

*Unofficial translation of certain articles*

**Circular 45/2014/TT-BNNPTNT of 03 December 2014 of the Ministry of Agriculture and Rural Development on inspection and certification on food safety conditions of manufacturers and traders of agricultural materials and agro-forestry and fishery products**

**Article 1. Scope**

The Circular lays down the on inspection and certification on food safety conditions of manufacturers and traders of agricultural materials and agro-forestry and fishery products under the management of the Ministry of Agriculture and Rural Development; responsibilities and rights of the concerned parties.

**Article 2. Subjects of application**

3. Manufacturers and traders of agro-forestry-fishery products, including:

a) Primary production establishments of agro-forestry-fishery products having business registration certificates or investment certificates or farm economy certificates; Fishing vessels having main power  $\geq 90CV$ ;

b) Food collecting, handling, processing and trading establishments under the management of the Ministry of Agriculture and Rural Development;

c) Production and trading establishments of ice used for food preservation and processing under the management of the Ministry of Agriculture and Rural Development;

d) Production and trading establishments of equipment, packaging or containing materials related to manufacturers and traders of agro-forestry-fishery products;

đ) Food production establishments under the management of both Ministry of Agriculture and Rural Development and Ministry of Industry and Trade (Paragraph 4, Article 3 of the Joint Circular No. 13/2014/TTLT-BYT-BNNPTNT-BCT of 09 April 2014).

**Article 4. Legal basis for inspection and certification**

1. Vietnamese standards and technical regulations.

2. Legal documents and regulations related to quality of agricultural materials and food safety of agro-forestry-fishery products.

**Article 5. Inspection bodies**

1. Central-level inspection bodies: Are specific departments and directorates under the Ministry of Agriculture and Rural Development according to the assignment of the Ministry of Agriculture and Rural Development.

2. Local-level inspection bodies: To be decided by the Provincial People's Committees based on assignment of the Ministry of Agriculture and Rural

Development, local situation and proposals of the provincial Department of Agriculture and Rural Development.

### **Article 6. Types of inspection**

1. Inspection and classification: means type of inspection with prior notice in order to fully inspect the establishments' food safety conditions; apply for:

a) Establishments are inspected first time (not having Certificate of food safety compliance yet);

b) Establishments which have repaired or upgraded or expanded after having satisfactory inspection results;

c) Establishments implemented corrective actions after having unsatisfactory inspection results;

d) Establishments delayed the regular inspection for more than 06 (six) months after having satisfactory inspection results;

đ) Establishments have changed owners or food safety conditions, or revoked the Certificate of food safety compliance.

2. Regular inspection: means a type of inspection without prior notice, apply for establishments which have satisfactory inspection results in order to supervise the maintenance of their food safety conditions.

3. Irregular inspection: means a type of inspection without prior notice, was applied when:

a) There are complaints of organizations or individuals related to establishments violated of food safety conditions;

b) There is information of consumers or the public media on violations related to food safety conditions;

c) Depending on the management requirements and direction of the competent authorities.

### **Article 7. Inspection contents and method**

1. Inspection contents:

a) Facilities, equipment;

b) Human resources involved in production and management of food safety;

c) The quality management program; standards and labeling regulations in use;

d) Sampling: Sampling is performed when the product is likely to be unsafe. Sampling is focused on establishments classified "C". The testing criteria are decided basing on risk assessment and focused on the unsatisfactory contents of food safety conditions. Sampling and testing samples must be in accordance with current regulations.

2. Inspection methods: Inspect current conditions of facilities, equipment and human resources involved in food production; Inspect documents, files and interview related persons; take samples as needed.

## **Article 8. Classification of establishment**

1. Class “A” (Good): Apply for establishments which fully satisfy the requirements on food safety conditions.

2. Class “B” (Pass): Apply for establishments which basically meet the requirements on food safety conditions, there are still some mistakes but not seriously affect to food safety.

3. Class “C” (Fail): Apply for establishments that fail to meet the requirements on food safety conditions.

The specific criteria for classification of each type of establishments are regulated in the Inspection Minutes issued together with this Circular.

## **Article 9. Follow-up inspection frequency**

2. Inspection frequency applicable to establishments (manufacturers and traders) of agro-forestry and fishery products are prescribed as follows:

a) Class “A”: once per year;

B) Class “B”: twice per year;

C) Class “C”: Inspection frequency depends on time-limit for corrective actions but no later than 3 months from date of inspection. If inspection time is in the end of production season, the re-inspection will be conducted at the beginning of the next season.

## **Article 12. Listing of establishments**

Inspection body shall list of establishments under its management as described in Article 5 by the form in Appendix 5 enclosed with the Circular. The list is basis for inspection body to set up inspection plan.

## **Article 13. Announcement of inspection plan**

1. Inspection for issuance of certificate of compliance: Inspection body shall notify the concerned establishment at least 05 working days prior to the inspection (by one of such means as direct communication, fax, email, post). The inspection plan shall include:

a) Scheduled time of the inspection;

b) Scope, content, method of the inspection

c) Requirement on representative of establishment and documents reserved for the inspection

2. Routine and unexpected inspection, the inspection plan shall be communicated by inspection team at the opening meeting.

## **Article 14. Establishing inspection team**

1. Head of inspection body shall issue decision establishing inspection team that shall include:

a) Legal basis;

b) Scope, content, method of the inspection

- c) Name and address of establishment to be inspected
- d) Full names, positions of inspection team leader and members
- đ) Responsibilities of inspected establishment and inspection team.

2. In case the establishment manufactures/trades various agricultural inputs and agro-forestry and fishery products, head of leading agency shall request relevant agencies to send their staff participating in the inspection team.

#### **Article 15. On the spot inspection**

1. Inspection team shall announce the decision establishing inspection team including the objectives and content of the inspection

2. On the spot inspection (conditions of premise, equipments and staff involving into production and trade), documents check and interview (if necessary), sampling as regulated in Item 1, Article 7 of the Circular

3. Making inspection report, closing meeting and announcement of inspection result.

#### **Article 16. Inspection report**

1. Form of inspection report

a) Establishments of agricultural inputs, rural water: using the form in Appendix II enclosed with the Circular.

b) Establishments of agro-forestry and fishery products: using the forms in Appendix III enclosed with the Circular. The other establishments shall use the form in Appendix IV enclosed with the Circular.

2. Requirements on inspection report

a) Being made on the spot after the inspection completed.

b) Pointing out sufficient and exact inspection findings

c) Indicating deficiencies and deadline for corrective actions

d) Giving out general conclusion on food safety conditions and grade

đ) Including opinions given by authorized representative of establishment about findings and commitment to carry out corrective actions (if any);

e) Including signatures of head of inspection team and authorized representative of establishment; overlapping stamp (if available) of such establishment, otherwise signature in each page;

g) If authorized representative of such establishment does not agree to sign on inspection report, it shall be clearly stated in the report "the representative of establishment did not sign the report" and reasons. Such report shall be still authentic in case of having signatures of all inspection team members.

h) Being duplicated: 1 (one) for inspection body, 1 (one) for establishment, it is possible to increase quantity if necessary.

#### **Article 17. Processing of inspection result**

After verifying the inspection report (it is possible to undertake on-site verification if necessary), within 07 working days from the inspection date, the inspection body shall:

1. Inspection for issuance of certificate of compliance:

a) Approve and notify the inspection result to establishment graded A or B. For establishment manufactures/trades various groups of products, frequency of routine inspection shall be defined upon the lowest graded group of products.

b) Notify and require the C-graded establishment to address deficiencies. Depending on deficiencies of the establishment, the inspection body shall propose the competent agency to handle the violation in accordance with the regulations in force and decide time-limit for corrective actions and timing of re-inspection. If the re-inspection results show that the establishments fail to address deficiencies and continue to be graded C, the inspection body shall notify the competent agency to request the revocation of the establishment's business registration certificate.

2. Routine and unexpected inspection

a) B downgraded establishment: notify the downgrading and frequency of routine inspection imposed on the establishment in the next time.

b) C downgraded establishment: notify and require establishment to address deficiencies. Depending on deficiencies of the establishment, the inspection body shall propose the competent agency to handle the violation in accordance with the regulations in force and decide time-limit for corrective actions and timing of re-inspection. If the re-inspection results show that the establishments fail to address deficiencies and continue to be graded C, the inspection body shall notify the competent agency to request the revocation of the establishment's business registration certificate.

3. Issue Certificate of Compliance for establishment graded A or B as described in Article 18 of the Circular.

4. If the analysis results show that the products violate the regulations on food quality and safety, the inspection body shall propose the competent agency to the violation in accordance with the regulations in force and publish the analysis results on the media.

5. Inspection body shall not recognize establishments graded A or B if the establishments have analysis results violated regulations on food quality and safety. The recognition of establishments graded A or B shall be taken into consideration after the establishments investigate the causes and implement corrective actions and have satisfactory verification taken by the inspection body.

6. Inspection body shall publish the list of non-compliant establishments and list of compliant establishments on the media.

**Article 18. Procedures for issuance, renewal, withdrawal of Certificate of Compliance**

1. Agencies issuing Certificate of Compliance: are the agencies regulated in Article 5 of the Circular. Any agency that carry out inspection shall issue Certificate of Compliance.

2. Certificate of Compliance shall valid for 03 (three) years. The form of Certificate is drawn up in Appendix V of the Circular.

3. Registration dossier for Certificate of Compliance:

a) Registration for Certificate of Compliance by the form in Appendix VI;

b) Business registration certificate or Investment certificate or farm business certificate (apart from fishing vessels with a capacity of above 90 CV): certified copies or copies accompanied with original for comparison;

c) Status report on food safety conditions of establishment by the form in Appendix VII (apart from fishing vessels with a capacity of above 90 CV);

d) List of establishment owner and staffs granted certificate of food safety knowledge validation (endorsed by the establishment);

d) List of establishment owner and staffs granted with medical fitness certificates issued by health centers at the district level upwards (endorsed by the establishment);

4. Procedures for issuance of Certificate of Compliance:

a) Establishment shall submit 01 (one) registration dossier to competent authority as described Item 1, Article 18 of the Circular. The dossier can be submitted by one of such means as in person, via postal, email, fax, electronic mail or online (then the original shall be sent later).

b) Within 03 (three) working days of receipt of registration dossier, inspecting, the competent authority shall review eligibility of the registration document, request for supplemental documents to complete the registration;

c) Within 15 (fifteen) working days of receipt of completed registration dossier, competent authority shall verify the registration documents or perform on site inspection (in case of the initial registration) and issue Certificate of Compliance. In case the establishment fail to be issue Certificate of Compliance, the competent authority shall notify in writting.

5. Renewal of Certificate of Compliance:

a) Six (6) months before the expiry date of the Certificate, the establishment shall submit a dossier for renewal of the Certificate in case of continuation of production and trade.

The competent authority shall renew the Certificate, the validity period of the Cerificate, the dossier and procedures for the renewal of the Certificate in this case are similar to the issuance of the Certificate regulated in Item 1, 2, 3 and 4, Article 18 of this Circular.

b) In cases the Certificate still remain valid but are lost, damaged or missing, or there is any change or supplementation of information on the Certificate, the

establishments shall request the renewal in writing by the form in Appendix V to the competent authority.

Within 5 (five) working days from the receipt date of the written request for renewal of Certificate by establishment, the competent authority shall verify the dossier and consider the renewal. The expiry date of renewed Certificate shall coincide with the one of the previously granted Certificate. In case of refusal, the competent authority shall notify reasons to establishment in writing.

#### 6. Withdrawal of Certificate of Compliance:

a) The establishment shall be withdrawn Certificate of Compliance according to the Article 13 of the Decree 38/2012/ND-CP detailing the implementation of certain articles of Food Safety Law.

b) Competency of withdrawal of Certificate of Compliance: The agency that issued Certificate of Compliance shall be competent to withdraw the Certificate.

7. In case there are specialized regulations on procedures on issuance, renewal, withdrawal of Certificate of Compliance applied to establishments of agro-forestry and fishery products, such regulations shall be imposed on.

### **Article 23. Local inspection body**

1. To organize the inspection, assessment and classification of establishments according to the assignment by the Ministry of Agriculture and Rural Development and the Provincial People's Committees.

2. To organize training, professional guidance for officials assigned to conduct the inspection.

3. To publicly announce on the mass media a list of establishments that are compliant and non-compliant with conditions of quality and food safety under management.

4. To keep documents related to statistics, inspection and classification of establishments under management.

5. To report on the implementation results of this Circular to the provincial / municipal Department of Agriculture and Rural Development (through the provincial/municipal Sub-department of Agro-forestry and Fisheries Quality Assurance) according to the current reporting regime.

### **Article 24. Establishments**

1. Arrange competent persons to represent the establishment to work with the inspection team.

2. To facilitate inspection teams to conduct inspection and sampling; To supply adequate information, evidence, dossiers and relevant documents at the request of inspection teams.

3. To fully address deficiencies stated in the inspection report and send written reports to the inspection body within the time limit stated in the inspection report.
4. To publicly post inspection report at premise.
5. To pay inspection and certification charges and fees according to regulations in force.
6. To recall and handle unsafe products in compliance with legislation in force.
7. To complain with the inspection body in case of disagreement with the inspection results of the inspection teams.
8. To notify the inspection body in case of stopping production, trade, dissolution, change of production place, change of production conditions or change of owner.