

THE MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT

Circular No. 33/2015/TT-BNNPTNT dated October 08, 2015 of the Ministry of Agriculture and Rural Development on regulations on monitoring of food hygiene and safety in harvests of bivalve mollusks

Pursuant to the Law on Product and Goods Quality No. 05/2007/QH12 dated November 21, 2007;

Pursuant to the Law of Food Safety No. 55/2010/QH12 dated June 17, 2010;

Pursuant to the Government's Decree No. 132/2008/ND-CP dated December 31, 2008, detailing the implementation of a number of articles of the Law on Product and Goods Quality;

Pursuant to the Government's Decree No. 38/2012/ND-CP dated April 25, 2012, detailing the implementation of some articles of the Law on Food Safety;

Pursuant to the Government's Decree No. 199/2013/ND-CP dated November 26, 2013 defining the functions, tasks, entitlements and organizational structure of the Ministry of Agriculture and Rural Development;

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

The Minister of Agriculture and Rural Development promulgates the Circular regulating supervision of food safety and hygiene in the harvest of bivalve mollusk.

Chapter I

GENERAL PROVISIONS

Article 1. Scope of adjustment

This Circular regulates content, order and procedures on implementation of the program for monitoring food hygiene and safety in harvests of bivalve mollusk (hereinafter referred to as “Monitoring Program”) at the request of local authorities; responsibilities and authorities of relevant agencies, organizations and individuals in the Monitoring Program.

Article 2. Subject of application



This Circular applies to facilities harvesting, purchasing, cleaning, rearing and processing bivalve mollusks, Inspection Agencies, Controlling Agencies and Testing Facilities.

Article 3. Interpretation of terms

In this Circular, some terms are construed as follows:

1. Bivalve mollusks means species of mollusks that have calcareous shells in common and all are filter feeders including coelenterates, echinoderms and marine gastropods.
2. Areas harvested include territorial waters, estuary or lagoons where bivalve mollusks are raised or naturally distributed and harvested as a source of food.
3. Rearing means activities of keeping bivalve mollusks in the rearing area within a certain period of time to reduce pollution to an appropriate level so that they can be used as food.
4. Rearing area means territorial waters, estuary or lagoons that have clearly defined borders and are marked by floats or other fixed objects.
5. Bivalve mollusk cleaning facilities (Cleaning Facilities) mean places with clean saltwater containers to keep live bivalve mollusks within a certain period of time being used to reduce pollution to an appropriate level so that they can be used as food.
6. Bivalve mollusks harvesting facilities (Harvesting Facilities) mean places where bivalve mollusks are developed, harvested and brought to markets for consumption.
7. Bivalve mollusks purchasing facilities (Purchasing Facilities) mean places where activities of collection, storage and transport of live bivalve mollusks from Harvesting Facilities to consumption areas or to Processing Facilities take place.
8. Bivalve mollusks processing facilities (Processing Facilities) mean places where one or more of the following activities take place: removal of shells and internal organs, heating, smoking, cooking, drying, salting, seasoning, freezing, packaging and storage.
9. Bivalve mollusks rearing facilities (Rearing Facilities) mean places where bivalve mollusks are reared in the rearing areas
10. Biological toxins mean poisonous substance accumulated in bivalve mollusks due to consumption of toxin-containing marine algae.

Article 4. Principles, content and foundations for developing Monitoring Program

1. Principles

Monitoring Program is deployed in harvested areas must meet following conditions:

- a) Harvested areas must have organizations (teams, cooperatives) or individuals to ensure activities of harvesting bivalve mollusks.
- b) Harvested areas must be located within planning area for growing or exploiting aquatic resources by the Ministry of Agriculture and Rural Development and localities.

2. Content

- a) Establish plans for developing Monitoring Program
 - a) Organization of implementation of Monitoring Program includes sampling and testing, notifications of harvesting and post-harvest handling mode, harvesting control, issuance of Certificate of Origin or harvesting control notes, handling of warnings, classification of harvested areas, control on bivalve mollusks outside classified areas.
 - c) Verification of implementation of Monitoring Program;
3. Foundations for developing Monitoring Program include Vietnam's national technical regulations on seafood safety. Exported bivalve mollusks must not only satisfy regulatory requirements of Vietnam but also requirements of exporting countries or provisions set out in International Agreement of which Vietnam is a signatory.

Article 5. Inspection and Controlling Agencies

1. Inspection Agencies being National Agro - Forestry - Fisheries Quality Assurance Department (including affiliated units) shall be responsible for organizing the implementation of Monitoring Program.
2. Controlling Agencies include Branch of Agro - Forestry - Fisheries Quality Assurance or agencies assigned by the Service of Agriculture and Rural Development to manage seafood quality shall be responsible for implementing the sampling of bivalve mollusk and control on the harvesting of bivalve mollusks in localities.

Article 6. Requirements for organizations and individuals taking part in Monitoring Program



1. Persons carrying out sampling and controlling harvesting and officers from inspection and controlling agencies that take part in Monitoring Program must be provided with training in professional competence of food hygiene and safety in harvesting of bivalve mollusks organized by National Agro - Forestry - Fisheries Quality Assurance Department to ensure adequate qualifications for assigned tasks.

2. Testing Facilities taking part in Monitoring Program must satisfy following requirements:

a) Be appointed by competent agencies as prescribed in the Ministry of Agriculture and Rural Development's Circular No. 16/2011/TT-BNNPTNT dated April 01, 2011 regulating assessment, appointment and management of laboratories pertaining to sector of agriculture and rural development and Joint Circular No. 20/2013/TTLT-BYT-BCT-BNNPTNT dated August 01, 2013 by the Ministry of Health, the Ministry of Industry and Trade and the Ministry of Agriculture and Rural Development regulating conditions, order and procedures on appointment of food testing facilities to perform state administration;

b) Satisfy requirements for reference test methods in proportion to test criteria (if any) as prescribed in Appendix 1 enclosed herewith.

3. Bivalve mollusks cleaning and rearing facilities must satisfy requirements for food hygiene and safety as specified in Appendix II enclosed herewith.

Article 7. Expenditure on developing Monitoring Program

Expenditure on activities of inspection and controlling undertaken by inspection and supervision agencies shall be implemented in accordance with current decentralization of state budget. Establishment of cost estimates shall be implemented under the Law on State Budget and guiding documents.

Chapter II

CONDUCTING A SURVEY OF HARVESTED AREAS AND ESTABLISHING PLANS FOR DEVELOPING MONITORING PROGRAM

Article 8. Conducting a survey to bring harvested areas into Monitoring Program

1. Contents of survey:

a) Verify and collect information and figures about biological characteristics, seasons, areas, productivity, growing and exploiting manners, distribution of species of bivalve mollusks; impacts of hydrometeorology, geology and geography on harvested areas;



b) Carry out site survey to identify and assess sources of pollution that may have impact on harvested areas (including industrial production zones, agricultural cultivation areas, husbandry or aquaculture farms, boats, ships and residential areas...);

c) Zone harvested areas;

d) Test samples of bivalve mollusks and water to determine representative sample;

dd) Map harvested areas;

2. Organization of survey:

a) The Service of Agriculture and Rural Development in localities shall make written proposals for the deployment of Monitoring Program according to Forms prescribed in Appendix III enclosed herewith.

b) Within ten working days since receipt of written proposals from the Service of Agriculture and Rural Development, Inspection Agencies shall consider and establish a plan for site survey of harvested areas and issue a written notice about the plan to the Service of Agriculture and Rural Development.

c) Inspection Agencies shall preside over and cooperate with the Service of Agriculture and Rural Development in organizing the survey according to requirements as prescribed in Clause 1 of this Article and Appendix IV enclosed herewith.

3. Process figures and make reports on survey:

Within 15 working days since the survey is completed, Inspection Agencies shall process figures, collect and supplement information (if necessary) and establish reports on survey results according to forms as prescribed in Appendix V enclosed herewith.

4. Handle survey results:

Based on reports on survey results, Inspection Agencies shall send written notice to the Service of Agriculture and Rural Development. Inspection Agencies shall make proposals to the Ministry of Agriculture and Rural Development for bringing harvested areas into Monitoring Program and granting approval for expenditure on deployment of training activities to Controlling Agencies if survey results meet requirements.

Article 9. Survey of classified harvested areas

1. Periodical survey



- a) Every six years, Inspection Agencies shall conduct a survey of harvested areas.
 - b) Content and requirements of survey: as prescribed in Clause 1, Article 8 and Appendix IV enclosed herewith.
 - c) Within 15 working days since the survey is completed, Inspection Agencies shall organize assessment of survey result and consider adjustment of Monitoring Program for harvested areas in case of need. Inspection Agencies must issue a written notice to Controlling Agencies in case adjustment is made to Monitoring Program.
2. Survey of the harvested areas shall be conducted upon finding criteria of E.coli in periodically monitored sample are larger than 46,000 MPN/100g of meat of bivalve mollusks, increase sharply or show abnormal signs (sources of pollution arise, bivalve mollusks die on a mass scale...).

Article 10. Establish annual plan for taking samples for monitoring (hereinafter referred to as the sampling plan)

1. At the beginning of fourth quarter annually, Controlling Agencies shall organize collection of information and figures about harvested areas or adjust the sampling plan to suite actual conditions including:
 - a) Update space area of harvested areas and bivalve mollusks that need to be controlled and make proposals to Inspection Agencies for adjustment of the sampling plan (in case of changes);
 - b) Establish the sampling plan; plan expenditure (from state budget) and send it to Inspection Agencies before November 15 annually;
2. Upon receipt of the plan from Controlling Agencies, Inspection Agencies shall carry out verification and adjustment of the plan as prescribed in Article 11 hereof (if any), compile the plan and send planned expenditure to the Ministry of Agriculture and Rural Development for consideration and approval.
3. Within five working days since the approval is granted by the Ministry of Agriculture and Rural Development, Inspection Agencies shall send a written notice about the sampling plan accompanied by planned expenditure to Controlling Agencies for implementation.

Article 11. Adjustment of sampling plan

1. Inspection Agencies may consider and adjust the sampling plan within Monitoring Program by decreasing frequency of sampling biological toxins at a harvested area or for a specific species of bivalve mollusk if risks of toxins or availability of toxic algae are found low.



2. For harvested areas that have been monitored from three years and over, frequency of microbiological monitoring may be once a month. For off-shore harvested areas (> 5km), Inspection Agencies may consider reducing frequency of taking and monitoring microbiological samples to once per two months if result of classification from three previous years is the same.

Chapter III

IMPLEMENTATION OF MONITORING PROGRAM

Section 1. TAKING AND TESTING SAMPLES, AND CONTROLLING HARVEST

Article 12. Taking and testing samples

1. Based on the approved sampling plan or at the request of Inspection Agencies in case of need, Controlling Agencies shall organize taking and sending samples to Testing Facilities within 48 hours since the time of sampling, and at the same time sending sample information notes (as prescribed in Appendix VI enclosed herewith) to Inspection Agencies.
2. Frequency of sampling as prescribed in Appendix I enclosed herewith.
3. Subjects to be sampled:
 - a) Sample of water for testing poisonous algae (qualitative and quantitative); sample of bivalve mollusks for testing criteria of microbiology, biological toxins and pollutants (if any);
 - b) In case harvested areas have many species of bivalve mollusks, take all their samples;
4. Quantity of bivalve mollusks must satisfy test requirements of Testing Facilities and provisions set out in Point c, Clause 6 of this Article.
5. Requirements for transport to Testing Facilities as prescribed in Appendix VII enclosed herewith.
6. Sample testing:
 - a) Testing Facilities shall conduct the test and provide result to Inspection Agencies within three working days since receipt of sample for criteria of toxic algae, microbiology and biological toxins and no more than four working days since receipt of sample for other criteria in Monitoring Program.
 - b) Test criteria as prescribed in Appendix 1 enclosed herewith or based on specified test criteria of individual samples (if any);

c) Requirements for a test sample: A test sample of bivalve mollusk must satisfy requirements of test method but include at least ten individuals and ensure that minimum quantity of sample is 50g including meat and intracellular fluid.

Article 13. Updating information about harvested areas

Within 01 working day since receipt of test result, Inspection Agencies shall check the result against limits of criteria as prescribed in Appendix I enclosed herewith and handle as follows:

1. Publish and maintain information about permission for harvests on websites of Inspection Agencies when test result of food hygiene and safety criteria falls within permissible limits. Post-harvest handling for bivalve mollusks is prescribed in Appendix VIII enclosed herewith.
2. Update information about conditions of harvested areas (suspending harvested areas, warnings) of Inspection Agencies when test result of food hygiene and safety criteria falls within permissible limits.

Article 14. Control of harvests and issuance of Certificate of Origin, harvest control notes

1. Requirements for bivalve mollusks under Monitoring Program:

a) Bivalve mollusks under Monitoring Program before being launched for consumption must be accompanied by Certificate of Origin or harvest control notes issued as prescribed in Clause 3 of this Article.

b) Bivalve mollusks must be handled after harvest as prescribed in Appendix VIII enclosed herewith; exported bivalve mollusks must be handled after harvest in accordance with requirements of exporting countries in case the exporting country has other requirements for post-harvest handling.

2. Registration for harvests

a) Within one working day before the harvest day, Harvesting Facilities must carry out registration for harvests with Controlling Agencies including following information: time, location, quantity of bivalve mollusks, planned harvests.

b) Registration can be made direct, by post, phone or email.

c) Upon receipt of registration from Harvesting Facilities, Controlling Agencies shall record information in the Register and establish the plan for organizing the control of harvests at the site. Information recorded in the Register includes

name and address of the harvesting facility, time and location of harvests, quantity planned to be harvested.

3. Control of harvests and issuance of Certificate of Origin, harvest control notes:

a) Based on registration from the harvesting facility, written permission for harvests and requirements for post-handling of Inspection Agencies, Controlling Agencies shall organize the control of harvests at the site and at the same time issue Certificate of Origin for controlled batches of raw bivalve mollusks according to forms as prescribed in Appendix IX enclosed herewith. Certificate of Origin is numbered as prescribed in Appendix X enclosed herewith and is made into two copies. One original is issued to the harvesting facility and one copy is kept in Controlling Agencies.

b) In case representative of Controlling Agencies has not signed and affixed its seal on Certificate of Origin, Controlling Agencies shall issue harvest control notes according to forms as prescribed in Appendix XI enclosed herewith for batches of raw bivalve mollusks. The harvest control note is made into two originals. One is issued to the harvesting facility and one is kept in Controlling Agencies. In case raw bivalve mollusks are brought into Processing Facilities, the harvest control note may act in lieu of Certificate of Origin during the transport of such raw material to Processing Facilities.

4. Procedures on changing harvest control notes into Certificate of Origin :

a) Within three working days since the harvest day, representatives of the harvesting facility (or Processing Facilities) must send an original of the harvest control note to Controlling Agencies for issuance of Certificate of Origin.

b) The harvest control note may be sent to Controlling Agencies directly or by post.

c) Within one working day since receipt of the harvest control note, Controlling Agencies shall consider eligibility of the harvest control note and issue Certificate of Origin (if eligible) or otherwise issue a written notice about refusal to issue Certificate of Origin.

Section 2. HANDLING OF WARNINGS IN MONITORING PROGRAM

Article 15. In case density of toxic algae in saltwater exceeds permissible limit but content of biological toxin in bivalve mollusks is yet to exceed permissible limit



In case density of toxic algae in saltwater exceeds permissible limit but content of biological toxin in bivalve mollusks is yet to exceed permissible limit, Inspection Agencies shall:

1. Issue warnings according to forms as prescribed in Appendix XII enclosed herewith along with requests for following handling measures:
 - a) Controlling Agencies shall increase frequency of monitoring toxic algae and biological toxin to 2 - 3 days/time;
 - b) Processing Facilities may launch into the market for consumption or export batches of bivalve mollusks produced from raw material harvested from previous sampling period if test result for biological toxin is satisfactory.
2. Update warnings on the website of Inspection Agencies;
3. Warning regime shall be postponed when test result for toxic algae and biological toxin from the two consecutive reinforced monitoring periods falls within permissible limits. Inspection Agencies shall issue public notice about postponement of warning according to forms as prescribed in Appendix XIII enclosed herewith and update information about harvested areas on the website of Inspection Agencies.

Article 16. In case test result shows biological toxin contained in bivalve mollusks exceeds permissible limit

In case test result shows biological toxin contained in bivalve mollusks exceeds permissible limit, Inspection Agencies shall:

1. Issue warnings about harvested areas and species of bivalve mollusks found with biological toxins according to forms as prescribed in Appendix XII enclosed herewith along with requests for following handling measures:
 - a) Refuse to grant permission for harvests (no issuance of Certificate of Origin) of bivalve mollusks for processing and exportation into EU;
 - b) Controlling Agencies must reinforce sampling and testing toxic algae and biological toxins from 2 – 3 days/time at positions where samples of bivalve mollusks are found with toxins;
 - b) Processing Facilities may launch into the market for consumption or export batches of bivalve mollusks produced from raw material harvested from previous harvest periods if test result for biological toxin test is satisfactory.
2. Update conditions of harvested areas on the website;

3. Harvested areas shall be granted permission for harvests again when test result for toxic algae and biological toxins fall within permissible limits after two consecutive times of reinforced sampling and monitoring.

Article 17. In case pollutants contained in bivalve mollusks exceed permissible limits

In case pollutants of pesticides, heavy metal, PCBs, dioxins and PAHs contained in bivalve mollusks exceed permissible limits, Inspection Agencies shall:

1. Issue warnings about harvested areas and species of bivalve mollusks with pollutants in excess of permissible limits according to forms as prescribed in Appendix XII enclosed herewith along with requests for following handling measures:

a) Refuse to grant permission for harvests (no issuance of Certificate of Origin) of bivalve mollusks for processing and exportation into EU;

b) Controlling Agencies shall increase frequency of sampling and monitoring to 4 months/time;

c) Processing Facilities may launch into the market for consumption or export batches of bivalve mollusks produced from raw material harvested from previous harvest periods if test result for pollutants is satisfactory.

2. Update conditions of harvested areas on the website;

3. Harvested areas shall be granted permission for harvests again when test result falls within permissible limits after one time of reinforced sampling and monitoring.

Article 18. In case Controlling Agencies are unable to get the sample due to suspension from harvests for protection of aquatic resources, weather or no commercial bivalve mollusk sources

1. In case Controlling Agencies are unable to get the sample due to suspension from harvests for protection of aquatic resources, weather or no commercial bivalve mollusk sources, Inspection Agencies shall update information about harvested areas on the website.

2. In case harvests are suspended to protect aquatic resources, Controlling Agencies shall get the sample within one week before the harvested area reopens as planned.

3. Harvested areas shall be officially granted permission for harvests again when test result under monitoring plan is satisfactory.



Article 19. In case test result for microbiology exceeds permissible limits or increases sharply

1. In case test result for periodically monitored sample of bivalve mollusk shows E.coli in 100g meat and intra-cellular fluid of bivalve mollusk is larger than 46,000 MPN:

a) Inspection Agencies shall issue public notice for suspension from harvests, update information about harvested areas on the website and at the same time organize investigation and survey of causes and take sample for verification.

b) In case test result shows E.coli in 100g meat and intra-cellular fluid of bivalve mollusk is less than or equal to 46,000 MPN and result of investigation and survey also shows no increase in sources of pollution and level of pollution, Inspection Agencies shall issue notice about permission for harvests again and update information about harvested areas on the website.

2. In case test result for periodically monitored sample of bivalve mollusk shows E.coli is extraordinarily high (higher than 230 MPN/100g meat and intra-cellular fluid of bivalve mollusk for A Class area, higher than 4,600 MPN/100g meat of bivalve mollusks for B Class area), Inspection Agencies shall:

a) Issue warnings along with requests that criteria of E.coli, Salmonella and Norovirus in the batches of live bivalve mollusks (produced from bivalve mollusks harvested in A Class area in previous sampling period) must be analyzed (According to forms prescribed in Appendix XII enclosed herewith)

b) Organize investigation to find out the causes and take sample for verification; In case test result shows E.coli in 100g meat and intra-cellular fluid of bivalve mollusk is lower than 230 MPN for A Class area and lower than 4,600 MPN for B Class area, and result of investigation shows no increase in sources of pollution and level of pollution, Inspection Agencies shall issue notice about postponement of warning according to forms prescribed in Appendix XIII enclosed herewith. If test result shows E.coli is still extraordinarily high, Inspection Agencies shall re-classify harvested areas and maintain frequency of sampling bivalve mollusks to test criteria of E.coli once a week. Warnings shall be removed when test result shows criteria of E.coli are consistent with classified limits of the harvested area.

3. Upon finding Salmonella, Norovirus present in periodically monitored samples of A Class area, Inspection Agencies shall issue warnings (according to forms prescribed in Appendix XII enclosed herewith) that bivalve mollusks harvested from this area are not permitted to be used as fresh food, and at the same time organize investigation and take samples for verification. Bivalve

mollusks harvested from this area shall be used as fresh food when result of monitoring Salmonella, Norovirus in the next monitoring period is satisfactory.

Section 3. CLASSIFICATION OF HARVESTED AREAS

Article 20. Principles of classification of harvested areas

1. Harvested areas shall be classified on the basis of result of E.coli monitoring as prescribed in Appendix XIV enclosed herewith.
2. For harvested areas with multiple spots for taking representative samples of the same species of bivalve mollusk, Inspection Agencies shall assess result of monitoring at each spot and classify harvested areas on the basis of highest level of E.coli pollution.
3. For harvested areas with multiple species of bivalve mollusk, Inspection Agencies shall decide classification of harvested areas on the basis of highest level of E.coli pollution of species of highest infection rate or classify specific species of bivalve mollusks in harvested areas.

Section 21. CLASSIFICATION OF HARVESTED AREAS

1. Preliminary classification of new harvested areas:
 - a) Preliminary classification is applied to new harvested areas when requirements as prescribed in Appendix XIV enclosed herewith are satisfied.
 - b) Technical requirements for preliminary classification of harvested areas are prescribed in Appendix XIV enclosed herewith.
 - c) Bivalve mollusks in these harvested areas shall be harvested for consumption in the market after appropriate result of classification is available.
2. Initial classification of harvested areas:
 - a) Initial classification is applied to new harvested areas after preliminary classification is made but does not meet requirements as prescribed in Clause 3 of this Article.
 - b) Technical requirements for initial classification of harvested areas are prescribed in Appendix XIV enclosed herewith.
3. Full classification of harvested areas:
 - a) Full classification is applied to harvested areas that have adopted Monitoring Program from one year and over and have at least 24 test samples.
 - b) Technical requirements for full classification of harvested areas are prescribed in Appendix XIV enclosed herewith.

4. Full classification of harvested areas:

After classification of harvested areas is done, Inspection Agencies shall make the updates on their website.

Section 4. CONTROL OF ESCALLOP, MARINE GASTROPODS OUTSIDE CLASSIFIED AREAS

Article 22. Requirements for scallop, marine gastropods harvested outside classified areas

Bivalve mollusk harvesting, purchasing and processing facilities must meet following requirements upon harvesting and treating scallop (under pectinidae family) and marine gastropods harvested outside classified areas as prescribed in Appendix XIV enclosed herewith:

1. Scallop and marine gastropods shall be launched into the market for consumption after being processed to meet food safety conditions as prescribed by the Ministry of Agriculture and Rural Development; products that meet requirements for microbiology, biological toxins as prescribed in Appendix 1 enclosed herewith shall be proved by food quality and safety control system of facilities. Requirements for control of biological toxins as prescribed in Appendix XV enclosed herewith.

2. Before scallop or marine gastropods are processed, Processing Facilities should make written notice to Inspection Agencies for consideration and establishing plans to take samples for verification (hereinafter referred to as sampling plan) as prescribed in Article 23 hereof.

3. Upon carrying out treatment of scallop and marine gastropods, Processing Facilities should comply with following requirements:

a) Batches of raw scallop and marine gastropods must be accompanied by Origin declaration sheet according to forms as prescribed in Appendix XVI enclosed herewith;

b) Packaging scallop and marine gastropods for retails should satisfy requirements for labeling according to applicable regulations.

Article 23. Taking samples for verification and handling of verification result

1. Processing Facilities must send written notice about plans for treating scallop and marine gastropods (by stage) to Inspection Agencies at least one (01) working day before the treatment takes place.



2. Upon receipt of notice from Processing Facilities, Inspection Agencies shall carry out consideration, making plans and take samples of scallop and marine gastropods for verification as prescribed in Appendix XVII enclosed herewith. Verification of samples may be carried out in combination with inspection of food safety conditions or taking test samples of batches of bivalve mollusks as prescribed in the Ministry of Agriculture and Rural Development's Circular No. 48/2013/TT-BNNPTNT dated November 12, 2013 regulating inspection and certification of food safety for exported seafood.

3. Handling of verification result:

a) In case verification result is satisfactory, Inspection Agencies shall make notifications to facilities

b) In case verification result is not satisfactory, Inspection Agencies shall make notifications to facilities and request the facilities to temporarily suspend harvests of scallop and marine gastropods in the areas where result of verification is not satisfactory and take appropriate remedial measures for batches of products produced from such non-conformable raw material. Inspection Agencies shall grant permission for harvests when sample is taken for verification again and the result is found satisfactory.

Section 5. VERIFICATION OF IMPLEMENTATION OF MONITORING PROGRAM

Article 24. Verification of the implementation of Monitoring Program by Controlling Agencies and Testing Facilities

1. Frequency of verification is once a year (or irregularly if necessary). Inspection Agencies shall organize verification of the implementation of Monitoring Program by Controlling Agencies and Testing Facilities.

2. Contents of verification:

a) For Controlling Agencies, following activities shall be placed under the verification: establishing control plans, taking samples and dispatching samples, controlling harvests, issuing certificates of origin and harvest control notes.

b) For Testing Facilities, following activities shall be placed under the verification: receiving samples, testing samples and announcing test result.

Article 25. Verification of the implementation of Monitoring Program by facilities cleaning, rearing, purchasing and processing bivalve mollusks

1. Frequency of verification is once a year (or irregularly if necessary). Inspection Agencies shall preside over and cooperate with Controlling Agencies in verifying compliance with provisions set out hereof by facilities cleaning,



rearing, purchasing and processing bivalve mollusks. The verification may be carried out in combination with the verification of implementation of Monitoring Program by Controlling Agencies or inspection of food safety conditions of facilities, testing samples of batches of bivalve mollusks as prescribed in the Ministry of Agriculture and Rural Development's Circular No. 48/2013/TT-BNNPTNT dated November 12, 2013 regulating inspection and certification of food safety for exported seafood.

2. Contents of verification:

- a) Origin of raw bivalve mollusks;
- b) Performance of post-harvest handling in facilities;
- c) Conformity between quantity of raw bivalve mollusks received and actual production capacity of facilities;
- d) Conformity between HACCP (Hazard Analysis and Critical Control Points) (if any) and facilities' actual production of bivalve mollusks;
- dd) Take samples of bivalve mollusks from facilities to verify biological toxins and microbiology and other pollutants in case of need;

Article 26. Handling of violations after verification

1. For Controlling Agencies, Inspection Agencies shall take handling measures (including temporary suspension from Monitoring Program in the administrative division) and issue written requests to the Service of Agriculture and Rural Development for taking appropriate measures in case Controlling Agencies are found to have committed one of following violations:

- a) Failure to control harvests and issue Certificate of Origin and harvest control note for batches of raw bivalve mollusks harvested in the areas within local Monitoring Program;
- b) Issuance of Certificate of Origin without organization of harvest control;
- c) Issuance of Certificate of Origin for batches of raw bivalve mollusks of species that are not controlled under local Monitoring Program, or bivalve mollusks from areas suspended from harvests, or bivalve mollusks from harvested areas outside local management;
- d) Falsification of figures and documents on implementation of Monitoring Program in localities;
- dd) Failure to organize activities of taking samples from harvested areas within local Monitoring Program;

During the time Controlling Agencies halt Monitoring Program to correct and remedy the mistakes, Inspection Agencies shall be directly involved in organization and implementation of activities of developing Monitoring Program by Controlling Agencies in the administrative division.

2. For Testing Facilities, Inspection Agencies shall take handling measures (including temporary suspension from testing activities under Monitoring Program) and issue written requests to Testing Facilities for taking appropriate remedial measures in case Testing Facilities are found to have violated provisions set out in Article 30 hereof.

3. For facilities cleaning, rearing, purchasing and processing bivalve mollusks, Inspection Agencies shall take appropriate handling measures according to applicable regulations in case such facilities are found to have violated provisions as prescribed in Articles 31, 32, 33 and 34 hereof.

4. For temporary suspension from Monitoring Program as prescribed in Clauses 1, 2 of this Article, within 15 working days since receipt of reports on correction and remedy of mistakes from the Service of Agriculture and Rural Development or from Testing Facilities, Inspection Agencies shall carry out verification of the reports (including site verification if necessary). Within five working days after verification, Inspection Agencies shall issue a written notice about whether permission for participation again in Monitoring Program is granted or not.

Chapter IV

RESPONSIBILITY AND AUTHORITY OF AGENCIES, ORGANIZATIONS AND INDIVIDUALS RELATED TO MONITORING PROGRAM

Article 27. National Agro - Forestry - Fisheries Quality Assurance Department

1. Establish and issue a handbook instructing implementation of technical requirements for execution of provisions set out hereof;
2. Periodically, update and publicly announce testing criteria and limits of testing criteria in Monitoring Program in accordance with laws of Vietnam and importing countries
3. Preside over and organize implementation, provide guidance on implementation and verification of the implementation of this Circular;
4. Based on actual circumstances, preside over and cooperate with relevant agencies in organizing survey of harvested areas to establish and adjust



Monitoring Program to suit realities and make the submission to the Ministry of Agriculture and Rural Development for approval;

5. Annually, update and publicly announce lists of harvested areas and classify harvested areas (if any);
6. Manage, use and allocate budget approved by the Ministry of Agriculture and Rural Development according to the Ministry of Finance's applicable regulations;
7. Preside over and organize training courses in professional competence of monitoring food hygiene and safety in harvests of bivalve mollusks for personnel of Inspection Agencies and Controlling Agencies;
8. Make annual reports on performance of Monitoring Program in harvests of bivalve mollusks to the Ministry of Agriculture and Rural Development.
9. International cooperation: Receive and work with inspectorate from competent agencies of importing countries; report and supply information at the request of competent agencies of importing countries; negotiate and sign cooperation documents with competent agencies of importing countries for the implementation of Monitoring Program as assigned by the Ministry of Agriculture and Rural Development;

Article 28. The Service of Agriculture and Rural Development participating in Monitoring Program

1. Direct Controlling Agencies to preside over and organize implementation of Monitoring Program in harvested areas within the administrative division;
2. Guarantee capability of Controlling Agencies to perform duties (policies, human resources, budget, means and facilities)
3. Direct Controlling Agencies to disseminate provisions set out hereof and provisions on monitoring in localities to facilities harvesting, cleaning, rearing, purchasing and processing bivalve mollusks in administrative division;
4. Annually, based on actual fluctuation of bivalve mollusk sources in localities, make proposals to Inspection Agencies for investigation or adjustment to scale of monitoring harvested areas under Monitoring Program for the following year;
5. Upon receipt of warnings or notice about suspension of harvests issued by Controlling Agencies, direct relevant affiliates to cooperate with Controlling Agencies in tightening control and preventing harvests of bivalve mollusks in suspended areas until permission is issued again.



Article 29. Controlling Agencies

1. Annually, preside over and organize collection of information from harvested areas within management to for the establishment of sampling plan and planned budgets as prescribed in Article 10 hereof.
2. Establish statistical reports on facilities harvesting, cleaning, rearing, purchasing and processing bivalve mollusks within management and make notifications to facilities about scope and species of bivalve mollusks under annual Monitoring Program in the administrative division;;
3. Preside over and organize taking and dispatching samples to Testing Facilities under approved plan or at the request of Inspection Agencies;
4. Make notifications of harvesting and post-harvest handling mode of Inspection Agencies to facilities harvesting, cleaning, rearing, purchasing and processing bivalve mollusks within local management;
5. Organize inspection and prevent harvests of bivalve mollusks in suspended areas and transport of bivalve mollusks from uncontrolled areas to controlled areas;
6. Organize verification of implementation of harvesting mode in individual harvested areas under Monitoring Program; issue Certificate of Origin, harvest control note according to provisions prescribed in Clauses 3, 4, Article 14 hereof;
7. Upon receipt of notice about suspension of harvests issued by Controlling Agencies, immediately cooperate with local functional agencies in tightening control and preventing harvests of bivalve mollusks in suspended areas until permission is issued again.
8. Establish statistical reports and retain figures about harvests of bivalve mollusks in individual harvested areas, harvest control documents (Certificate of Origin, harvest control notes and warning notices...)
9. Cooperate with Inspection Agencies in organizing training courses in monitoring food hygiene and safety in harvests of bivalve mollusks; provide guidance on provisions set out hereof to facilities purchasing, cleaning, rearing and processing bivalve mollusks within local management;
10. Reporting mode:
 - a) Make monthly reports on performance of harvest control in localities to Inspection Agencies (according to forms prescribed in Appendix XVIII enclosed herewith);

- b) Every six months, make reports on performance of harvest control in localities to the Service of Agriculture and Rural Development;
- c) Before December 25 annually, make reports on yearly performance of harvest control in localities to Inspection Agencies;
- 11. Instruct and request relevant entities to comply with sampling mode under Monitoring Program;
- 12. Conduct periodical inspection and monitoring of food hygiene and safety conditions of facilities cleaning and rearing bivalve mollusks as assigned;
- 13. Communicate and provide information about test samples in violation to media agencies as prescribed by the Ministry of Agriculture and Rural Development, People's committees of provinces and within authorities assigned;
- 14. Collect fees and charges for harvest control, issuance of Certificate of Origin according to the Ministry of Finance's applicable regulations;

Article 30. Testing Facilities

1. Responsibilities:

- a) Comply strictly with testing process, ensure testing capability, confidentiality of information about test result as prescribed;
- b) Ensure test result is accurate, objective and honest; use reference test methods in proportion to test criteria as prescribed in Appendix 1 enclosed herewith;
- c) Report test result to Inspection Agencies and satisfy sample testing time under Monitoring Program as prescribed (in case samples are sent by Inspection Agencies or Controlling Agencies);
- d) Be responsible for test result under Monitoring Program;
- dd) Take part in test programs at the request of the Ministry of Agriculture and Rural Development or Inspection Agencies;
- e) Store documents, materials concerning testing activities as prescribed and present it at the request of Inspection Agencies;

2. Authorities:

- a) Reject samples that are technically unsatisfactory; reject to test samples and criteria outside certified scope;
- b) Be provided with information about samples under Monitoring Program and training courses to enhance testing capability (if requested);



c) Collect fees, charges for tests as prescribed;

Article 31. Harvesting Facilities

1. Carry out registration for harvests, sampling, harvest control and issuance of Certificate of Origin or harvest control note as prescribed hereof;
2. Be provided with training courses associated with Monitoring Program organized by Inspection Agencies, Controlling Agencies and other relevant units;
3. Establish procedures on traceability and product recall as prescribed in the Ministry of Agriculture and Rural Development's Circular No. 03/2011/TT-BNNPTNT dated January 21, 2011 regulating tracing and recalling products failing to meet food quality and safety requirements in fisheries and other relevant provisions; store documents about tracing, production and food safety control in facilities;
4. Pay fees and charges for harvest control, issuance of Certificate of Origin to Controlling Agencies as prescribed;

Article 32. Cleaning and rearing facilities

1. Obey post-handling mode as prescribed hereof and instructions provided by Inspection Agencies;
2. Bring fresh and cleaned bivalve mollusks to the market for consumption after Controlling Agencies issue Certificate of Origin or harvest control note;
3. Maintain food safety conditions during the process of cleaning, rearing bivalve mollusks and storing relevant documents;
4. Be provided with training courses associated with Monitoring Program organized by Inspection Agencies, Controlling Agencies and other relevant units;
5. Implement provisions as prescribed in Clause 3, Article 31 hereof;

Article 33. Purchasing Facilities

1. Be provided with training courses associated with Monitoring Program organized by Inspection Agencies, Controlling Agencies and other relevant units;
2. Receive Certificate of Origin or harvest control note issued to individual batches of raw bivalve mollusks;



3. Comply with provisions on food safety in purchase, preservation and transport of raw bivalve mollusks as prescribed by the Ministry of Agriculture and Rural Development;

4. Implement provisions as prescribed in Clause 3, Article 31 hereof;

Article 34. Processing Facilities

1. Do not use bivalve mollusks with unclear origin or harvested in suspended areas as raw material for processing; Only process batches of raw material with food safety conditions being fully ensured and apply post-handling mode as notified by Inspection Agencies;

2. Comply with provisions on food safety conditions in fishery processing prescribed by the Ministry of Agriculture and Rural Development and store relevant documents adequately;

3. Be provided with training courses associated with Monitoring Program organized by Inspection Agencies, Controlling Agencies and other relevant units;

4. Implement provisions as prescribed in Clause 3, Article 31 hereof;

Chapter V

IMPLEMENTARY PROVISIONS

Article 35. Implementation effect

1. This Circular takes effect on December 10, 2015.

2. This Circular supersedes the Ministry of Agriculture and Rural Development's Decision No. 131/2008/QĐ-BNN dated December 31, 2008 promulgating the regulation on monitoring hygiene and safety in harvests of bivalve mollusks and annuls Circular No. 23/2011/TT-BNNPTNT dated April 06, 2011 amending and supplementing a number of articles concerning administrative procedures in fishery management according to Resolution No. 57/NQ-CP dated December 15, 2010.

Article 36. Amendments and supplements

National Agro - Forestry - Fisheries Quality Assurance Department shall be responsible for compiling difficulties and shortcomings arising during the implementation of this Circular and reporting to the Ministry of Agriculture and Rural Development for amendments and supplements as appropriate (if any).

The Minister

Cao Duc Phat

