FORMAT FOR SUBMITTING PERIODIC STATEMENTS DETAILS OF SAMPLES TESTED AND RESULTS

(Name of the laboratory, address & contact details)

| | | | | | | | | | | | | |
|--|-----------------|-------------|------------------|-----------------|-----------------------|---|-----------------|--|-----------------|---|--|---|
| Period of statement | Validation data | | | | | | | | | | | |
| Total number of samples | LOD (µg/kg) | LOQ (µg/kg) | CC alpha (µg/kg) | CC beta (µg/kg) | Foreseen to be tested | Number of samples in the RMP/NRCP for the laboratory' | Received in lab | Other residue samples taken outside the RMP/NRCP (e.g. private samples) should be listed in brackets [] | Actually tested | 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 |
| Analyte group as listed in Annex I to Council Directive 96/23/EC | | | | | | | | | | | | |
| Substance | | | | | | | | | | | | |
| Analyte (and number of non-complaints) | | | | | | | | | | | | |
| Matrix / Species | | | | | | | | | | | | |
| method used (Screening /Confirmatory) | | | | | | | | | | | | |

Appendix 3

FORMAT FOR COMMUNICATION OF FAILURES OBSERVED DURING TESTING

| | | | | | | | | | | | | | | |
|-----|-------------------------|-----------------|----------------------------|--|---------------------------|-----------------|----------------------|---|-----------------|--|-------------------|---|--------------------|-----------------------------|
| Sl. | 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 |
| | | | | | | | | | | | | | | |

* wherever applicable

| National Accreditation Board for Testing and Calibration Laboratories | | | | |
|---|--|----------------|-------------------------|--------------------|
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| Issue No.: 01 | Issue Date: 19-Nov-2018 | Amend. No.: 03 | Amend Date: 02-May-2020 | Page No.: 14 of 36 |

Appendix 4

Format for annual proposed plan for proficiency testing

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

Appendix 5**FORMAT OF TEST REPORT**

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

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 / CC α / CC β , as applicable (e.g. LOQ in case of pesticides, CC β , for Screening test, CC α for drugs & contaminants, etc) | LOD, as applicable | ***MR L / MRP L / ML / Limits | Analytical Method (e.g. ELISA, Delvos et, 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 $\mu\text{g/Kg}$, 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 $x \pm U$ 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

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3. Additional Requirements of Agricultural and Processed Food Products Export Development Authority (APEDA)

- 3.1. This document describes specific requirements of APEDA, which, a testing laboratory has to comply in conjunction with the requirements of ISO/IEC 17025: 2005 or ISO/IEC 17025: 2017.
- 3.2. Laboratories recognized by APEDA shall cater to APEDA Scheduled Products & Organic Products for sampling, analysis; residue monitoring plans for exports of APEDA scheduled products as per the laid down procedures by APEDA from time to time.
- 3.3. The assessment shall be conducted 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.
- 3.4. The testing under the scope for recognition shall be in compliance to the methods of validation as per the requirements of the importing countries.
- 3.5. The Laboratory shall be audited for internationally accepted harmonized methods of sampling, sample preparation and analysis purpose.
- 3.6. Sampling and analysis charges for each product shall also be submitted together with application by the applicant laboratory, whenever, prescribed by APEDA.
- 3.7. 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.
- 3.8. Based on the finding of the verification assessment, NABL along with APEDA shall take appropriate action including suspension /withdrawal of approval of the laboratory as per NABL 216 document.
- 3.9. The applicant laboratories seeking recognition and accreditation as per integrated assessment process shall have complete range of Chemical, Microbiological and GMO analysis before applying to NABL for Recognition/ Accreditation. Applications for partial recognition (except for GMO analysis only) shall not be entertained.
- 3.10. The applicant laboratories would be accorded recognition for:
 - 3.10.1. Chemical, Microbiological and GMO analysis for the products specified by APEDA.

- 3.10.2. Premises only where actual analysis is being carried out shall be recognized. In case analysis is carried out at more than one premise, recognition of all these facilities shall have to be obtained.
- 3.11. The laboratories shall comply with the following before applying to APEDA for recognition and NABL for accreditation;
- 3.11.1. Availability of high precision GC-MS/MS, HPLC-MS/MS, ICP-MS, etc. with appropriate back-up, supporting equipments as well as accessories.
- 3.11.2. Recognition 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/ Management system document of the laboratory.
- 3.11.3. Sensitize personnel for drawing the sample, preparation of samples for analysis as well as analysis of Control sample, retention and storage in controlled temperature of appropriate capacity.
- 3.11.4. Method validation for sampling and residual analysis, participation in P.T. programs, estimation of uncertainty, traceability, etc.
- 3.12. The laboratories seeking GMO analysis recognition shall also comply with the following in addition to the above. The laboratories shall submit list of experts, method of sampling and list of equipments as well as any other relevant information that would be appropriate for analysis of GMO in agro products.
- The following basic criteria shall be met by the applicant laboratories:
- The laboratories shall have basic equipments like RT-PCR, DNA sequence, etc.
 - The laboratories shall have validated method of sampling and analysis for GMO
 - The laboratories shall have relevant expertise to analyze GMO products in terms of technically qualified personnel
- 3.13. Copies of SOPs on methods of sampling and analysis as well as evidence to sensitized team for drawl of product samples retention facility in controlled temperature shall be submitted by the applicant laboratory.

- 3.14. Details of Sampling and analysis charges for each product shall also be submitted together with application by the applicant laboratory.
- 3.15. Each application received for recognition shall be considered by APEDA based on the need of a laboratory in the region/area for scheduling an assessment of the laboratory.
- 3.16. The applicant/recognized laboratory shall participate in P.T. programs organized by respective National Referral Laboratory (NRL) nominated by APEDA from time-to-time for the purposes of following harmonized methods of sampling and analysis.
- 3.17. The successful laboratory shall be part of the traceability programs implemented by APEDA or any other agencies nominated by APEDA for the products specified by it from time to time and abide by the procedures to be complied therewith such as uploading of data, chromatograms, etc. as announced by APEDA or the NRL.
- 3.18. The laboratory shall be audited for following harmonized methods of sampling, sample preparation and analysis purposes.
- 3.19. Whenever required, the recognized laboratory shall draw samples only by its own trained, authorized and approved samplers. The approved samplers shall have the minimum qualification of graduation along with minimum sampling experience with training imparted by NRL, NIPHM, DMI or any other government institution on application of methods of sampling.
- 3.20. Recognition to successful laboratories would be granted for analysis for the products and parameters found to be in order based on the assessment outcome for Chemical, Microbiological and GMO analysis. Evaluation of samplers for authorization of sampling to assess the technical competence in a specific area shall also be conducted during the assessment.
- 3.21. The laboratory shall be audited periodically to check utilization of harmonized methods of sampling, sample preparation and analysis. The laboratory shall also be audited by Directorate of Marketing and Inspection for the purpose of authorization for issue of Agmark Grading Certificates.
- 3.22. Issue of recognition may be refused or, if issued, may be cancelled or suspended:
- 3.23. If the laboratory does not conform or fail to perform as per requirements.
- 3.24. If there are adverse reports from the financial institutions/banks against any of the owner/directors/partners/trustees.
- 3.25. If skilled/semi-skilled personnel are not available to manage the laboratory.
- 3.26. If there are adverse reports from the exporters, importers, etc.
- 3.27. Any other complaints made to APEDA by any other entity.
- 3.28. On expiry of the recognition date specified in the Recognition Certificate.

- 3.29. Lab to submit the following annexure (I, II and III) with application form (NABL 154):
- 3.30. When physical checks are to be undertaken, sampling plans for exported products should take into account the level of risk, the presentation and type of commodity to be sampled, the reliability of controls of the importing country and of those responsible for handling the product in the importing country.
- 3.31. Inspection services should draw up control programmes based on precise objectives and appropriate risk analysis. Accreditation certificate shall be attached with technical annex. There shall be documented validation reports, proficiency tests results, analytical spectrum and methods, standard operating procedures for analytical method, resources and training etc.
- 3.32. Control Programmes shall be designed with consensus of APEDA. Every effort should be made to apply risk analysis based on internationally-accepted methodology, where available. The elements of the control programme should be formally documented including methods and techniques.
- 3.33. In the drawing and analysis of samples, adequate sampling and appropriately validated analytical methods should be established to ensure that the results are representative and reliable in relation to the specific objectives and during export rejections our results shall stand robust and traceable in International market.
- 3.34. Non-conformities/ Export Rejections:
Where an exported product is found not to be in conformity, the resulting measures should take into account the following criteria to ensure that any action is proportionate to the degree of public health risk, potential fraud or deception of consumers:
- a. Repeated non-conformity in the same importing country or in the same product or in the same category of products
 - b. History of non-conformity of those responsible for handling the products;
 - c. Reliability of checks.
 - d. In respect of the product not in conformity, control programmes to ensure problems do not re-occur.
 - e. Analytical report of non-compliant samples shall be documented and retained in records.
- 3.35. Authenticity and Validity of Certificates
- A. Certification procedures should include procedures to ensure the authenticity and validity of certificates at all the relevant stages and to prevent fraudulent certification.
 - B. In particular, personnel:
 - Should not certify matters without their personal knowledge or which cannot be ascertained by them;

- Should not sign blank or incomplete certificates, or certificates for products which have not been produced under appropriate control programmes. Where a certificate is signed on the basis of another supporting document, the person signing the certificate should be in possession of that document;
 - Should have no direct commercial interest in the products/exporters being certified.
- 3.36. During the visit of International delegations, the laboratory shall ensure the availability of inspectors/samplers/auditors who had conducted the onsite inspections/sampling for a specific audit/sampling.
- 3.37. The application for recognition shall be considered based on the testing requirements of APEDA. NABL/APEDA reserves the right to reject an application for one or more of the following reasons:
- a. The Laboratory is seeking approval for the scope, which is not the need of APEDA at that time.
 - b. The Laboratory does not have adequate facilities for the scope for approval and adequacy audit fee, as applicable has not been submitted.
 - c. The laboratory is subcontracting any test under the scope for approval.
 - d. Any other reason as deemed fit by NABL/ APEDA.
- 3.38. The scope covered shall not include any test by sub-contracting.
- 3.39. The recognized laboratory can request NABL for approval of additional **personnel responsible for authorizing the results**/ samplers. In such cases an onsite assessment shall be conducted for the additional authorized samplers/signatories as per the procedure.
- 3.40. If complaint is received from importing country (e.g. 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-informed in advance/ uninformed depending upon the nature of complaint) by a joint assessment team comprising of officer/ assessors from APEDA and NABL immediately. The expenditure incurring for the verification assessment shall be borne by the laboratory. Such verification assessment shall also be conducted in case of any other complaints in sampling, testing and test reports or any other reasons.
- 3.41. The recognized laboratory shall not make any change in the Quality Management System, which forms the basis for the grant of the recognition and which prevents its compliance to the Scheme without prior approval of APEDA/NABL.

- 3.42. Any change in key personnel in relation to quality assurance, key technical functions (including personnel responsible for authorizing the results and samplers) or senior management shall be duly intimated to APEDA/NABL within a period of 15 days.
- The recognized laboratory shall inform NABL/ APEDA, immediately about the major changes/breakdown of equipment with reasons thereof etc. affecting 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 APEDA, when there is major change in the Management System, which may affect performance of the testing.
- 3.43. Sample shall always be accompanied by a test request specifying the parameter, specification and purpose. Samples shall be not be accepted by them if they are not accompanied by such test requests. The samplers shall strictly adhere to the sampling procedure of the lab based on Executive Instructions issued by APEDA for various food products from time to time/ EC regulations/ Importing country requirements, and provide sampling details as per APEDA 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.
- 3.44. The samplers 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.
- 3.45. 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 regulatory authority / authorized representative of laboratory / processor / exporter. A statement / report to this effect be made receipt of sample and in the rest report by the concerned laboratory.
- 3.46. The laboratory shall carry out the tests as per the conditions stipulated in the relevant standard method approved by APEDA, 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.
- 3.47. The laboratory shall keep the remnants of the sample after testing for a minimum period of one month and reference sample for a period of three 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

APEDA/ importing country's requirement. The mode of disposal of sample after test shall be recorded and indicated in the test request as well.

- 3.48. 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.
- 3.49. 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 for testing by the relevant specification.
- 3.50. The laboratory shall only utilize the service of authorized signatory and authorized samplers complying with the following requirements of NABL/APEDA.
- 3.51. In case of withdrawal/ cancellation of recognition, the laboratory shall give an undertaking to make available of the records of APEDA related testing of three years.
- 3.52. The approved laboratories generating Pre export test reports with digital signatures shall issue test reports directly to APEDA 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 signed by the CEO of the laboratory with respect to above.
- 3.53. 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. The Annual proposed plan for participation in Proficiency testing programs pertaining to approved scope for the forthcoming year shall be submitted to APEDA/NABL before 31st December of each year as per Annexure 4. 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 APEDA/NABL immediately with appropriate root cause analysis.
- 3.54. The approved laboratory shall permit access to APEDA officer (s) / team (s) deputed for the purpose of any assessment, surveillance or investigation. It shall give access to all relevant records, documents and equipments etc. for the purpose of verifying any details.
- 3.55. An approved testing laboratory shall not use its approval in such a manner as to bring APEDA/ NABL/Government of India into disrepute/ dispute and shall not make any statement relevant to its approval, which APEDA may consider to be misleading.

- 3.56. Laboratory may relinquish approval by giving three months notice in writing to NABL/APEDA. It shall however wither complete testing of all samples pending with it or return the samples pending along with the test requests. NABL/APEDA may, at its discretion cancel or suspend approval, reduce its scope or direct re assessment due to change in personnel/equipment, breakdown 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.
- 3.57. An approved testing 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 APEDA approval and withdraw all promotional and advertising materials 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 APEDA.
- 3.58. The recognized laboratory shall submit periodic statements to APEDA containing the particulars, as per the schedule given below in prescribed format

| | | |
|------|--|---|
| 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 - |

- 3.59. The laboratory shall return the pending samples (s) in appropriate conditions to the customer for onward transmission to another laboratory and undertake to retain records as per requirements stated above on cancellation/ withdrawal / non renewal/ expiry of approval.
- 3.60. The testing charges for the products and parameters shall be applicable as fixed by APEDA from time to time. However, in case the testing charges are not fixed by APEDA, then mutually agreed charges shall be applied. No testing charges shall be applicable for the samples submitted by APEDA for the purpose of ILC (Inter laboratory comparison), proficiency testing, reference sample testing / verification due to complaints, if any, etc.

3.61. For qualification & experience requirements for personnel responsible for authorizing the results, please refer NABL 165 “NABL’s Policies for Accreditation as per ISO/IEC 17025:2017”

(Annexure I)

Sampling and Analysis Charges

| Sl. | Parameter/Matrix | Analysis charge | Sampling charge |
|-----|------------------|-----------------|-----------------|
| 1. | | | |
| 2. | | | |
| 3. | | | |

(Annexure II)

List of products presently being analyzed by laboratory

| Sl. | Products | Tick, as applicable |
|-----|--|---------------------|
| 1. | Fresh fruits and vegetables | |
| 2. | Processes fruit and vegetable | |
| 3. | Cereals (rice, wheat, maize) and products | |
| 4. | Meat, poultry, dairy products and honey | |
| 5. | Nuts and Oil seeds (walnuts, ground nuts) and products | |
| 6. | Guar Gum | |
| 7. | Pulses | |
| 8. | Other processed foods | |
| 9. | GMO & DNA analysis | |
| 10. | Organic Foods | |

(Annexure III)

Products interested for recognition of sampling and analysis

| Sl. | Products | Tick, as applicable |
|-----|--|---------------------|
| 1. | Fresh fruits and vegetables | |
| 2. | Processes fruit and vegetable | |
| 3. | Cereals (rice, wheat, maize) and products | |
| 4. | Meat, poultry, dairy products and honey | |
| 5. | Nuts and Oil seeds (walnuts, ground nuts) and products | |
| 6. | Guar Gum | |
| 7. | Pulses | |
| 8. | Other processed foods | |
| 9. | GMO & DNA analysis | |
| 10. | Organic Foods | |

Format for annual proposed plan for proficiency testing

| Sl. | Analytes | Matrix | Proficiency test (Program ID Number / Round Robin No.) | Start date of proficiency test |
|-----|----------|--------|--|--------------------------------|
| 1. | | | | |
| 2. | | | | |

4. Additional Requirements of Commodity Board (s)

- 4.1. This document describes specific requirements that a testing laboratory seeking for approval from commodity board e.g. Tea Board has to meet, in parallel to the requirements of ISO/IEC 17025 for accreditation by NABL.
- 4.2. The scope covered shall not include any test by sub-contracting. Sub-contracting is permitted with prior permission of NABL and Commodity Board(s) to another approved laboratory with valid scope of approval only in case of failure of instrument. Subcontracting is not permitted from the laboratory, which is not approved by commodity board.
- 4.3. The assessment shall be conducted to 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.
- 4.4. 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 commodity board.
- 4.5. The approved laboratory shall inform NABL/ concerned commodity board, 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 commodity board, when there is major change in the Management System, which may affect performance of the testing.
- 4.6. 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.
- 4.7. The laboratory is liable to maintain confidentiality of samples and information thereof.
- 4.8. 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 importing country's requirement. The mode of disposal of sample after test shall be recorded and indicated in the test request as well.

- 4.9. The testing under the scope for approval shall be in compliance to the methods of validation as per the requirements of the importing countries if any.
- 4.10. The Laboratory shall be audited for the harmonized methods of sampling, sample preparation and analysis purpose being followed as per applied scope.
- 4.11. Details of sampling and analysis charges for each product shall also be submitted together with application by the applicant laboratory.
- 4.12. 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.
- 4.13. For qualification & experience requirements for **personnel responsible for authorizing the results**, please refer NABL 165 “NABL’s Policies for Accreditation as per ISO/IEC 17025:2017”

5. Additional Requirements of Indian Oilseeds and Produce Export Promotion Council (IOPEPC)

- 5.1. This document describes the specific requirements of the Indian Oilseeds and Produce Export Promotion Council (IOPEPC), which a testing laboratory is to comply with in conjunction with the requirements of ISO/IEC 17025.
- 5.2. The laboratory seeking approval shall have implemented and maintained Laboratory Management System in accordance with ISO/IEC 17025; 'General Requirements for Competence of Testing and Calibration Laboratories.' Besides, the laboratory shall have adequate capability and competence for sampling and microbiological testing for Salmonella in sesame seed samples as per requirements of the European Union and the IOPEPC. For the purpose of certification of sesame seed consignments for export, the samples shall be tested in accordance with European Commission regulations and guidelines.
- 5.3. The application shall be considered on the basis of testing requirements of the IOPEPC and may be rejected on the basis of any one or more of the following grounds:
- The laboratory does not have adequate facilities for the scope of work.
 - The laboratory is subcontracting the test or part thereof under the scope for approval.
 - Any other reason as may be deemed fit by NABL / IOPEPC.
- 5.4. The scope covered shall not include any test by sub-contracting. Sub-contracting may, however, be permitted with prior permission of IOPEPC, to any another IOPEPC approved laboratory with valid scope of approval only in case of any unforeseen breakdown of a major laboratory instrument/equipment/facility and the repairs of which may unduly delay the analysis.
- 5.5. Laboratory will have to obtain membership of the IOPEPC and also registration for online export portal called sesame.net by paying requisite registration fees. All the existing stakeholders in export of sesame seed to EU are registered on sesame.net and the information is uploaded on the portal.
- 5.6. Shortly after the information/request is uploaded by the exporter, the Laboratory will have to depute its trained staff for sampling the sesame seed consignments at the designated and registered processing unit or the warehouse, and subsequently upload the Certificate of Analysis and also the Stuffing Certificate on the portal. The entire procedure of export of sesame seed is being executed online through this portal only.
- 5.7. The charges for sampling and analysis of samples for Salmonella shall be indicated by laboratory while filing the application.
- 5.8. Copies of SOPs on methods of sampling and analysis as well as evidences for sensitization/training of team members for drawing requisite samples from the consignment and

the retention facility available with the laboratory shall also be submitted by the applicant laboratory.

- 5.9. Only the premises where actual analysis is carried out shall be recognized. In case, the analysis is required to be carried out at more than one premise, recognition of all such premises and facilities shall have to be obtained.
- 5.10. The applicant/approved laboratory shall participate in P.T. programs organized by the respective Referral Laboratory nominated by IOPEPC from time-to-time for the purposes of adopting a harmonized and uniform method of sampling and analysis.
- 5.11. Evaluation of samplers for their competence in the specific area shall also be conducted. The sampler shall have a minimum qualification of graduation.
- 5.12. The testing of Salmonella under the scope for approval shall be in compliance with the requirements of the European Union (ISO-6579-1:2017) and the relevant Regulations, Directives and Decisions of the European Commission.
- 5.13. The approved laboratory can request the NABL for granting approval of additional samplers/signatories. In such cases an onsite assessment of competence of samplers shall be conducted.
- 5.14. During the period of validity of approval, if the laboratory is found to violate any of the specified terms and conditions, the approval is liable to be suspended. The laboratory, however, may represent for verification visits by officials of NABL/IOPEPC to verify the facts and compliance. The laboratory will have to bear the expenses for such paying visits.
- 5.15. If a complaint is received from any of the importing country of the European Union (e.g. RASFF- Rapid Alert System on Food and Feed) against a consignment for presence of Salmonella, the laboratory which had drawn and tested the samples, shall be subjected to audit (verification audit, with or without advance intimation depending upon the nature of complaint) by a joint team of officers/assessors from the IOPEPC and the NABL. The expenditure for the verification assessment shall be borne by the laboratory. Such verification assessment shall also be conducted in case of other complaints regarding sampling, testing and test reports etc.
- 5.16. Based on the findings of the verification assessment, the NABL in association with the IOPEPC shall take appropriate action which may even amount to suspension / withdrawal of approval as per NABL 216 document.
- 5.17. Any change in key personnel associated with quality assurance technical functions (including personnel responsible for authorizing the results and samplers) or senior management shall have to be duly intimated to IOPEPC/NABL within a period of 15 days.

- 5.18. The approved laboratory shall inform NABL/IOPEPC, immediately about any major changes/breakdown of equipment etc. which may affect the testing of samples in compliance with the specifications. And the laboratory shall not carry out sampling or accept any sample for testing during the period of breakdown of the equipment.
- 5.19. The following instructions shall be followed by the approved laboratory for drawing samples of sesame seed at the registered processing unit or warehouse as the case may be.
- 5.20. Only trained, authorized and approved samplers of the laboratory shall draw the samples. The samplers shall strictly adhere to the sampling procedure specified in the regulation for export of sesame seed to European Union. The sampling will be done by following the codex general guidelines (CAC/GL 50-2004), as per EC regulation 2073/2005 and IOPEPC. The details of the sampling procedure are given in Annexure.
- 5.21. Once sampled and sealed, the laboratory would ensure that unit does not shift the consignment to another location or approved premises. In case of exigency, this may be done only under the supervision of the representative of the laboratory. The stuffing will also take place at the same location where the sampling was carried out.
- 5.22. A bag once sampled will not be sampled again.
- 5.23. In case one consignment comprises material from more than one processing lot, the material from different lots will be sampled separately.
- 5.24. The laboratory shall ensure the integrity and chain of custody of sample during transportation. Further, laboratory shall ensure that the lot seal is intact with the details of the seal till the consignment is stuffed.
- 5.25. The laboratory is liable to maintain confidentiality of samples and information thereof.
- 5.26. In order to save time, the consignment may be stuffed in the container soon after drawing the samples in presence of the laboratory representative even before issuance of test report. However, shipment of such container will be allowed only after issuance of Certificate of Export from IOPEPC. The exporter availing this facility will be solely responsible for any liability towards shipping lines, customs and excise authorities, etc., or any consequence arising due to availing the said option.
- 5.27. The laboratory shall carry out the tests as per the conditions stipulated in the relevant standard method of testing of salmonella (ISO-6579-1:2017).The laboratory shall keep the leftover samples for a minimum period of three months after the testing.
- 5.28. 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 laboratory pertaining to each activity which affects the quality of test results.

- 5.29. The laboratory shall issue the test reports immediately after completion of the tests and not later than a maximum period of seven days after the sampling.
- 5.30. The laboratory shall utilize the services of only authorized signatory (ies) and authorized sampler(s) in compliance with the requirements of NABL/IOPEPC.
- 5.31. In case of withdrawal/cancellation of approval, the laboratory shall give an undertaking to make available the records of IOPEPC related testing of the past three years.
- 5.32. The approved laboratory shall permit access to IOPEPC officer(s) / team(s) deputed for the purpose of any assessment, surveillance or investigation. It shall give access to all the relevant records, documents and equipments etc. for the purpose of verifying any details.
- 5.33. An approved testing laboratory shall not use its approval in such a manner as to bring IOPEPC/Government of India into disrepute/dispute and shall not make any statement relevant to its approval, which IOPEPC may consider to be misleading.
- 5.34. A laboratory may relinquish approval by giving three months notice in writing to both NABL and IOPEPC. It shall, however, complete testing of all samples pending with it or return the samples pending along with the test requests.
- 5.35. NABL/IOPEPC may, at its discretion cancel or suspend approval or direct reassessment due to change in personnel/equipment, breakdown 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 adequate.
- 5.36. The approval of laboratories may also be suspended / cancelled any time during the approval period for any kind and or the reasons given below:
- If the laboratory is found violating the terms and conditions of the approval; and If the laboratory is unable to maintain the criteria for approval.
 - If 'IOPEPC' is of the opinion that no useful purpose is being served by the continuation of the approval.
- 5.37. The Laboratory may submit a fresh application not earlier than six months from the date of cancellation / withdrawal / non-renewal of approval.
- 5.38. The laboratory shall return the pending sample (s) in appropriate conditions to the customer for onward transmission to another laboratory and undertake to retain records as per requirements stated above on cancellation/ withdrawal / non renewal/ expiry of approval.
- 5.39. For qualification & experience requirements for **personnel responsible for authorizing the results** please refer NABL 165 "NABL's Policies for Accreditation as per ISO/IEC 17025:2017"

6. Additional requirements for Food Safety and Standard Authority of India (FSSAI)

- 6.1. FSSAI is mandated under Section 43 of the FSSA to recognize by notification, food laboratories and research institutions accredited by National Accreditation Board for Testing and Calibration Laboratories for the purpose of carrying out analysis of samples by the Food Analysts under this Act.
- 6.2. Laboratories are expected to follow for obtaining recognition from FSSAI for undertaking testing of food products for FSSAI or having their test results/reports accepted by FSSAI as demonstration of compliance to its regulations.
- 6.3. Recognition/authorization of Laboratories under FSSAI is an open and continuous process to be pursued until any further amendment/orders by FSSAI.
- 6.4. Laboratory has to comply in conjunction with the requirements of ISO/IEC 17025.
- 6.5. Laboratories recognized by FSSAI shall cater to Food Safety and Standards (Food Products Standards, Food Additives, Contaminants, Toxins and Residues) Regulations, 2011 for sampling and analysis.
- 6.6. Laboratory shall implement the methods of sampling and analysis mentioned in the manuals as specified by the Food Safety and Standards Authority of India from time to time (as applicable).
- 6.7. The range of testing of specific parameter under applied scope shall be in line with Food Safety and Standards (Food Products Standards, Food Additives, Contaminants, Toxins and Residues) Regulations, 2011 as amended from time to time.
- 6.8. Equipments and Machinery with their least count and range against the parameters tested as per relevant Food Safety and Standards (Food Products Standards, Food Additives, Contaminants, Toxins and Residues) Regulations, 2011 as amended from time to time.
- 6.9. The application for approval shall be considered based on the requirement of FSSAI. NABL/FSSAI reserves the right to reject an application for one or more of the following reasons:
 - 6.9.1. The Laboratory is seeking approval for the scope, which is not the need of FSSAI at that time.
 - 6.9.2. The Laboratory does not have adequate facilities for the scope for approval and
 - 6.9.3. Any subcontracted parameter in the scope.
 - 6.9.4. Any other reason as deemed fit by NABL/ FSSAI, without giving any reason.
- 6.10. The FSSAI recognition of Food Laboratory shall be maintained on the following conditions;
 - a. The Food Laboratory continues to maintain the NABL accreditation (in accordance ISO/IEC 17025 and the FSSAI criteria) for the relevant scope;

- b. There are no adverse reports/information/complaint with the FSSAI about the Food Laboratory regarding the testing activities performed by the laboratory which are found valid by FSSAI.
 - c. The FSSAI recognition of the Food lab is valid subject to:
 - i. Validity of NABL accreditation;
 - ii. the specific period as indicated by FSSAI; and
 - iii. maintains integrity in its operations at all times
 - iv. In case of NABL accreditation cancellation, FSSAI authorization will automatically stand cancelled.
- 6.11. FSSAI shall reserve the right to call for any information from the recognized Food Laboratory, conduct an audit or investigation at its premises, refer any complaint regarding its functioning to NABL and seek any reports from NABL.
- 6.12. FSSAI may suspend/withdraw recognition jointly with NABL in case its own investigations/audits reveal any adverse findings with due notice to the lab.
- 6.13. Withdrawal/ Debar of FSSAI recognition under integrated process, the Food Laboratory shall be eligible to seek fresh recognition from FSSAI as a new applicant subject to conformance as per requirement of FSSAI after 6 months.
- 6.14. All Food Laboratories that are recognized by FSSAI are permitted to mention the same on their stationary, publicity media, communications etc. However, it shall be the responsibility of the recognized Food Laboratory that the recognition is not misrepresented and FSSAI is not brought into disrepute in any manner.
- 6.15. The laboratory seeking FSSAI recognition shall have adequate capability and competence for testing all the safety and quality parameters for at least one food category/ product group specified in Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 and all other regulations associated therein. Applications with partial scope shall not be considered, unless otherwise permitted by FSSAI.
- 6.16. Relaxation from clause 6.15 may be provided in cases where the laboratory is accredited for majority of safety parameters (e.g. contaminants, hazards or toxins) but does not have capability and competence for remaining parameters/ analytes. In such cases, a conditional recognition may be granted despite the limited scope provided the laboratory submits an undertaking towards development of capability and competence for remaining scope within one year from the grant of recognition, failing which, recognition shall be withdrawn.

Example: if a laboratory has the capacity to test pesticides, heavy metals and antibiotics but does not have capability to test toxins or a few of pesticides/ heavy metals/ antibiotics, then conditional recognition may be given subject to

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|--|--|----------------|-------------------------|--------------------|
| National Accreditation Board for Testing and Calibration Laboratories | | | | |
| Doc. No.: NABL 127 | Procedure for Integrated Assessment & Additional; Requirements of Regulatory Body (ies) for Testing Laboratories | | | |
| Issue No.: 01 | Issue Date: 19-Nov-2018 | Amend. No.: 03 | Amend Date: 02-May-2020 | Page No.: 34 of 36 |

submission of an undertaking by the laboratory stating that the laboratory will have the facilities of testing toxins or remaining pesticides/ heavy metals/ antibiotics, as the case may be, within one year.

- 6.17. The laboratory shall have a Food Analyst in terms of Rule 2.1.4 of the Food Safety and Standards Rules, 2011. However, a food laboratory accredited by NABL having an authorized signatory (as accepted and approved by NABL), shall also be considered for granting recognition subject to the condition that such authorized signatory shall, within one year from the date of recognition, acquire the qualification and experience required for being appointed as Food Analyst under the said rule.
- 6.18. Notwithstanding anything mentioned above, all other terms and conditions pertaining to recognition and notification of laboratories shall be governed by Food Safety and Standards (Recognition and Notification of laboratories) Regulations, 2018.
- 6.19. Laboratory shall have the access to view the certificate of recognition after obtaining the password from FSSAI. Lab shall provide the details of Food analysts available in the laboratory as annexure 1. Lab shall have qualified food analyst.

Annexure 1

| Sr. No. | Name of qualification of Food analyst* | Whether qualified under Rule 2.1.4 of the Food Safety and standards Rules,2011 | Certificate no. and year of passing | Details of Training / Specialized trainings attended by Food analyst |
|---------|--|--|-------------------------------------|--|
| | | | | |
| | | | | |

*If qualified food analyst is not available with laboratory, then laboratory shall appoint qualified food analyst within 1 year of grant of accreditation.

6.20. Lab shall provide the details of laboratory capacity sample handling as annexure 2.

Annexure 2

| S. No. | Food product/item | Testing time | Numbers of samples can be tested in a month (capacity) |
|--------|-------------------|--------------|--|
| | | | |
| | | | |

6.21. Laboratory shall have Infrastructure available in terms of land; building, laboratory space etc (enclose a layout plan of the laboratory with measurements of areas).

6.22. Laboratory shall provide the details of any adverse decision taken against the laboratory (Suspended/debarred/black-list or any action by court of law, central government/ state government or any public authorities including Food authority in the past and whether such proceedings are pending / contemplated against the laboratory).

6.23. For qualification & experience requirements for **personnel responsible for authorizing the results**, please refer NABL 165 “NABL’s Policies for Accreditation as per ISO/IEC 17025:2017”

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