

# **PHILIPPINE NATIONAL STANDARD**

PNS/BAFS 89:2021  
ICS 67.120.30

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## **Live and Raw Bivalve Molluscs – Product Standard**



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## Foreword

The Integrated Services for the Development of Fisheries and Aquaculture (ISDA) Inc. and Southeast Asian Fisheries Development Center/Aquaculture Department (SEAFDEC/AQD) requested the DA-Bureau of Agriculture and Fisheries Standards (BAFS) to review and amend, if applicable, the PNS Live and Raw Bivalve Molluscs (PNS/BAFPS 89:2011) to harmonize with Codex Standard for Live and Raw Bivalve Molluscs (CXS 292-2008 Rev. 2015). In 2020, the BAFS initiated the amendment of PNS/BAFPS 89:2011 to align with the Codex standard CXS 292-2008 Rev. 2015.

A Technical Working Group (TWG) was created through Special Order (SO) No. 442, series of 2020 (Creation of Technical Committees and its TWGs for the Development of PNS for Agriculture and Fisheries Products, Machinery, and Structures) and SO No. 81, series of 2021 (Creation of TWGs for the Development of PNS for Agriculture and Fishery Products, Machinery, and Equipment) to provide scientific advice to the amended PNS. The TWG was composed of representatives from relevant government agencies, academe, research institution, non-government organization, civil society organizations, and private sector organizations. The draft PNS underwent a series of consultations and TWG meetings via online platforms before it was finalized and endorsed to the DA Secretary for approval.

This PNS/BAFS edition includes the following significant changes compared to the previous PNS/BAFPS 89:2011:

1. Amendment of title to “Live and Raw Bivalve Molluscs – Product Standard”
2. Inclusion of a normative reference;
3. Inclusion of the definitions for “freezing”, “live bivalve molluscs”, “raw bivalve molluscs”, and “relaying”;
4. Deletion of the definitions for “food additives” and “ingredient”;
5. Amendment of the definition for “bivalve molluscs”, “contaminant”, “deuration”, “glaze”, “label”, “lot”, and “retail”;
6. Harmonization of minimum requirements and contaminants with the provisions of the Codex Standard CXS 292-2008 Rev. 2015; and
7. Inclusion of microbiological safety requirements and method of analysis in bivalve molluscs.

In the amendment of this standard, the Codex Standard for Live and Raw Bivalve Molluscs (CXS 292-2008 Rev. 2015) was generally adopted with modifications to suit the local conditions in the Philippines.

This Standard cancel and replaces PNS/BAFPS 89:2011 which has been technically amended. This document was drafted in accordance with the editorial rules of the BPS Directives Part 2.

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## 1 Scope

This standard applies to both live and raw bivalve molluscs that have been shucked, chilled, frozen, or post-harvest treated to reduce human pathogenic microorganisms while essentially retaining their sensory characteristics. Raw bivalve molluscs are marketed either in chilled or frozen state. Both live and raw bivalve molluscs may be intended for direct consumption or further processing.

This standard includes economically important bivalve species and does not include species of scallops, which is covered in a separate standard (PNS/BAFS 240:2018: Fresh and quick frozen raw scallop products).

## 2 Normative References

The following documents are referred to in the text in such a way that some or all of their contents constitute requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

Bureau of Fisheries and Aquatic Resources (BFAR) – Department of Agriculture (DA). (2017). Philippine national shellfish sanitation manual for the production of safe bivalve molluscs. [https://issuu.com/naniegonzales/docs/bfar\\_pnssp](https://issuu.com/naniegonzales/docs/bfar_pnssp)

Codex Alimentarius Commission (CAC). (1999). Guidelines for the sensory evaluation of fish and shellfish in laboratories (CAC/GL 31-1999). [http://files.foodmate.com/2013/files\\_1771.html](http://files.foodmate.com/2013/files_1771.html)

CAC. (2004). General guidelines on sampling (CAC/GL 50-2004). [http://files.foodmate.com/2013/files\\_1787.html](http://files.foodmate.com/2013/files_1787.html)

CAC. (2015). Standard for live and raw bivalve molluscs (CXS 292-2008 Rev. 2015). [http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXS%2B292-2008%252FCXS\\_292e\\_2015.pdf](http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXS%2B292-2008%252FCXS_292e_2015.pdf)

CAC. (2018). Maximum Residue Limits (MRLs) and Risk Management Recommendations (RMRs) for residues of veterinary drugs in foods (CX/MRL 2-2018). <http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXM%2B2%252FMRL2e.pdf>

CAC. (2019). General Standard for Contaminants and Toxins in Food and Feed (GSCTFF) (CXS 193-1995 Rev. 13). [http://www.fao.org/input/download/standards/17/CXS\\_193e\\_2015.pdf](http://www.fao.org/input/download/standards/17/CXS_193e_2015.pdf)

European Commission (EC). (2005). Commission regulation on microbiological criteria for foodstuffs (EC 2073/2005). <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02005R2073-20140601&from=DA>

Food and Drug Administration (FDA) - Department of Health (DOH). (2013). Revised guidelines for the assessment of microbiological quality of processed food. Table 11. Fish and fishery products – fresh and frozen bivalve molluscs (DOH-FDA Circular No. 2013-010). <https://www.fda.gov/wp-content/uploads/2021/03/FDA-Circular-No.-2013-010.pdf>

### **3 Terms and Definitions**

For the purposes of this document, the following terms and definitions apply:

#### **3.1**

##### **biotoxins**

poisonous substances naturally present in fish and fishery products or accumulated by the animals feeding on toxin producing algae or in water containing toxins produced by such organisms

#### **3.2**

##### **bivalve molluscs**

group of soft-bodied organisms with muscular foot and siphons and are enclosed in two-part hinged shells

#### **3.3**

##### **contaminant**

any biological or chemical agent, foreign matter or other substances not intentionally added to food that may compromise food safety or wholesomeness

#### **3.4**

##### **depuration**

process of holding live bivalve molluscs for a period of time under approved, controlled conditions in natural or artificial seawater suitable for the process, which may be treated or untreated, to reduce microorganisms to an acceptable level

#### **3.5**

##### **freezing**

process that is carried out in appropriate equipment in which the initial temperature of the product is reduced to -18°C or below with most of the tissue water turning into ice. The process shall not be regarded complete until the product temperature has reached -18°C or below at the thermal center after thermal stabilization

#### **3.6**

##### **glaze**

application of a layer of ice to the surface of a frozen product by spraying it with, or dipping it into chilled potable water or chilled clean seawater

#### **3.7**

##### **label**

display of written, printed or graphic matter upon the immediate container, tag, literature or other suitable material affixed thereto for the purpose of giving information

as to identify components, ingredients, attributes, directions for use, specifications and such other information as may be required by law or regulations

**3.8****live bivalve molluscs**

products that are alive immediately prior to consumption

**3.9****lot**

set of units of a product which has been produced and/or manufactured and/or packaged under similar conditions. A lot can consist of several batches

**3.10****raw bivalve molluscs**

products that are prepared for direct consumption or for further processing that were alive immediately prior to the commencement of processing

**3.11****relaying**

removal of bivalve molluscs from a microbiologically contaminated growing area to an acceptable growing or holding area under the supervision of the competent authority and holding them there for the duration necessary for the reduction of contamination to an acceptable level for human consumption

**3.12****retail**

handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centers, and wholesale outlets

**3.13****thawing**

process of taking a frozen product from frozen to a temperature (usually above 0°C) where there is no residual ice

**4 Process of Live and Raw Bivalve Molluscs****4.1 General**

Both relaying and depuration of live and raw bivalve molluscs should be subjected to appropriate controls implemented by the competent authority.

**4.2 Minimum Requirement****4.2.1 Live Bivalve Molluscs**

Live bivalve molluscs should be harvested alive from a harvesting area either approved for direct human consumption or subject to an approved method of

purification (e.g. relaying or depuration) prior to human consumption. It should undergo visual inspection. Bivalve molluscs that are dead, with broken shells, with adhering soil or otherwise unwholesome, should be rejected for human consumption.

#### 4.2.2 Raw Bivalve Molluscs

**4.2.2.1** Raw bivalve molluscs should have an approved method of purification (e.g. relaying or depuration) before they can be prepared for direct consumption or further processing.

**4.2.2.2** Where raw bivalve molluscs are post-harvest treated, the treatment should be intended to eliminate, reduce, or limit human pathogenic microorganisms to comply with microbiological guidelines stated in Table 1 (Microbiological safety requirements).

### 5 Essential Composition and Quality Factors

#### 5.1 Live Bivalve Molluscs

Live bivalve molluscs should possess sensory characteristics associated with freshness, with adequate response to percussion (e.g. the shellfish will close by themselves when tapped), and free from extraneous matter, as required by competent authority.

#### 5.2 Raw Bivalve Molluscs

**5.2.1** Raw bivalve molluscs intended for human consumption should be safe and of good quality.

**5.2.2** The packing medium used should be of food grade quality and conform to all applicable Codex standards.

### 6 Microbiological Safety

**6.1** The final product should conform to the following microbiological quality requirements indicated in Table 1 (Microbiological safety requirements) based on the DOH-FDA Revised Guidelines for the Assessment of Microbiological Quality of Processed Food. Table 11. Fish and Fishery Products – Fresh and Frozen Bivalve Molluscs (DOH-FDA Circular 2013-010) and EC Regulation on Microbiological Criteria for Foodstuffs (EC No. 2073/2005).

**Table 1. Microbiological safety requirements**

Microbiological Parameter	Limit
1. Aerobic Plate Count/ Standard Plate Count (APC/SPC) <sup>2</sup>	500,000 cfu/g
2. <i>Escherichia coli</i> <sup>1, 2</sup>	230 MPN/100g (live) 16 MPN/g (fresh, frozen)
3. <i>Salmonella</i> <sup>2</sup>	Absent in 25 g

Microbiological Parameter	Limit
4. <i>Vibrio parahaemolyticus</i> <sup>2</sup>	100 cfu/g
Legend: cfu - colony forming unit MPN -most probable number	
Footnote:  <sup>1</sup> European Commission (EC). (2005). Commission regulation on microbiological criteria for foodstuffs (EC 2073/2005). <a href="https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02005R2073-20140601&amp;from=DA">https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02005R2073-20140601&amp;from=DA</a>  <sup>2</sup> Food and Drug Administration (FDA) - Department of Health (DOH). (2013). Revised guidelines for the assessment of microbiological quality of processed food. Table 11. Fish and fishery products – fresh and frozen bivalve molluscs (DOH-FDA Circular No. 2013-010). <a href="https://ww2.fda.gov.ph/attachments/article/17218/FC2013-010.pdf">https://ww2.fda.gov.ph/attachments/article/17218/FC2013-010.pdf</a>	

## 7 Contaminants

**7.1** The products covered by this standard should comply with the Maximum Levels (MLs) of the Codex GSCTFF (CXS 193-1995) and Codex MRLs and RMRs for Residues of Veterinary Drugs (CX/MRL 2-2018).

**7.2** The product should conform to the following ML of biotoxins in Table 2 (Maximum level of biotoxin per kg of mollusc flesh) as specified in the Codex Standard for Live and Raw Bivalve Molluscs (CXS 292-2008 Rev. 3).

**Table 2. Maximum level of biotoxin per kg of mollusc flesh**

Name of Biotoxin Groups	Maximum Level / kg of Mollusc Flesh
Azaspiracid <sup>2</sup>	≤0.16 mg
Brevotoxin <sup>2</sup>	≤200 mouse units or equivalent
Domoic acid <sup>2</sup>	≤20 mg domoic acid
Okadaic acid <sup>2</sup>	≤0.16 mg of okadaic equivalent
Saxitoxin <sup>1</sup>	≤ 0.6 mg (2HCL) of saxitoxin equivalent
<b>NOTE 1</b> The following provisions apply to the edible parts of live bivalve mollusc (the whole part or any part intended to be eaten separately).	
Footnote:  <sup>1</sup> Bureau of Fisheries and Aquatic Resources (BFAR)-Department of Agriculture (DA). (2010). Safety and quality control standards for Paralytic Shellfish Poisoning (PSP) (Fisheries Administrative Order [FAO] No. 235, series of 2010). <a href="https://www.bfar.da.gov.ph/LAW?fi=397#post">https://www.bfar.da.gov.ph/LAW?fi=397#post</a>  <sup>2</sup> Codex Alimentarius Commission (CAC). (2015). Standard for live and raw bivalve molluscs (CXS 292-2008 Rev. 2015). <a href="http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&amp;url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B292-2008%252FCXS_292e_2015.pdf">http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&amp;url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B292-2008%252FCXS_292e_2015.pdf</a>	



## 8 Hygiene and Handling

**8.1** Products covered by this standard should be prepared and handled in accordance with the appropriate sections of the Codex General Principles of Food Hygiene (CAC/RCP 1 – 1969), and the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003).

**8.2** The products should comply with any microbiological criteria established in accordance with the Codex Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).

**8.3** Growing area monitoring programs, irrespective of the type of indicator microorganism used, must ensure that live bivalve molluscs intended for direct human consumption meet the *E. coli* limit as indicated in Table 1 (Microbiological safety requirements) and Annex A (Microbiological safety requirements) when tested in accordance with a MPN method specified in the International Organization for Standardization (ISO) 16649-3:2015 (Microbiology of the food chain - Horizontal method for the enumeration of beta-glucuronidase-positive *Escherichia coli* - Part 3: MPN technique using 5-bromo-4-chloro-3-indolyl- $\beta$ -D-glucuronide) or equivalent.

**8.4** Where the microbiological criteria are not met, actions should be taken as deemed appropriate by the competent authority. In following up, consideration should be given to detention, recall and further processing in a manner to eliminate the hazard from implicated lots. In addition, assessment of the status of harvesting areas and/or establishment controls should be undertaken.

## 9 Presentation, Packaging, and Labelling

### 9.1 Presentation

**9.1.1** Any presentation of the product should be permitted provided that it meets all requirements of this standard and is adequately described on the label to avoid confusing or misleading the consumers.

**9.1.2** The bivalve molluscs may be packed by weight, count, count per unit of weight, volume or per package.

### 9.2 Packaging

**9.2.1** The product should be packed in appropriate food grade materials, which are clean and free from any foreign matter or contaminant. Mixed species should not be packed in bulk.

**9.2.2** All packaging materials should be stored in a clean and sanitary manner. Product containers should not have been used for any purpose that may lead to contamination of the product. Packaging materials should be inspected immediately before use to ensure that they are in a satisfactory condition. Only packaging materials required for immediate use should be kept in the packing or filling area.

**9.2.3** In raw bivalve molluscs, shucked and post-harvest treated product should be packed and chilled or frozen as soon as possible. Freezing should be done quickly as slow freezing will damage meat.

### **9.3 Labeling**

**9.3.1** The product label should include pertinent instructions for use such as proper storage, preparation, and cooking as indicated in the provisions of the Codex General Standard for the Labeling of Prepackaged Foods (CXS 1-1985) and DOH-FDA AO 2014-0030 (Revised Rules and Regulations Governing the Labeling of Prepackaged Food Products Further Amending Certain Provisions of Administrative Order No. 88-B s. 1984 or the “Rules and Regulations Governing the Labeling of Prepackaged Food Products Distributed in the Philippines,” and For Other Purposes) and their future amendments.

#### **9.3.2 Name of the Product**

**9.3.2.1** The name of the product to be declared on the label should be the common or usual name of the species of bivalve molluscs in accordance with the law and custom of the country in which the food is sold and, in a manner, not to mislead the consumer.

**9.3.2** The name of the product should be “Live” or “Raw” and the corresponding English or common/local name with its scientific name in parenthesis, e.g. Live Green Mussels (*Perna viridis*) or Raw Green Mussels (*Perna viridis*). The products may be called by other common/local names provided that such names are accepted in the country of distribution.

**9.3.3** The label should specify the conditions for storage and/or temperature that will maintain the product safety/viability during transportation, storage, and distribution.

**9.3.4** The label should state the name and address of either of the following: manufacturer, packer, distributor, importer, exporter, or vendor.

**9.3.5** The label should indicate the lot identification code/number.

**9.3.6** The pictorial presentation (optional) of the product on the label should not mislead the consumer with respect to the product so illustrated.

**9.3.7** The net content by weight in the metric system and/or number of pieces based on other systems of measurement required by importing countries should appear in parenthesis after the metric net weight.

**9.3.8** The label should state that the product should be kept under suitable conditions (e.g. keep refrigerated/chilled/frozen) that will maintain the quality and safety during transport, storage, and distribution.

**9.3.9** The words “best before” followed by the day, month and year indicating end of the period at which the product shall retain its optimum quality attributes at a stated storage condition. The declaration of day and year are numerical while the month must be in words to avoid confusion (e.g. 01January2021 or 01Jan21).

**9.3.10** Labels should be clearly printed and must comply with the labelling laws of the country where the product is marketed. The packaging material or label may be used as a means to convey appropriate storage and/or cooking instructions to the consumer after retail purchase. The date of packaging should be included.

### **9.3.11 Live Bivalve Molluscs**

**9.3.11.1** Date of minimum shelf life may be replaced by the statement “Bivalves must be alive when sold”.

**9.3.11.2** Labelling for live bivalve molluscs should contain information that might be needed in the event of a food safety problem. It should include lot identification which could be lot code or date and location of harvest, information about harvest area, date of harvesting, purification or relaying as appropriate, as well as identification of the dispatch center or other establishment from which they were shipped.

### **9.3.12 Raw Bivalve Molluscs**

**9.3.12.1** The name and address of the manufacturer, packer, distributor, importer or exporter or vendor of the food shall be declared on the label.

**9.3.12.2** Every package containing bivalve molluscs that have undergone relaying or depuration to reduce or limit human pathogenic microorganisms should be provided with a label certifying that all molluscs have been processed to reduce the human pathogenic microorganisms to levels acceptable as specified in Tables 1 (Microbiological safety requirements) and 2 (Maximum level of biotoxin per kg of mollusc flesh).

**9.3.12.3** Safety claims for bivalve molluscs processed to reduce or limit human pathogenic microorganisms should be specific to the human pathogenic microorganisms that have been reduced or limited as described in the relevant code of practice.

**9.3.12.4** The label should indicate the name “Product of the Philippines” or the country of origin if imported.

## **10 Sampling, Examination and Analyses - General**

### **10.1 Sampling**

**10.1.1** Sampling of lots for examination of net weight should be carried out in accordance with an appropriate sampling plan meeting the criteria established in the Codex General Guidelines on Sampling (CAC/GL 50-2004).

**10.1.2** Each sample should contain a sufficient number of bivalve molluscs as listed in BFAR-DA Philippine National Shellfish Sanitation Manual for the Production of Safe Bivalve Molluscs (Appendix 4: Shellfish Species and Minimum Sample Sizes for Biotoxins Testing) to ensure that the sample is representative.

**10.1.3** The portion of the bivalve molluscs analyzed should be the edible part. This is generally the whole tissue.

**10.1.4** Where whole-tissue analysis is not possible or practical, the most contaminated tissue (e.g. the digestive gland) may be dissected and analyzed and the results converted to an edible tissue basis. The conversion factor should be supported by adequate data.

**10.1.5** For frozen product, thawing of the sample unit should be enclosed in a film type bag and immersing in water at room temperature (not greater than 35 °C).

## 10.2 Sensory and Physical Examination

Samples taken for sensory and physical examination should be assessed by persons trained in such examination and in accordance with procedures elaborated in clause 10.4 through 11.3 of this Standard and in the Codex Guidelines for the Sensory Evaluation of Fish and Shellfish in Laboratories (CAC/GL 31-1999).

## 10.3 Determination of Count per Unit Weight or Volume

When declared on the label, the count of bivalve molluscs should be determined by counting the numbers of bivalve molluscs in the container or a representative sample thereof and dividing the count of bivalve molluscs by the actual weight/volume to determine the count per unit weight or volume.

## 10.4 Method of Analysis in Bivalve Molluscs

The method of determining the following microorganisms and biotoxins should be in accordance with the methods of analyses presented in Table 3 (Method of analysis in bivalve molluscs).

**Table 3. Method of analysis in bivalve molluscs**

Microorganisms/Biotoxins	Method of Analysis
Aerobic Plate Count/ Standard Plate Count (APC/SPC)	US Food and Drug Administration (FDA) Bacteriological Analytical Manual (BAM) Chapter 3: Aerobic Plate Count
<i>Escherichia coli</i>	<ol style="list-style-type: none"> <li>1. USFDA BAM Chapter 4: Enumeration of <i>Escherichia coli</i> and the Coliform Bacteria; or</li> <li>2. ISO/TS 16649-3 – Horizontal method for the enumeration of beta- glucuronidase-positive <i>Escherichia coli</i> – Part 3: Most probable number technique using 5-bromo-4-chloro-3-indolyl-beta-D-glucuronide; or</li> <li>3. Other validated methods in accordance with the protocol set out in the ISO 16140 - Microbiology of the food chain — Method validation — Part 3: Protocol for the verification of reference methods and validated alternative methods in a single</li> </ol>

Microorganisms/Biotoxins	Method of Analysis
	laboratory or other internationally accepted similar protocol
<i>Salmonella</i>	<ol style="list-style-type: none"> <li>1. USFDA BAM Chapter 5: <i>Salmonella</i>; or</li> <li>2. ISO 6579 - Microbiology of the food chain — Horizontal method for the detection, enumeration and serotyping of <i>Salmonella</i>; or</li> <li>3. Other validated methods that provide equivalent sensitivity, reproducibility, and reliability.</li> </ol>
<i>Vibrio parahaemolyticus</i>	<ol style="list-style-type: none"> <li>1. USFDA BAM Chapter 9: <i>Vibrio</i>; or</li> <li>2. Macrorestriction Fragment Length Polymorphism (MFLP)-37 – Detection, isolation, and enumeration of <i>Vibrio parahaemolyticus</i> and/or <i>Vibrio vulnificus</i> in seafood</li> </ol>
Paralytic Shellfish Toxin	<ol style="list-style-type: none"> <li>1. Association of Official Analytical Chemists (AOAC) Method No. 959.08 - Paralytic shellfish poison. Biological method; or</li> <li>2. AOAC Method No. 2011.27 - Paralytic Shellfish Toxins (PSTs) in Shellfish. Receptor Binding Assay; or</li> <li>3. AOAC Method No. 2005.06 - High Performance Liquid Chromatography with Fluorescence Detection (HPLC-FL) – Lawrence Method; or</li> <li>4. Enzyme Linked Immunosorbent Assay (ELISA)</li> </ol>
Saxitoxin (STX) group	AOAC Method No. 2005.06 (Paralytic Shellfish Poisoning Toxins in Shellfish)
Okadaic acid (OA) group	<ol style="list-style-type: none"> <li>1. Liquid chromatography tandem mass spectrometry (LC-MS/MS); or</li> <li>2. European Union Reference Laboratory (EURL) – LC-MS/MS; or</li> <li>3. Protein Phosphatase 2A Assay (PP2A Okatest)</li> </ol>
Domoic acid (DA) group	<ol style="list-style-type: none"> <li>1. AOAC Method No. 991.26 - Domoic acid in mussels;</li> <li>2. Liquid chromatographic method; or</li> <li>3. Enzyme-Linked Immunosorbent Assay (ELISA)</li> </ol>
Brevetoxin (BTX) group	<ol style="list-style-type: none"> <li>1. LC-MS/MS; or</li> <li>2. Receptor Binding Assay</li> </ol>
Azaspiracid (AZP) group	<ol style="list-style-type: none"> <li>1. LC-MS/MS; or</li> <li>2. EURL-LCMSMS</li> </ol>

## **11 Determination of Net Weight - Raw Bivalve Molluscs**

The net weight of all sample units should be determined by the procedures described or mentioned in Clauses 11.1-11.3 of this Standard.

### **11.1 Determination of Net Weight**

The method of determining net weight should be based on the following:

**11.1.1** The unopened container should be weighed.

**11.1.2** The container should be opened and the contents should be removed.

**11.1.3** The empty container should be weighed, (including the end) after removing excess liquid and adhering meat.

**11.1.4** The weight of the empty container should be subtracted from the weight of the unopened container.

**11.1.5** The resultant figure should be the total net content.

### **11.2 Determination of Net Weight of Frozen Products Not Covered by Glaze**

The net weight (exclusive of packaging material) of each sample unit representing a lot should be determined in the frozen state.

### **11.3 Determination of Net Weight of Products Covered by Glaze**

The method of determining net weight of products covered by glaze should be in accordance with AOAC official method 963.18 (Net contents of frozen seafood). The AOAC official method 963.26 (Net contents of frozen food containers) should be used to determine the net weight of products with water added that is inside a block-frozen product.

## **12 Defectives**

A product should be considered as defective when it exhibits any of the properties defined below.

### **12.1 Foreign Matter**

The presence in the product of any matter which has not been derived from bivalve molluscs should be considered as defective. It should not pose a threat to human health and is readily recognized without magnification. It should be present at a level determined by any method including magnification, that indicates non-compliance with good manufacturing and sanitation practices.

### **12.2 Dead or Damaged Product**

The presence of dead or damaged product should be considered as defective only in live bivalve molluscs. Dead product should be characterized by no response to percussion (e.g. live shellfish will close by themselves when tapped). Damaged product should include product that is damaged to the extent that it can no longer function biologically. A sample unit should be considered defective if dead or damaged bivalve molluscs exceed 5 % by count.

### **12.3 Deep Dehydration (Frozen Products)**

Raw bivalve molluscs should be considered defective if greater than 10 % of the weight in the sample unit of the thawed product or greater than 10 % of the surface area of the frozen block exhibits excessive loss of moisture clearly shown as white or abnormal color on the surface which masks the color of the flesh and penetrates below the surface. It should not be easily removed by scraping with a knife or other sharp instrument without unduly affecting the appearance of the bivalve molluscs.

### **12.4 Odor/flavor**

Persistent and distinct objectionable odors or flavors should be considered defective in raw bivalve molluscs which indicate decomposition or rancidity.

### **12.5 Texture**

Textural breakdown of the flesh should be considered defective in raw bivalve molluscs, which indicates decomposition, characterized by muscle structure that is mushy or paste-like.

## **13 Lot Acceptance**

A lot should be considered as meeting the requirements of this standard when:

**13.1** the total number of defectives as classified according to Clause 12 (Defectives) does not exceed the acceptance number (c) of the appropriate sampling plan in the Codex General Guidelines on Sampling (CAC/GL 50-2004);

**13.2** the total number of sample units not meeting the count designation as defined in Clause 10.3 (Determination of count per unit weight or volume) does not exceed the acceptance number(c) of the appropriate sampling plan in the Codex General Guidelines on Sampling (CAC/GL 50-2004); and

**13.3** the average net weight of all sample units is not less than the declared weight, provided there is no unreasonable shortage in any individual container.

**Annex A  
(Normative)****Microbiological safety requirements**

In the analysis involving five 100 g samples of the edible parts (the whole part or any part intended to be eaten separately), none may contain more than 700 *E. coli* and not more than one of five samples may contain between 230 and 700 *E. coli*, or equivalent as decided by the competent authority having jurisdiction

Microorganism = *E. coli*      n=5      c=1      m=230      M=700      3 Class Plan

where:

‘n’ is the number of sample units;

‘c’ is the number of sample units that may exceed the limit ‘m’; and

‘M’ is the limit which no sample unit may exceed.

In analysis involving five 25 g samples of the edible parts (the whole part or any part intended to be eaten separately), no sample may indicate the presence of *Salmonella* when tested using a method validated against the reference method ISO 6579.

Microorganism = *Salmonella*      n=5      c=0      m=0/25      2 Class Plan

where:

‘n’ is the number of samples that must conform to the criteria;

‘c’ is the maximum allowable number of defective sample units; and

‘m’ is a microbiological limit which separates good quality from defective quality.



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