## MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT

------No. 38/2018/TT-BNNPTNT SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness

-----

Hanoi, December 25, 2018

#### CIRCULAR

#### PRESCRIBING ASSESSMENT AND CERTIFICATION OF COMPLIANCE WITH FOOD SAFETY REGULATIONS OF AGRO-FORESTRY-FISHERY FOOD MANUFACTURING AND TRADING BUSINESSES UNDER THE MANAGEMENT OF MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT

Pursuant to the Government's Decree No. 15/2017/ND-CP dated February 17, 2017, defining the functions, tasks, powers and organizational structure of the Ministry of Agriculture and Rural Development;

Pursuant to the 2010 Law on Food Safety and the Government's Decree No. 15/2018/ND-CP dated February 22, 2018, elaborating on the implementation of a number of articles of the Law on Food Safety;

Upon the request of the Director of the National Agro-Forestry-Fisheries Quality Assurance Department,

The Minister of Agriculture and Rural Development hereby promulgates the Circular prescribing the assessment and certification of compliance with food safety regulations of agro-forestry-fishery food manufacturing and trading businesses under the management of Ministry of Agriculture and Rural Development.

#### **Chapter I**

## **GENERAL PROVISIONS**

#### Article 1. Scope

This Circular deals with the assessment and certification of compliance with food safety regulations of agro-forestry-fishery food manufacturing and trading businesses under the management of Ministry of Agriculture and Rural Development; responsibilities and authority of parties involved.

#### Article 2. Subjects of application

1. Agro-forestry-fishery food manufacturing and trading businesses that are put under the control of Ministry of Agriculture and Rural Development, except the followings:

a) Small-scale initial production businesses;

b) Food production and trading businesses that do not have fixed locations or fishing vessels with the maximum length of at least 15 meters;

c) Small-scale food processing businesses;

d) Small-scale food trading businesses;

dd) Ready-to-eat food trading businesses;

e) Agro-forestry-fishery production and trading businesses that have already been awarded one of the following certificates: Good Manufacturing Practices (GMP), Hazard Analysis and Critical Control Point (HACCP) System, Food Safety Management System ISO 22000, International Food Standard (IFS), Global Standard for Food Safety (BRC), Food Safety System Certificate (FSSC 22000) or equivalent, all of which must remain valid.

g) Agro-forestry-fishery production and trading businesses that export their products to countries and territories imposing requirements for health certification (food safety certification) granted by competent authorities under the management of the Ministry of Agriculture and Rural Development in accordance with its regulations.

(hereinafter referred to as business).

2. Entities, organizations or individuals whose business activities are related to agro-forestryfishery food product manufacturing and trading activities of those prescribed in clause 1 of this Article.

#### Article 3. Definition

For the purposes of this Circular, terms used herein shall be construed as follows:

1. Extremely serious defect means a deviation from technical standards regulations or national standards or regulations that results in impacts on food safety.

2. Serious defect means a deviation from technical standards or national standards or regulations that will result in impacts on food safety if it lasts long, but is not deemed extremely serious.

3. Minor defect means a deviation from technical standards regulations or national standards or regulations that may cause impacts on food safety or hinder the control of food safety.

4. Agro-forestry-fishery food trading business refers to an entity performing a single, certain or all of activities and services, such as launching, preserving, transporting or trading agro-forestry-fishery food or salt products.

5. Business carrying out the initial manufacturing of an agro-forestry-fishery food product means an entity performing a single, certain or all of activities and services, such as growing, farming, cultivation, harvest, catching and production of agro-forestry-fishery food products and manufacturing of salt products.

6. Tracing of a product origin means a search for the product creation and circulation process.

7. Assessment means an inspection and verification of legitimacy of documentation and actual conditions of food safety of an agro-forestry-fishery food production and trading business.

# Article 4. Bases for assessment of requirements for compliance with food safety regulations

1. National technical regulations and national standards.

2. Legislative documents and regulatory documents related to food safety of agro-forestryfishery products.

## **Article 5. Assessment bodies**

1. Assessment bodies at the central level shall be General Departments or specialized Administrations affiliated to the Ministry of Agriculture and Rural Development that perform tasks assigned by the Ministry of Agriculture and Rural Development.

2. Assessment bodies at the local level shall be designated under decisions of provincial People's Committees, depending on their authority delegated by the Ministry of Agriculture and Rural Development, actual situations of localities and proposals of Departments of Agriculture and Rural Development.

## Article 6. Assessment forms

1. Assessment serving ranking purposes refers to a form of assessment that is carried out upon receipt of a prior notice, is aimed at fully checking and verifying information regarding requirements for compliance with food safety regulations of those business entities stipulated in clause 1 of Article 7 herein. This assessment shall be applied to:

a) Businesses subject to the initial assessment;

b) Businesses that have already been assessed as those satisfying requirements for compliance with food safety regulations, and are repaired or expanded since then;

c) Businesses that have already been assessed as those not satisfying requirements for compliance with food safety regulations and then have already taken actions to correct and remedy defects or defects;

d) Businesses that have already been assessed as those satisfying requirements for compliance with food safety regulations, but have suspended periodic assessments longer than the prescribed duration of 06 months;

dd) Businesses that have already been awarded certificates of compliance with food safety regulations which have been revoked though, or have changed their owners and have changed requirements for their compliance with food safety regulations compared with those determined in the initial assessment.

2. Periodic assessment serving evaluation purposes refers to a form of assessment which is carried out without a prior notice, is applied to businesses that have already been ranked as those meeting requirements for compliance with food safety regulations in order to oversee their maintenance of conformance to requirements for compliance with food safety regulations.

## Article 7. Assessment contents and methods

1. Assessment contents:

a) Facilities, equipment;

b) Personnel participating in food product manufacturing, trading and food safety management activities;

c) Compliance with regulations, national technical standards and regulations on the program for management of food safety and labeling of products;

d) Collection of test samples: The sampling shall be carried out in case there is any suspicion that food products fail to meet requirements for compliance with food safety regulations; shall focus on those businesses that are presumed to attain rank C. Analysis indicators shall be designated based on the evaluation of food safety risks and must focus on matters failing the assessment designed for the purpose of evaluation of requirements for compliance with food safety regulations. The sampling and analysis of samples must be subject to applicable regulations.

2. Method of assessment: Reviewing and evaluating documents, materials and current conditions of conformance to requirements for compliance with food safety regulations, interviewing related persons and carrying out sampling where necessary.

# Article 8. Rating forms

1. Rating forms shall comprise:

a) Rank A (good): Apply to businesses fully conforming to requirements for compliance with food safety regulations.

b) Rank B (satisfactory): Apply to businesses basically meeting requirements for compliance with food safety regulations. Certain defects still exist but do not cause any serious impact on food safety.

c) Rank C (unsatisfactory): Apply to businesses that have not yet conformed to requirements for compliance with food safety regulations.

2. Criteria for detailed ranking of businesses classified by types shall be defined in manuals for assessment, ranking and completion of assessment reports as provided in Appendix II and III hereto.

## Article 9. Assessment frequency rate

Regulations on the frequency rate of assessment serving periodic evaluation purposes shall be applied to agro-forestry-fishery food production and trading businesses as follows:

1. Rank-A businesses: 1 time/ 18 months;

2. Rank-B businesses: 1 time/ 12 months;

3. Rank-C businesses: The time of re-assessment shall vary depending on the degree of defect of each business subject to the assessment and must be decided by the assessment body provided that such re-assessment is made at the time after 3 months from the time of the assessment giving them the rank C. If the time of the assessment coincides with the farming season that has already been completed, the re-assessment shall commence at the beginning of the succeeding season.

## Article 10. Eligibility requirements of the Head and Member of the Assessment Team

1. Eligibility requirements of the Head of the Assessment Team:

a) Have professional qualifications in the assessment sector;

b) Have already completed professional and skill training courses in the assessment sector and other assessor training courses;

c) Have already participated in at least 05 assessments in the assessment sector.

2. Eligibility requirements of the Member of the Assessment Team

a) Have professional qualifications in the assessment sector;

b) Have already taken part in professional and skill training courses in the assessment sector and other assessor training courses.

3. Eligibility requirements of the sampling technician

a) Have appropriate professional qualifications;

b) Hold diplomas or certificates in sampling or obtain diplomas or certificates of completion of sampling training courses.

#### Article 11. Fees

Collection of fees for the assessment serving the purposes of granting food safety certificates, fees for the assessment designed for the periodic evaluation of conformance to requirements for compliance with food safety regulations, and fees for the assessment serving the purposes of testing food safety knowledge, shall be subject to laws on fees and charges.

#### **Chapter II**

## ASSESSMENT AND CERTIFICATION OF COMPLIANCE OF AGRO-FORESTRY-FISHERY FOOD PRODUCTION AND TRADING BUSINESSES WITH FOOD SAFETY REGULATIONS

# Section 1. ASSESSMENT OF AGRO-FORESTRY-FISHERY FOOD PRODUCTION AND TRADING BUSINESSES

# Article 12. Statistics of and update on the list of agro-forestry-fishery food production and trading businesses

On a quarterly basis, the assessment body shall make a statistics of and update on the list of agroforestry-fishery food production and trading businesses under its assigned duties or delegated authority as prescribed in Article 5 herein by using the form given in the Appendix I hereto. The list shall serve as a basis for the assessment body's carrying out the assessment and ranking of requirements for compliance with food safety regulations and the unscheduled inspection in case of any food safety emergency.

#### Article 13. Establishment of the Assessment Team

1. The Heads of the assessment bodies prescribed in Article 5 herein shall be vested with authority to issue decisions on establishment of assessment teams. The decision on establishment of an assessment team shall be comprised of the following information:

- a) Bases for carrying out the assessment;
- b) Assessment scope, contents and forms;
- c) Name and address of the assessed business;
- d) Full name and title of the Head and Members of the Assessment Team;
- dd) Responsibilities of the assessed business and the Assessment Team.

2. In case of assessment of businesses manufacturing and trading multiple groups of agroforestry-fishery food products, the Head of the assessment body assigned to preside over assessment activities shall be responsible for informing related cooperating bodies to request them to assign their staff to participate in the Assessment Team.

## Article 14. On-site assessment

1. The assessment body shall inform the proposed time of assessment based on which the rank of the assessed business is determined 05 working days prior to the assessment.

2. The Assessment Team shall release its establishment decision and clearly state the assessment contents.

3. Carrying out the physical assessment: Checking and verifying documents, materials and actual conditions of facilities, equipment and human resources involved in production and trading activities; conducting interviews and carrying out sampling where necessary as provided in clause 1 of Article 7 herein.

4. Preparing the assessment report and informing the assessment results.

5. In case of discovering that the assessed business commits administrative violations, the Assessment Team shall issue a notice of administrative violation and submit it to the competent person to seek his/her administrative penalty decision in accordance with laws.

## Article 15. Assessment report

1. The assessment report shall be prepared using the form given in Appendix II and II hereto.

2. Requirements of an assessment report:

a) Must be prepared by the Assessment Team at the assessed business immediately after completion of the assessment;

b) Fully and accurately represent the assessment results;

c) Clarify which items fail to conform to food safety requirements and the deadline for taking remedial actions to correct defects;

d) Draw general conclusions on requirements for compliance with food safety regulations and predict the rank of the assessed business;

dd) Give comments of the assessed business' authorized representative on the assessment results and commitments to correcting defects (if any);

e) Carry the signature of the Leader of the Assessment Team, the signature of the assessed business' authorized representative, show the adjoining stamp of the assessed business (if any) in

the assessment report or sign on each page of the assessment report in case the assessed business does not have its registered stamp;

g) In case where the assessed business' authorized representative refuses to sign the assessment report, the Assessment Team must write: "The assessed business' representative has not signed the report" and clearly explain the reasons for such refusal. The assessment report shall have legal value if it bears signatures of all of members of the Assessment Team;

h) The report shall be made into 02 copies, including 01 copy deposited with the assessment body, 01 copy deposited with the assessed business; where necessary, the number of copies may be increased.

#### Article 16. Processing of assessment results

After checking the assessment report submitted by the Assessment Team (where necessary, the on-site physical checking may be carried out), within duration of 07 working days after completion of such checking, the assessment body shall perform the following tasks:

1. As for the assessment carried out for ranking purposes

a) Grant the recognition and inform the assessment results to rank-A or B businesses. As for businesses involved in a variety of goods industries and sectors, the frequency rate of assessment serving periodic evaluation purposes shall be determined by the goods industry or sector holding the lowest rank.

b) Inform penalties for food safety violations in accordance with laws to the rank-C business, request its action to correct defects, inform the deadline for correction of defects and carry out the re-assessment.

2. As for the assessment carried out for periodic evaluation purposes

a) If the assessed business is ranked down to B, informing the assessed business of this and the frequency rate of assessment applied in the next time.

b) If the assessed business is ranked down to C, informing penalties for food safety violations in accordance with laws to this business, requesting its action to correct defects, informing the deadline for correction of defects and carrying out the re-assessment.

3. Granting certificates of compliance with food safety regulations to agro-forestry-fishery food production and trading businesses ranked A or B as prescribed in Article 17 herein.

4. If the test results show that the assessed product violates food safety regulations, the assessment body shall appeal to the competent regulatory authority to impose sanction according to law.

5. The assessment body shall refuse to confer rank-A or rank-B to the assessed business that receives the test results indicating violations against food safety regulations. The decision on whether the recognition of rank A or B is granted shall be issued immediately after the assessed business carries out investigation into causes and take remedial actions, and is assessed by the assessment body to meet requirements for compliance with food safety regulations.

6. The assessment body shall publish businesses meeting or having yet to meet requirements for compliance with food safety regulations via mass media.

## Section 2. CERTIFICATION OF COMPLIANCE OF AGRO-FORESTRY-FISHERY FOOD PRODUCTION AND TRADING BUSINESSES WITH FOOD SAFETY REGULATIONS

# Article 17. Processes, procedures, re-issuance and revocation of certificates of compliance with food safety regulations (hereinafter referred to as food safety certificates)

1. The body having authority to grant food safety certificates must be the assessment body referred to in Article 5 herein according to the principles wherein the body carrying out the assessment of requirements for compliance with food safety regulations of an agro-forestry-fishery food production and trading business is entitled to grant the food safety certificate to that business.

2. Each food safety certificate shall be valid for 3 years. The sample certificate is given in the Appendix IV hereto.

3. Application documentation for food safety certificates shall be comprised of the followings:

a) Application form for food safety certificate, prepared by using the form given in Appendix V hereto;

b) Interpretation of requirements for compliance with food safety regulations of the applicant business, prepared by using the form given in Appendix VI hereto.

4. Processes and procedures for grant of food safety certificates

a) The applicant business submits one set of application documents for food safety certificate to the body having authority to grant food safety certificates as provided in clause 1 of Article 17 herein. The application documentation may be submitted according to one of the following methods: directly, via fax, email or electronic networks (then the original set of these documents must be sent along); by post;

b) Within 03 working days of receipt of application documentation from the applicant business, the body having authority to grant food safety certificates must confirm the adequacy of these submitted documents and inform the applicant business in writing in case their application documents are not sufficient;

c) From the date of receipt of all required documents, the body having authority to grant food safety certificates shall check and verify these submitted documents, rank the applicant business and confer food safety certificates within 07 working days (if the applicant business has been assessed and ranked A or B); conduct the on-site physical assessment of conditions for conformance to requirements for compliance with food safety regulations at the workplace of the applicant business and grant food safety certificates within duration of 15 working days (in case the applicant business has not yet been assessed and ranked). In case of refusal to grant the food safety certificate, they must send a written response clearly stating reasons for such refusal.

5. Re-issue of food safety certificates

a) 6 months before a food safety certificate expires, the business holding this certificate must submit application documentation for re-issue of their certificate if they wish to continue their business activities. Re-issue of food safety certificates shall be subject to regulations laid down in clause 1, 2, 3 and 4 of this Article;

b) In case the food safety certificate remains unexpired but has been lost, damaged, revised or supplemented in terms of information inscribed on food safety certificates, the business must submit the application for re-issue of the food safety certificate by using the form given in Appendix V hereto to the body having authority to grant food safety certificates for its consideration of re-issue thereof.

Within duration of 05 working days of receipt of the application form for re-issue, the body having authority to grant food safety certificates shall check and verify the submitted documentation, and consider re-issuing the food safety certificate. The expiry date of the food safety certificate which is re-issued must coincide with that of the preexisting certificate. In case of refusal to reissue the certificate, the body having authority to re-issue the food safety certificate must issue the written notice clearly stating reasons.

6. Revocation of food safety certificates

a) Food safety certificates of agro-forestry-fishery food production and trading businesses shall be revoked if these businesses fail to meet requirements prescribed in clause 1 of Article 34 in the Law on Food Safety;

b) Authority to revoke food safety certificates

The body having authority to grant food safety certificates shall be authorized to revoke food safety certificates.

7. In case where there are particular regulations on processes and procedures for issue and reissue of food safety certificates to agro-forestry-fishery food production and trading businesses having particular characteristics, and revocation thereof, these regulations shall apply.

# Article 18. Grant of certificates of food safety knowledge to business owners and persons directly manufacturing and trading agro-forestry-fishery food products (hereinafter referred to as food safety knowledge certificate)

1. The body granting food safety knowledge certificates must be the competent bodies prescribed in Article 5 herein according to the principles wherein the body granting food safety certificates is entitled to grant food safety knowledge certificates. The body granting food safety knowledge certificates shall be entitled to assign tasks of and delegate authority over grant of certificates to its affiliates under laws.

2. Persons awarded food safety knowledge certificates

a) Business owners: The business owner or the person hired or authorized by the business owner to directly manage agro-forestry-fishery food business activities;

b) Persons directly involved in business activities: Persons directly involved in stages of manufacturing and trading of agro-forestry-fishery food products at businesses.

3. Persons granted exemption from grant of food safety knowledge certificates: Business owners or persons directly involved in manufacturing and trading agro-forestry-fishery food products must hold suitable educational qualifications in business sectors or industries at the intermediate level or higher and must have taken food safety training programs. Businesses must deposit certified true copies of degrees or professional diplomas and duplicate copies of training courses that these eligible persons have taken.

4. Documentation requirements for grant of food safety knowledge certificates, processes for certification and management of food safety knowledge certificates shall be subject to Article 10, Article 11 and Article 12 in the Joint Circular No. 13/2014/TTLT-BYT-BNNPTNT-BCT dated April 9, 2014 of the Ministry of Health - the Ministry of Agriculture and Rural Development - the Ministry of Industry and Trade on providing guidance on assignment of tasks of and cooperation in the state management of food safety.

5. The assessment and evaluation test on food safety knowledge shall be carried out by using a set of 30 multiple-choice questions, including 20 questions about general knowledge and 10 questions about specialized knowledge, and shall be conducted for the duration of 45 minutes.

6. Materials on food safety knowledge and the set of questions used for assessment of food safety knowledge shall be designed, published or submitted to the Ministry of Agriculture and Rural Development to seek its approval of release thereof by the National Agro-Forestry-Fisheries Quality Assurance Department.

# **Chapter III**

# IMPLEMENTATION ORGANIZATION

# Article 19. People's Committees of centrally-affiliated cities and provinces

1. Designate assessment bodies as prescribed in clause 2 of Article 5 herein based on the recommendations of Departments of Agriculture and Rural Development.

2. Direct Departments of Finance to assess and appeal for approval of annual state budget allocations granted to assessment bodies in accordance with regulations in force.

# Article 20. Departments of Agriculture and Rural Developments in provinces and centrally-affiliated cities

1. Counsel provincial People's Committees to appoint assessment bodies as stipulated in clause 2 of Article 5 herein within their localities.

2. Direct and provide guidance on implementation of this Circular within their jurisdiction on their localities.

3. Report on results of implementation of this Circular to the Ministry of Agriculture and Rural Development (via the National Agro - Forestry - Fisheries Quality Assurance Department) according to the applicable reporting regime.

## Article 21. Centrally-affiliated assessment bodies

1. Provide instructions on assessment in the entire system from the local through central level within their remit.

2. Provide guidance on consistent use of materials, forms and methods of assessment by businesses under their delegated authority. Where necessary, propose, design and appeal to the Ministry of Agriculture and Rural Development to promulgate detailed forms and templates of assessment report relevant to the particular characteristics of each business.

3. Provide professional training and instructions for members of assessment teams.

4. Directly conduct the assessment on and grant the certificate of compliance with food safety regulations to businesses under their authority delegated by the Ministry of Agriculture and Rural Development.

5. Publish the list of businesses conforming or failing to conform to requirements for compliance with food safety regulations under their management on electronic information portals of assessment bodies and the Ministry of Agriculture and Rural Development.

6. Inspect the implementation of this Circular by local assessment bodies.

7. Systematically archive documentation related to the statistics, assessment, evaluation and ranking of businesses within their delegated authority and assigned duties; ensure information security in accordance with regulations in force.

8. Report on results of implementation of this Circular to the Ministry of Agriculture and Rural Development (via the National Agro - Forestry - Fisheries Quality Assurance Department) according to the applicable reporting regime.

## Article 22. Local assessment bodies

1. Conduct the assessment, evaluation and ranking of businesses under their authority delegated by the Ministry of Agriculture and Rural Development and within their duties assigned by provincial People's Committees.

2. Provide professional training and instructions for officers tasked with carrying out assessments.

3. Inform businesses conforming or having yet to conform to requirements for compliance with food safety regulations under their mandate in provinces or cities via mass media.

4. Systematically deposit documentation related to the statistics, assessment and ranking of agroforestry-fishery food production and trading businesses within their delegated authority or assigned duties.

5. Report on results of implementation of this Circular to the Departments of Agriculture and Rural Development in cities or provinces (via National Agro - Forestry - Fisheries Quality Assurance Subdepartments or entities designated by Departments of Agriculture and Rural Development) according to the applicable reporting regime.

# Article 23. Head and members of the assessment team

1. Head of the assessment team

a) Manage and direct members of the assessment body in order to ensure their compliance with the assessment decision.

b) Ensure objectivity, accuracy and authenticity during the assessment process.

c) Sign on the assessment report, report on assessment results and bear responsibility to the head of the assessment body and legal liability for results of the assessment carried out by the assessment team.

d) Arrive at final conclusions of the assessment team on assessment results.

dd) Protect information about undisclosed business information of assessed businesses and protect confidential assessment results before they are recognized and informed by the assessment body.

2. Members of an assessment body

a) Carry out the assessment and evaluation of relevance of food safety requirements of the assessed business to related regulatory technical regulations.

b) Carry out tasks assigned by the head of the assessment team.

c) Comply with procedures, processes and methods for assessment and sampling; ensure the objectivity, accuracy and authenticity during the assessment and sampling process.

d) Bear responsibility and report on implementation of assigned tasks to the head of the assessment team.

dd) Protect information about undisclosed business information of assessed businesses and protect confidential assessment results before they are recognized and informed by the assessment body.

## Article 24. Agro-forestry-fishery food production and trading businesses

1. Assign persons having competence to act as the representative of the assessed business to work with the assessment team.

2. Provide necessary conditions for the assessment team to carry out the assessment and sampling at their workplace; provide a full amount of relevant information, physical samples, documents and materials upon the request of the assessment team.

3. Fully correct defects specified in the assessment report and send written reports to assessment bodies by the deadline defined in the assessment report.

4. Publicly post the assessment report at their workplace.

5. Pay fees for the assessment serving the purposes of granting food safety certificates, fees for the assessment designed for the periodic evaluation of conformance to requirements for compliance with food safety regulations, and fees for the assessment serving the purposes of testing food safety knowledge in accordance with regulations in force.

6. Recall and handle products that do not satisfy food safety requirements in accordance with regulations in force.

7. Have the right to file complaints to the assessment body in case they do not agree to assessment results informed by the assessment team.

8. Inform the assessment body in case of business suspension, dissolution, closure, change of business location, production conditions or business owners.

## **Chapter IV**

## **IMPLEMENTARY PROVISIONS**

## Article 25. Entry into force

1. This Circular shall enter into force from February 7, 2019.

2. This Circular shall replace the Circular No. 45/2014/TT-BNNPTNT dated December 3, 2014 of the Minister of Agriculture and Rural Development on the inspection of agricultural supplies manufacturing and trading businesses, the examination and certification of compliance of agro-forestry-fishery food production and trading business with food safety regulations.

#### Article 26. Amendments and supplements

In the course of implementation of this Circular, if there is any difficulty or query that arises, entities and persons involved shall report to the Ministry of Agriculture and Rural Development to seek its decision on necessary amendments and supplements./.

#### PP. MINISTER DEPUTY MINISTER

Phung Duc Tien