Joint Circular 20/2013/TTLT-BYTBCT-BNNPTNT of 01 August 2013 on conditions and procedures for accrediting food testing agencies for state Inspection.

Chapter II

CONDITIONS OF LABORATORY

Article 4. Legal requirements

The laboratory shall be founded in compliance with the law with food testing services or being designated by competent authorities.

Article 5. Competence requirements

The designated laboratory shall meet the following requirements:

1. Quality management system shall be accredited to ISO/IEC 17025:2007 (national standard) or ISO/IEC 17025:2005;

2. Laboratory shall be provided with adequate laboratory equipments and facilities for parameters / tests registered for designation;

3. Laboratory shall have at least two (02) analysts who are technically university qualified for registered parameters / tests and have at least three (03) year experience in the fields;

4. Laboratory shall use updated and calibrated test methods, be competent to perform tests for registered parameters in compliance with related technical regulations and other requirements of involved Ministry;

5. Laboratory's proficiency tests or inter-laboratory comparisons results are satisfactory for at least 01 registered parameter/test.

Chapter III

DOSSIERS, PROCEDURE FOR REGISTER, DESIGNATION

Article 6. Register for designation

1. Laboratoties meeting the requirements as set in Articles 4 and 5 shall submit one (01) register dossier for designation to the competent authorities as set forth in Article 3 (in person or by post).

2. Competent authorities as set forth in Article 3 shall process the register dossier, perform audit to laboratories testing food under single jurisdiction or cooperate with other competent authorities to perform joint audit to laboratories testing food under multiple jurisdiction following the procedure set in this Joint Circular and consider the designation accordingly.

3. Register dossier includes:

a) Application (Appendix 1);

b) Establishment decision or Business registration certificate (certified true copy);

c) Technical documents and procedures of registered parameters/tests.

d) Laboratory competency report:

- List and profile of main equipments, facilities;

- List and profile of analysts for registered parameters/tests, accompanied with respective qualification certificate (certified true copy);

- Documents on laboratory quality management system: plan, proficiency tests or inter-laboratory comparisons results; Report on analyst proficiency test for registered parameters/tests;

- Report on laboratory capability (Appendix 2);

- Form of an analyis report (Appendix 3);

- Testing report for registered parameters/tests in recent twelve (12) months (Appendix 4);

đ) For laboratories accredited with national standard ISO/IEC 17025:2007 or international standard ISO/IEC 17025:2005 by Vietnam or foreign accreditation bodies - members of International Laboratory Accreditation Cooperation (ILAC), Asian Pacific Laboratory Accreditation Cooperation (APLAC) registering for designation of accredited parameters/tests: submit documents as required at Points a, b, c and d, Paragraph 3, this Article; Certificate of Accreditation (certified true copy), designation scope.

Article 7. Register for designation renewal

Within ninety (90) days before the expiry of designation, laboratory shall submit a register dossier for designation renewal to the competent authorities. The dossier includes:

1. Application (Appendix 1);

2. Report on proficiency tests, inter-laboratory comparisons for registered parameters/tests;

3. Testing report in designation period (Appendix 4).

Article 8. Register for amendment of designation scope

Designated laboratory wishing to amend its designation scope shall submit a register dossier for designation scope amendment to the competent authorities. The dossier shall follow Article 6. In case that laboratory have changed its legal status or location, the laboratory shall inform in written the competent authorities of these changes.

Article 9. Designation procedure

1. Within ten (10) working days since receipt of register dossier, the competent authorities shall check the documents. In case of requiry for more details, the competent authorities shall require in written the laboratory to complete the dossier. In case of the completed dossier, the competent authorities shall perform audit to the laboratory as set forth in Article 10.

2. For laboratories not set forth at point đ, Paragraph 3, Article 6:

a) Within fifteen (15) working days since receipt of completed dossier, the competent authorities shall issue the decision setting up the audit team.

b) Members of the audit team shall have professional knowledge and experience on the field.

c) Decision setting up the audit team shall specify audit scope, audit content, list of audit members and responsibilities of each member. Within five (05) working days since the audit, audit team must submit to the competent authorities the audit report (Appendix 5).

d) Within fifteen (15) working days since receipt of audit report, the competent authorities shall consider to issue decision of designation (by the form in Appendix 6). Otherwise, the competent authorities shall inform in written of the reason for refusal of designation.

đ) The competent authorities shall possibly set up an advisory council for final decision of designation if needed.

3. For laboratories set forth at point đ, Paragraph 3, Article 6:

a) Within thirty (30) working days since receipt of completed dossier, the competent authorities shall check the dossier. If the laboratory competence meet the requirements as set forth in Articles 4 and 5 and by relevant Ministries, the competent authorities issue the decision of designation accompanied with list of authorized parameters/tests.

Otherwise, the competent authorities shall inform in written of the reason for refusal of designation.

b) In case of necessity, the competent authorities shall set up audit team to assess laboratory competence.

4. A decision of designation shall be valid for three (3) years from the date of signation.

Article 10. Audit

The audit shall be applied to laboratories not set forth at point đ, Paragraph 3, Article 6 or point a, Paragraph 3, Article 9, including:

1. Assessing compliance and conformity of the laboratory with the competence requirements set forth in Article 5;

2. Making audit report by the form in Appendix 7;

3. Making recommendations by the form in Appendix 5. Depending on report of corrective actions by the laboratory, the competent authorities shall consider to perform verification to the laboratory in case of necessity.

Article 11. Laboratory identification numbering

1. The competent authorities shall be responsible to allocate and manage laboratory identification numbers (approval numbers) for designated laboratories.

2. Laboratory identification numbering:

(ordinal number)/(year)/BYT-KNTP (BCT-KNTP/BNN-KNTP)

Ex: **001/2011/BYT-KNTP**

3. Laboratory identification number format:

a) Laboratory identification number shall be written in capital letters, Times New Roman, font size 16, bold, regular. The ordinal number shall consist of 3 numerals.

b) The identification number shall be printed in the upper left corner of the test report sheet. The laboratory's designated parameters/tests shall be also printed in the test report sheet.

Article 12. Reference laboratory

Depending on management requirements, relevant Ministries shall designate reference laborotories in compliance with Articles 4 and 5 and other requirements by relevant Ministries.

Chapter IV

FOLLOW-UP INSPECTION, AUDIT

Article 13. Follow-up inspection frequency

1. Regular inspection, audit: once a year.

2. Ad hoc inspection, audit: unscheduled when required by competent authorities.

Article 14. Inter-laboratory comparisons

1. Inter-laboratory comparison organizers shall be accredited to ISO/IEC 17043:2010 or equivalent standard.

2. Competent authorities shall designate an inter-laboratory comparison organizer depending on organizer's capability.

Article 15. Inspection, audit content

1. Document check to laboratory's annual and half-year reports;

2. On-site inspection:

Laboratory shall be informed of the on-site inspection fifteen (15) days before. The audit shall include:

a) Assessing compliance and conformity of the laboratory with the competence requirements set forth in Article 5;

b) Check to procedure for designated parameters/tests. Testing methods shall meet relevant Technical regulation or other regulations in force.

c) Assessing conformity with requirements on document system, procedure for analysis;

d) Check to analysis records;

đ) Making audit report by the form in Appendix 8;

e) Verification of corrective actions, making verification report to the competent authorities. Depending on verification report, the competent authorities shall consider to perform on-site audit to the laboratory in case of necessity.

Article 16. Inspection exemption

1. Laboratories set forth at point đ, Paragraph 3, Article 6 shall be exempt from follow-up inspection when meeting requirements set forth in Article 4, 5 and others of the relevant Ministries.

2. Laboratories mentioned in Paragraph 1 of this Article shall submit a registration for inspection exemption to the competent authorities. The registration includes:

a) A request for inspection exemption;

b) Follow-up inspection report by the accreditation bodies with TCVN ISO/IEC 17025:2007 or ISO/IEC 17025:2005 (within twelve (12) months from the date of request);

c) Laboratory operation report within twelve (12) months from the date of request, declaring result of self-assessment of testing capability in comparison with requirements of relevant Ministries.

3. Within five (5) working days on receipt of completed registration, the competent authorities shall verify the registration and deliver in written the result to the laboratory.

4. Annually, the laboratory shall be exempt from regular inspection, audit in compliance with Paragraph this Article, but still subject to ad hoc inspection, audit by competent authorities.

Article 17. Communication on inspection, audit outcomes

Depending on non-conformities observed during the inspection, audit, the inspection team shall recommend competent authorities to:

1. Require laboratory to carry out and make report on corrective actions;

2. Suspend the designation decision. When the laboratory complete and make report on corrective actions as required by inspection team, competent authorities shall consider to lift the suspension.

3. Withdraw, repeal the designation decision and report the case to relevant Ministry when designated laboratory was dissolved, stopped operations related to designated parameters/tests; missed deadline for corrective actions or unable to correct non-conformities.

Chapter V

RIGHTS AND RESPONSIBILITIES

Article 18. Competent authorities

Article 19. Designated laboratories

1. To make regular and ad hoc reports:

a) Regular reports: half-year reports before 10 July and annual reports before 30 December by the form in Appendix 4.

b) Ad hoc reports: as required by competent authorities.

2. To make report on any changes relating to designation scope within thirty (30) days of the changes. The changes to be reported include:

a) Legal status;

b) Organization structure and leaders;

c) Policy and procedure;

d) Address, telephone, Fax, E-mail;

đ) Personnel, key staff, equipments, facilities, surroundings and other resources affecting quality management system;

e) Corrective actions as required by the form in Appendix 9.

3**.** Other responsibilities:

a) To assure reliability and accuracy of testing results regarding to designated parameters.

b) To be subject to laboratory inspections and audit by internal and external inspection delegations by request of competent authorities.

c) To create good conditions for audit team during the audit.

d) To pay audit and designation fee.

4. Other responsibilities set forth in Article 20, Law on Quality of products and commodities.