

**PROPOSED DRAFT STANDARD FOR LIVE AND [RAW] BIVALVE MOLLUSCS**  
**(At Step 3 of the Procedure)**

**1. SCOPE**

This standard applies to live and [raw] bivalve molluscs excluding scallop adductal muscle only, intended for direct human consumption or further processing.

**2. DESCRIPTION****2.1 Product Definition**

Live bivalve molluscs are products that are alive immediately prior to consumption. Presentation includes the shell. [Raw bivalve molluscs are products that are no longer alive immediately prior to consumption but were alive immediately prior to the commencement of processing or to shucking, freezing or other treatment that did not eliminate the sensory characteristics of live products.]

**2.2 Process Definition**

[Live bivalve molluscs shall be organisms which are harvested alive for direct human consumption from an approved growing area and/or from another appropriately classified area followed by an approved purification process such as natural container (raft, float or tank) relaying or depuration or from an approved purification centre.] The approval mentioned in this subsection must be given by the official agency having jurisdiction.

Frozen bivalve molluscs shall after suitable preparation be derived from organisms which meet the requirements for live bivalve molluscs and the product shall, after any suitable preparation [deshelling], be subjected to a freezing process and shall comply with the conditions laid down hereafter. The freezing process shall be carried out in appropriate equipment in such a way that the range of temperature of maximum crystallization is passed quickly. The freezing process shall not be regarded as complete unless and until the product temperature has reached  $-18^{\circ}\text{C}$  or colder at the thermal centre after thermal stabilization. The product shall be kept deep frozen so as to maintain the quality during transportation, storage and distribution. Frozen bivalve molluscs shall be processed and packaged so as to minimize dehydration and oxidation.

Processed bivalve molluscs shall be derived from organisms which meet the requirements for live bivalve molluscs.

Canned bivalve molluscs are packed in hermetically sealed containers and shall have received a processing treatment sufficient to ensure commercial sterility.

Other approved processes including heat processing (other than canning) may be applied to provide sterilisation.

Covered in Code of Practice.

[Post-harvest treated bivalve molluscs shall be organisms that meet the requirements for live bivalve molluscs, either because they are derived from organisms that meet these requirements or because they have received post-harvest treatment, or because of a combination of the two. The post-harvest treatment shall assure the elimination, reduction, or limitation of the target organisms to the satisfaction of the official agency having jurisdiction.]

### 2.3 PRESENTATION

Any presentation of the product shall be permitted provided that it:

- meets all requirements of this standard; and
- is adequately described on the label to avoid confusing or misleading the consumer.

The bivalve molluscs may be packed in count per unit of weight or per package.

In the case of live bivalve molluscs, they may be packed by weight, count, count per unit of weight, volume or per package.

## 3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

### 3.1 Live Bivalve Molluscs

Bivalve molluscs intended for direct consumption or intended to be processed shall be alive immediately prior to consumption or prior to the commencement of processing and of a quality fit for human consumption.

Bivalve molluscs must respond adequately to percussion and must contain a normal quantity of intravalvular liquid as determined by product specialists familiar with the species.

### 3.2 Glazing (for frozen bivalve molluscs)

If glazed, the water used for glazing or preparing glazing solutions shall be clean water. (Clean water defined in the Code.)

### 3.3 Other Ingredients

The packing medium and all other ingredients used shall be of food grade quality and conform to all applicable Codex standards.

### 3.4 Final Product

Products shall meet the requirements of this standard when lots examined in accordance with Section 9 comply with the provisions set out in Section 8. Products shall be examined by the methods given in Section 7.

## 4. FOOD ADDITIVES

Only the use of the following additives is permitted in processed bivalve molluscs

### Antioxidants

For fresh shucked molluscs any antioxidant listed in food category 09.1.2 (Fresh Mollusks, crustaceans and echinoderms) of the General Standard for Food Additives (CODEX STAN 192-1995) at levels not to exceed good manufacturing practices (GMP).

For fresh raw frozen molluscs any antioxidant listed in food category 09.2.1 (Frozen fish, fish fillets, and fish products, including mollusks, crustaceans, and echinoderms) of the General Standard for Food Additives (CODEX STAN 192-1995) at levels not to exceed good manufacturing practices (GMP).

For fresh raw frozen molluscs any antioxidant listed in food category 09.2.2 (Frozen battered fish, fish fillets and fish products, including mollusks, crustaceans, and echinoderms) of the General Standard for Food Additives (CODEX STAN 192-1995) at levels not to exceed good manufacturing practices (GMP).

For fresh raw frozen molluscs any antioxidant listed in food category 09.2.5 (Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms) of the General Standard for Food Additives (CODEX STAN 192-1995) at levels not to exceed good manufacturing practices (GMP).

## 5. HYGIENE AND HANDLING

5.1 The final product shall be free from any foreign material that poses a threat to human health.

5.2 Live bivalve molluscs intended for direct consumption should possess visual characteristics associated with freshness and viability, including shells free of dirt, an adequate response to percussion, and normal amounts of intravalvular liquid as determined by product specialists familiar with the species."

5.3 When tested by appropriate methods of sampling and examination prescribed by the Codex Alimentarius Commission (CAC), the following requirements shall be met:

(i) Live bivalve mollusc shall be free from micro-organisms or substances originating from micro-organisms or virus in amounts which may present a hazard to health in accordance with standards established by the CAC.

(ii) [Live bivalve molluscs must not contain more than 300 faecal coliforms or more than 230 E.coli per 100 g of mollusc flesh and intravalvular liquid. Determination by the 5 tube, 3 dilution MPN testing method or any other method equivalent.]

AND/OR – for discussion

[Live bivalve molluscs must not contain more than 330 fecal coliforms. In an analysis involving five (5) samples, none may contain more than 330 fecal coliforms; and if two (2) or more of the five (5) contain between 230 and 330 fecal coliforms, the five samples must be analyzed for E coli. In that analysis, no sample may contain more than 330 E coli, and not more than one (1) of the five (5) samples may contain between 230 and 330 E coli.]

(iii) [Live bivalve molluscs and products thereof must not contain Salmonella in 25 g flesh.]

[(iv) [In the edible parts of bivalve molluscs (the whole part or any part intended to be eaten separately.) the total Paralytic Shellfish Poison (PSP) content must not exceed 80 microgrammes of saxitoxin equivalent per 100 g of mollusc flesh

(v) [In the edible parts of the bivalve molluscs (the whole part or any part intended to be eaten separately) the Diarrhetic Shellfish Poison (DSP), using the customary biological testing methods (on rats or mice) there must not be a positive result.

In the edible parts of the bivalve molluscs (the whole part or any part intended to be eaten separately) the maximum level of Okadaic acid, Dynophysistoxins and Pectenotoxins together, must not exceed 160 microgrammes of Okadaic equivalents per kg.

(vi) [In the edible parts of bivalve molluscs (the whole part or any part intended to be eaten separately) the content of Amnesic Shellfish Poisoning (ASP) must not exceed 20 microgrammes domoic acid per g of mollusc flesh.

(vii) [In the edible parts of bivalve molluscs (the whole or any part intended to be eaten separately) the total Neurotoxic Shellfish Poison (NSP) content must not exceed 20 mouse units.

(viii) In the edible parts of bivalve molluscs (the whole or any part intended to be eaten separately) the level of Azaspiracid (AZP) must not exceed 16 microgrammes per 100g.

(ix) In the edible parts of bivalve molluscs (the whole or any part intended to be eaten separately) the level of Yessotoxins must not exceed 100 microgrammes per 100g.]

*(Note – comments on methodology is transferred to Section 7.)*

(x) The product must not contain any other substance in amounts which may present a hazard to health in accordance with standards established by the CAC.

5.4 It is recommended that the product covered by the provisions of this standard be prepared and handled in accordance with the following Codes: the appropriate sections of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 3 (1997));

- the Code of Practice for Fish and Fishery Products<sup>1</sup>;

## 6. LABELLING

In addition to the provisions of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985, Rev. 1, 1991) the following specific provisions apply:

### 6.1 The Name of the Food

The name of the product as declared on the label shall be [the name of the species of bivalve molluscs [the common or usual name of the species of bivalve molluscs] according to the law, custom or practice in the country in which the product is to be distributed.]

6.1.1 There shall appear on the label, reference to the presentation provided for in Section 2.3-Presentation in close proximity to the name of the product in such descriptive terms that will adequately and fully describe the nature of the presentation of the product to avoid misleading or confusing the consumer.

6.1.2 In addition to the specified labelling designations above, the usual or common trade names of the variety may be added so long as it is not misleading to the consumer in the country in which the product will be distributed.

### 6.2 Content Declaration

Live bivalve molluscs shall be labelled by weight, count, count per unit weight, or volume as appropriate to the product.

Processed bivalve molluscs shall have a net weight declaration in accordance with:- *Refer to other codex standards.*

### 6.3 Storage Instructions

The label shall specify the conditions for storage and/or temperature that will maintain the quality/viability during transportation, storage and distribution.

### 6.4 Labelling of Non-Retail Containers (for bulk transport of live and raw shucked bivalve molluscs)

Information shall specify on the container and in accompanying documents,

- the name of the food,

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<sup>1</sup> Reference to be inserted

- lot identification,
- harvesting location,
- date of harvest and/or
- date of processing and
- the name and address and authorisation or registration number of packer or manufacturer, and
- [storage instructions, as appropriate].

However, lot identification, and the name and address may be replaced by an identification mark, provided that such a mark is clearly identifiable with the accompanying documents in which this information is given.

### **6.5 Other Labelling Requirements**

6.5.1 For live bivalve molluscs this product shall declare the date of minimum durability, harvest date or packing date, or a statement to this effect.

6.5.2 [For live and raw shucked bivalve molluscs] OR [For live and processed bivalve molluscs], identification of the establishment approved by the official agency with the jurisdiction, for the production of the product.

6.5.3 [Safety claims made for post-harvest treated bivalve molluscs should be specific to the target organisms that have been eliminated, reduced, or limited by the post-harvest treatment.]

6.5.4 [Every package containing purified bivalve molluscs must be provided with a label certifying that all molluscs have been purified.]

## **7. SAMPLING, EXAMINATION AND ANALYSES**

### **7.1 Sampling**

(i) Sampling of lots for examination of the product shall be in accordance with the Codex Alimentarius Sampling Plans for Prepackaged Foods (AQL - 6.5) (CODEX STAN 233-1969).

(ii) Sampling of lots for examination of net weight shall be carried out in accordance with an appropriate sampling plan meeting the criteria established by the CAC.

### **7.2 Sensory and Physical Examination**

Samples taken for sensory and physical examination shall be assessed by persons trained in such examination and in accordance with procedures elaborated in Sections 7.3 through 7.6, and Guidelines for the Sensory Evaluation of Fish and Shellfish in Laboratories" (CAC/GL 31-1999).

### **7.3 Determination of Net Weight and Drained Weight**

The net weight and drained weight of all sample units shall be determined by the procedures described or mentioned in sections 7.3.1, 7.3.2, 7.3.3 and 7.3.4..

#### **7.3.1 Determination of Net Weight**

- (i) Weigh the unopened container;
- (ii) Open the container and remove the contents;
- (iii) Weigh the empty container, (including the end) after removing excess liquid and adhering meat;
- (iv) Subtract the weight of the empty container from the weight of the unopened container.
- (v) The resultant figure will be the total net content.

### 7.3.2 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 shall be determined in the frozen state.

### 7.3.3 Determination of Net Weight of Products Covered by Glaze

AOAC official method 963.18, Net Contents of Frozen Seafoods

7.3.4 The AOAC official method 963.26 should be used to determine the net weight of products with water added that is inside a "block-frozen" product.

### 7.3.5 Determination of Drained Weight

### 7.4 Determination of Count per Unit Weight or Volume

When declared on the label, the count of bivalve molluscs shall 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.

### 7.5 Sample Preparation

#### 7.5.1 Procedures for Thawing

For frozen product, the sample unit is thawed by enclosing it in a film type bag and immersing in water at room temperature (not greater than 35 °C). The complete thawing of the product is determined by gently squeezing the bag occasionally so as not to damage the texture of the bivalve molluscs, until no hard core or ice crystals are left.

#### 7.5.2 Cooking Methods

The following procedures are based on heating the product to an internal temperature of 65-70 °C.

The product must not be overcooked. Cooking times vary according to the size of the product and the temperature used. The exact times and conditions of cooking for the product should be determined by prior experimentation.

**Baking Procedure:** Wrap the product in aluminium foil and place it evenly on a shallow flat pan.

**Steaming Procedure:** Wrap the product in aluminium foil and place it on a wire rack suspended over boiling water in a covered container.

**Boil-in-Bag Procedure:** Place the product into a boilable film-type pouch and seal. Immerse the pouch into boiling water and cook.

**Microwave Procedure:** Enclose the product in a container suitable for microwave cooking. If plastic bags are used, check to ensure that no odour is imparted from the plastic bags. Cook according to equipment instructions.

### 7.6 MPN Method For Analyses of E.Coli/Faecal Coliforms

(to be elaborated)

Method for E. coli proposed by Germany:

Donavan et al. (1998): Modification of the standard UK method for the enumeration of *Escherichia coli* in live bivalve molluscs. Communicable Disease and Public Health 1, 188-196.

In the absence of routine virus testing procedures and the establishment of virological standards, an assessment of the risks from viruses must be based on faecal bacteria counts and sanitary shoreline survey.

This indicator may be amended or replaced in the future by more suitable indicators like bacteriophage.

### **7.7 Determination of Biotoxins**

(to be elaborated)

PSP - biological testing method in association if necessary with a chemical method for detection of Saxitoxin.

DSP - customary biological testing methods (on rats or mice).

Okadaic acid, Dynophysistoxins and Pectenotoxins – measurement of Okadaic acid equivalent. – biological methods (mouse bioassay, rat bioassay), authorised alternative chemical methods ELISA, HPLC, LCMS.

ASP - HPLC testing method.

NSP - current American Public Health Association Inc. method or other method approved by the official agency having jurisdiction.

AZP – HPLC or other method approved by the official agency having jurisdiction.

Yessotoxin – biological method or other method approved by the official agency having jurisdiction.

The above methods may be replaced by other acceptable chemical methods as they become available and approved for use.

## **8. DEFINITION OF DEFECTIVES**

The sample unit shall be considered as defective when it exhibits any of the properties defined below.

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

Greater than 10% of the weight of the bivalve molluscs in the sample unit or greater than 10% of the surface area of the block exhibits excessive loss of moisture clearly shown as white or abnormal colour on the surface which masks the colour of the flesh and penetrates below the surface, and cannot be easily removed by scraping with a knife or other sharp instrument without unduly affecting the appearance of the bivalve molluscs.

### **8.2 Foreign Matter**

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

### **8.3 Odour/Flavour**

Bivalve molluscs affected by persistent and distinct objectionable odours or flavours indicative of decomposition or rancidity.

### **8.4 Texture**

Textural breakdown of the flesh, indicative of decomposition, characterized by muscle structure which is mushy or paste-like.

**8.6 Dead or Damaged Product**

For bivalve molluscs sold live, the presence of dead or damaged product. Dead product is characterised by no response to percussion. Damaged product includes product that is damaged to the extent that they can no longer function biologically. Sample shall be rejected if dead or damaged product exceed 5% by count.

**9. LOT ACCEPTANCE**

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

- (i) the total number of defectives as classified according to section 8 does not exceed the acceptance number (c) of the appropriate sampling plan in the Sampling Plans for Prepackaged Foods (AQL-6.5) (CODEX STAN 233-1969);
- (ii) the total number of sample units not meeting the count designation as defined in section 2.3 does not exceed the acceptance number (c) of the appropriate sampling plan in the Sampling Plans for Prepackaged Foods (AQL - 6.5) (CODEX STAN 233-1969);
- (iii) 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;
- (iv) the Food Additives, Hygiene and Labelling requirements of Sections 4, 5.1, 5.2, 5.3 and 6 are met.