

No.: 28/2019/TT-BNNPTNT

Hanoi, December 31, 2019

CIRCULAR

TECHNICAL REQUIREMENTS FOR TESTING FOR CHEMICALS AND ANTIBIOTICS BANNED FROM BEING USED IN FISHERY FOODS

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

Pursuant to the Law on Food Safety dated June 17, 2010;

Pursuant to the Government's Decree No. 15/2018/ND-CP dated February 02, 2018 on elaboration of the Law on Food Safety;

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

The Minister of Agriculture and Rural Development promulgates a Circular providing technical requirements for testing for chemicals and antibiotics banned from being used in fishery foods.

Chapter I

GENERAL PROVISIONS

Article 1. Scope

1. This Circular provides technical requirements for testing for some indicators of chemicals and antibiotics banned from being used in fishery foods with prescribed minimum required performance levels (MRPL) under the management of the Ministry of Agriculture and Rural Development.
2. Exported fishery foods shall conform to domestic regulations of importing countries and not be governed by this Circular.

Article 2. Regulated entities

1. Food testing laboratories that serve the state management tasks, are designated by Ministry of Agriculture and Rural Development and qualified to test for chemical and antibiotic indicators in fishery foods according to the Joint Circular No. 20/2013/TTLT-BYT-BCT-BNNPTNT dated August 01, 2013 (hereinafter referred to as “testing laboratories”).
2. Regulatory authorities, organizations and individuals involving in the testing for fishery foods and fishery food safety authorities.
3. Organizations and individuals producing and/or trading fishery foods.

Article 3. Interpretation of terms

For the purposes of this Circular, the terms below are construed as follows:

1. “ β error” is the probability that the tested sample is truly non-compliant even though a compliant measurement has been obtained.
2. “detection capability ($CC\beta$)” means the smallest content of the substance that may be detected, identified and/or quantified in a sample with a β error. In the case of substances with no permitted limit, the detection capability is the lowest concentration at which a method is able to detect truly contaminated samples with a statistical certainty of $1 - \beta$.
3. “Minimum required performance limit (MRPL)” means the minimum content of an analyte in a sample, which at least has to be detected and confirmed. It is intended to harmonize the analytical performance of methods for substances for which no permitted limit has been established.

Chapter II

TECHNICAL REQUIREMENTS FOR TESTING FOR CHEMICALS AND ANTIBIOTICS BANNED FROM BEING USED IN FISHERY FOODS

Article 4. MRPLs and $CC\beta$ values for some chemicals and antibiotics banned from being used in fishery foods

1. MRPLs for some chemicals and antibiotics banned from being used in fishery foods are provided for in the Appendix enclosed herewith.
2. The $CC\beta$ value for a chemical or antibiotic banned from being used in fishery foods must be less than or equal to (\leq) the corresponding MRPL prescribed in the Appendix enclosed herewith.

Article 5. Requirements to be satisfied by testing laboratories

Each testing laboratory is required to:

1. Meet the requirements for testing laboratories laid down in Article 4 and Article 5 of the Joint Circular No. 20/2013/TTLT-BYT-BCT-BNNPTNT dated August 01, 2013.
2. Determine $CC\beta$ values of testing methods according to Section 3.1.2.6 of the Annex enclosed with the Decision No. 2002/657/EC dated August 17, 2002 of the European Commission, and specify $CC\beta$ values for banned chemicals/antibiotics in corresponding test reports.
3. Be assessed and designated by a competent authority to perform testing for some chemicals and antibiotics banned from being used in fishery foods with established permitted MRPLs in order to serve the performance of food safety management tasks by the Ministry of Agriculture and Rural Development as prescribed herein.

Article 6. Announcement of test results and actions against fishery foods

Testing laboratories shall announce test results by using the form of test report provided in Appendix 3 enclosed with the Joint Circular No. 20/2013/TTLT-BYT-BCT-BNNPTNT dated August 01, 2013 and take actions against fishery foods according to 3 circumstances as follows:

1. In case the test value for banned chemicals/antibiotics for the fishery food shipment/batch is smaller than ($<$) the $CC\beta$ value, “no detection” phrase shall be specified in the test report, and that shipment/batch may be sold on the market.
2. In case the test value for banned chemicals/antibiotics for the fishery food shipment/batch is higher than or equal to (\geq) the $CC\beta$ value but smaller than ($<$) the MRPL, the phrase “higher than or equal to the $CC\beta$ value but smaller than the MRPL” shall be specified in the test report, the entity producing and/or trading fishery foods is allowed to sell that shipment/batch on the market and must keep all documents about that shipment/batch.

If the test reports containing the phrase “higher than or equal to the $CC\beta$ value but smaller than the MRPL” are given to 04 batches with the same type of fishery foods and testing indicator within a period of 06 consecutive months, the entire food safety control system must be intermediately reviewed to find out appropriate remedial measures against non-compliant contents (if any).

3. In case the test value for banned chemicals/antibiotics for the fishery food shipment/batch is higher than or equal (\geq) the MRPL, the phrase “exceeding the MRPL” shall be specified in the test report, the origin of foods must be traced and any unqualified fisher food shipments/batches must be recalled and handled according to Article 54 and Article 55 of the Law on food safety.

Chapter III

RESPONSIBILITY OF RELEVANT PARTIES

Article 7. Responsibility of testing laboratories

1. Ensure the satisfaction of technical requirements for testing in Article 5 hereof.
2. Ensure the reliability and precision of test results and provide test results according to Article 6 hereof.
3. Comply with regulations on periodical and ad-hoc reports and bear the inspection of testing activities by regulatory authorities in charge of assessing and designating testing laboratories to serve state management tasks.

Article 8. Responsibility of organizations and individuals producing and/or trading fishery foods

1. Take actions against fishery foods as prescribed in Article 6 hereof.
2. Keep all documents about tested shipments/batches of fishery foods, take actions against fishery foods and submit reports thereof to food safety authorities as requested. Retention period of documents must be conformable with the expiry date of each type of fishery foods as prescribed in QCVN 02 - 02: 2009/BNNPTNT - National technical regulation - Fisheries Food Business Operators –HACCP-based Program for Quality and Safety Assurance.

Article 9. Responsibility of regulatory authorities in charge of assessing and designating testing laboratories

1. Provide professional training and drilling courses for testing laboratories.
2. Update regulations on MRPLs for chemicals and antibiotics banned from being used in fishery foods according to this Circular.
3. Assess and designate testing laboratories to perform testing for chemicals and antibiotics banned from being used in fishery foods with permitted MRPLs.

Article 10. Responsibility of food safety authorities

Regulatory authorities shall examine the compliance by organizations and individuals producing and/or trading fishery foods with provisions in Article 6 hereof when carrying out inspections, and the satisfaction of food safety conditions as prescribed.

Chapter IV

IMPLEMENTATION PROVISIONS

Article 11. Effect

1. This Circular comes into force from February 13, 2020.
2. Difficulties that arise during the implementation of this Circular should be reported to the Ministry of Agriculture and Rural Development for consideration./.

**PP. MINISTER
DEPUTY MINISTER**

Phung Duc Tien

APPENDIX

**MRPLs FOR SOME CHEMICALS AND ANTIBIOTICS BANNED FROM BEING
USED IN FISHERY FOODS**

*(Enclosed with Circular No. 28/2019/TT-BNNPTNT dated December 31, 2019 of the
Minister of Agriculture and Rural Development)*

No.	Name of chemical/ antibiotic	MRPL
1	Chloramphenicol	0,3 µg/kg
2	Nitrofurans metabolites <i>(including Nitrofurazon, Nitrofurantoin, Furazolidone, Furaltadon)</i>	1 µg/kg for each metabolite
3	Total Malachite Green, Leuco-Malachite Green	2 µg/kg

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