CODEX ALIMENTARIUS
INTERNATIONAL FOOD STANDARDS

Food and Agriculture Organization of the United Nations
World Health Organization

E-mail: codex@fao.org - www.codexalimentarius.org

# STANDARD FOR LIVE AND RAW BIVALVE MOLLUSCS

## CODEX STAN 292-2008

**Adopted in 2008. Amendment: 2013. Revision: 2014, 2015.**

## 1. SCOPE

This Standard applies to live bivalve molluscs and to raw bivalve molluscs that have been shucked and/or frozen, and/or processed to reduce or limit target organisms while essentially retaining the sensory characteristics of live bivalve molluscs. Raw bivalve molluscs are marketed either in a frozen or chilled state. Both live and raw bivalve molluscs may be intended for direct consumption or further processing. The Standard does not apply to scallops when the final product is the adductor muscle only.

Part I below applies to live bivalve molluscs while Part II applies to raw bivalve molluscs.

## PART I – LIVE BIVALVE MOLLUSCS

### 1.2. Description

#### 1.2.1 *Product Definition*

Live bivalve molluscs are products that are alive immediately prior to consumption. Presentation includes the shell.

#### 1.2.2 *Process Definition*

Live bivalve molluscs are harvested alive from a harvesting area either approved for direct human consumption or classified to permit harvesting for an approved method of purification, e.g. relaying or depuration, prior to human consumption. Both relaying and depuration must be subject to appropriate controls implemented by the official agency having jurisdiction.

#### 1.2.3 *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 by weight, count, count per unit of weight, volume or per package.

### 1.3. Essential composition and quality factors

#### 1.3.1 *Bivalve Molluscs*

Live bivalve molluscs should possess organoleptic characteristics associated with freshness, as well as an adequate response to percussion (i.e. the shellfish will close by themselves when tapped) and freedom from extraneous matter, as determined by specialists familiar with the species concerned.

#### 1.3.2 *Final Product*

Live bivalve molluscs shall meet the requirements of this standard when lots examined in accordance with Section 1.10 comply with the provisions set out in Section 1.9. Live bivalve molluscs shall be examined by the methods given in Section 1.8.

### 1.4. Food Additives

Food additives are not permitted in live bivalve molluscs.

### 1.5. Contaminants

The products covered by this Standard shall comply with the Maximum Levels of the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1995) and the maximum residue limits for pesticides and/or veterinary drugs established by the Codex Alimentarius Commission.

The following provisions apply to the edible parts of live bivalve mollusc (the whole part or any part intended to be eaten separately).

| Name of biotoxin groups | Maximum level /kg of mollusc flesh |
|---|---|
| Saxitoxin (STX) group | ≤0.8 milligrams (2HCL) of saxitoxin equivalent |
| Okadaic acid (OA) group | ≤0.16 milligrams of okadaic equivalent |
| Domoic acid (DA) group | ≤20 milligrams domoic acid |
| Brevetoxin (BTX) group | ≤200 mouse units or equivalent |

| | |
|---|---|
| Azaspiracid (AZP) group | ≤0.16 milligrams |

### 1.6. Hygiene

It is recommended that the products covered by provisions of this Standard be prepared and handled in accordance with the appropriate sections of the *General Principles of Food Hygiene* (CAC/RCP 1 – 1969), the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and other relevant Codex Codes of Hygienic Practice and Codes of Practice.

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

Growing area monitoring programs, irrespective of the type of indicator bacteria used, must ensure that live bivalve molluscs destined for direct human consumption meet the *E.coli* limit as identified below when tested in accordance with an MPN method specified in ISO 16649-3 or equivalent.

In analysis involving five (5) 100g 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 (1) of five (5) samples may contain between 230 and 700 *E.coli*, or equivalent as decided by the competent authority having jurisdiction.

Microorganism = *Escherichia coli* n=5 c=1 m=2 M=700 3 Class Plan

where ‘n’= the number of sample units, ‘c’= the number of sample units that may exceed the limit ‘m’, and ‘M’ is the limit which no sample unit may exceed.

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.

### 1.7. Labelling

In addition to the provisions of the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985) the following specific provisions apply:

#### 1.7.1 *The Name of the Food*

The name of the food to be declared on the label shall 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.

There shall appear on the label, reference to the presentation provided for in Section 1.2.3 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.

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.

#### 1.7.2 *Content Declaration*

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

#### 1.7.3 *Storage Instructions*

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

### 1.7.4 *Labelling of Non-retail Containers*

Labelling for live bivalve molluscs shall contain the following information:

(i) Identification of the product by common and/or scientific names as determined by the competent authority. The country where the product is sold can determine if the scientific name must be indicated on the label.

(ii) Information that might be needed in the event of a food safety problem, including 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 despatch centre or other establishment from which they were shipped.

(iii) Durability or shelf life.

Date of minimum durability may be replaced by the statement “Bivalves must be alive when sold”.

## 1.8. Sampling, examination and analyses

### 1.8.1 *Sampling*

(i) Each sample shall contain a sufficient number of bivalve molluscs to ensure that the sample is representative.

(ii) The portion of the bivalve mollusc analysed should be the edible part. This is generally the whole tissue. Where whole-tissue analysis is not possible or practical, the most contaminated tissue (e.g. the digestive gland) may be dissected and analysed and the results converted to an edible tissue basis. The conversion factor should be supported by adequate data.

### 1.8.2 *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 1.8.3 through 1.8.5, and *Guidelines for the Sensory Evaluation of Fish and Shellfish in Laboratories* (CAC/GL 31-1999).

### 1.8.3 *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.

### 1.8.4 *Method of Analysis of Escherichia coli in bivalve molluscs*

The ISO/TS 16649-3 – Horizontal method for the enumeration of beta-glucuronidase-positive Escherichia *coli* – Part 3: Most probable number technique using 5-bromo-4-chloro-3-indoly1.beta-D-glucuronide or other validated methods in accordance with the protocol set out in the ISO 16140 or other internationally accepted similar protocol.

### 1.8.5 *Determination of Biotoxins*

The method selected should be chosen on the basis of practicability and preference should be given to methods which have applicability for routine use.

#### *1.8.5.1 Criteria for Determination of Toxin Analogues by Chemical Methods*

Methods shall meet the numerical criteria listed in Table 1 and may either meet the minimum applicable range, or LOD and LOQ criteria listed.

**Table 1. Criteria for Determination of Toxin Analogues by Chemical Methods**

| Toxin Group | Toxin | Minimum applicable range (mg/kg) | LOD (mg/kg) | LOQ (mg/kg) | Precision ($RSD_R$) | Recovery percent |
|---|---|---|---|---|---|---|
| STX Group | Saxitoxin (STX) | 0.05 - 0.2 | 0.01 | 0.02 | <=44% | 50 - 130% |
| | (NEO) | 0.05 - 0.2 | 0.01 | 0.02 | <=44% | 50 - 130% |
| | (dcSTX) | 0.05 - 0.2 | 0.01 | 0.02 | <=44% | 50 - 130% |
| | GTX1 | 0.05 - 0.2 | 0.01 | 0.02 | <=44% | 50 - 130% |
| | GTX2 | 0.1 - 0.5 | 0.03 | 0.06 | <=38% | 50 - 130% |
| | GTX3 | 0.1 - 0.5 | 0.03 | 0.06 | <=38% | 50 - 130% |
| | GTX4 | 0.05 - 0.2 | 0.01 | 0.02 | <=44% | 50 - 130% |
| | GTX5 | 0.1 - 0.5 | 0.03 | 0.06 | <=38% | 50 - 130% |
| | GTX6 | 0.1 - 0.5 | 0.03 | 0.06 | <=38% | 50 - 130% |
| | dcGTX2 | 0.1 - 0.5 | 0.03 | 0.06 | <=38% | 50 - 130% |
| | dcGTX3 | 0.1 - 0.5 | 0.03 | 0.06 | <=38% | 50 - 130% |
| | C1 | 0.1 - 0.5 | 0.03 | 0.06 | <=38% | 50 - 130% |
| | C2 | 0.1 - 0.5 | 0.03 | 0.06 | <=38% | 50 - 130% |
| | C3 | 0.5 - 1.5 | 0.1 | 0.2 | <=32% | 50 - 130% |
| | C4 | 0.5 - 1.5 | 0.1 | 0.2 | <=32% | 50 - 130% |
| OA Group | OA | 0.03 - 0.2 | 0.01 | 0.02 | <=44% | 60 -115% |
| | DTX1 | 0.03 - 0.2 | 0.01 | 0.02 | <=44% | 60 -115% |
| | DTX2 | 0.1 - 0.5 | 0.03 | 0.06 | <=38% | 60 -115% |
| Domoic Acid | DA | 14 - 26 | 2 | 4 | <=20% | 80 -110% |
| AZA Group | AZA1 | 0.03 - 0.2 | 0.01 | 0.02 | <=44% | 40 - 120% |
| | AZA2 | 0.03 - 0.2 | 0.01 | 0.02 | <=44% | 40 - 120% |
| | AZA3 | 0.03 - 0.2 | 0.01 | 0.02 | <=44% | 40 - 120% |

Total toxicity is estimated as the sum of the molar concentrations of detected analogs multiplied by the relevant specific toxicity equivalency factors (TEFs). Internationally scientifically validated TEFs must be used. The science behind TEFs is developing. Current internationally validated TEF's can be found on the FAO website. Information on TEFs could be incorporated in this standard at a future date.

Methods should be validated and used for the relevant toxin analogues that may contribute to total toxicity. Currently known toxin analogues to consider are listed in Table 1.

Where toxin analogues that are not listed in Table 1 are determined the competent authority must assess the contribution of these analogs to total toxicity whilst conducting further investigations.

*1.8.5.2 Biological and Functional Methods to Determine Paralytic Shellfish Toxicity*

| **Provision** | **Method** |
|---|---|
| Paralytic shellfish toxicity | AOAC 959.08 |
| Paralytic shellfish toxicity | AOAC 2011.27 |

## 1.9 Definition of defectives

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

### 1.9.1 *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.

### 1.9.2 *Dead or Damaged Product*

The presence of dead or damaged product. Dead product is characterised by no response to percussion (i.e. shellfish will close by themselves when tapped). Damaged product includes product that is damaged to the extent that it can no longer function biologically. A Sample unit shall be considered defective if dead or damaged bivalve molluscs exceed 5% by count.

### 1.10 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 I-9 does not exceed the acceptance number (c) of the appropriate sampling plan in the *General Guidelines on Sampling* (CAC/GL 50-2004);

(ii) the total number of sample units not meeting the count designation as defined in Section I-8.3 does not exceed the acceptance number (c) of the appropriate sampling plan in the *General Guidelines on Sampling* (CAC/GL 50-2004);

(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, Contaminants, Hygiene and Labelling requirements of Sections 1.4, 1.5, 1.6 and 1.7 are met.

## PART II – RAW BIVALVE MOLLUSCS

### 2.2 Description

#### 2.2.1 *Product Definition*

Raw bivalve molluscs processed for direct consumption or for further processing are products that were alive immediately prior to the commencement of processing and comply with Section 1.2.2 relating to harvesting, purification and relaying. They have been shucked and/or frozen and/or processed to reduce or limit target organisms while essentially retaining the sensory characteristics of live bivalve molluscs. Raw bivalve molluscs are marketed in a frozen or chilled state.

#### 2.2.2 *Process Definition*

Raw bivalve molluscs must meet the process definition in 1.2.2 before they can be processed for direct consumption or further processing.

Bivalve molluscs that have been processed to reduce or limit target organisms while essentially retaining the sensory characteristics of live bivalve molluscs are ones that have been processed to assure reduction or limitation of the target organisms to the satisfaction of the official agency having jurisdiction.

#### 2.2.3 *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 by weight, count, count per unit of weight, volume or per package.

### 2.3 Essential composition and quality factors

#### 2.3.1 *Raw Bivalve Molluscs*

Raw bivalve molluscs shall be of a quality fit for human consumption.

#### 2.3.2 *Ingredients*

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

#### 2.3.3 *Final Product*

Raw bivalve molluscs shall meet the requirements of this standard when lots examined in accordance with Section 2.10 comply with the provisions set out in Section 2.9. Raw bivalve molluscs shall be examined by the methods given in Section 2.8.

### 2.4 Food Additives

Only the use of the following additives is permitted in raw bivalve molluscs:

- **Antioxidants**

  For chilled shucked molluscs any antioxidant listed in food category 09.1.2 (Fresh Molluscs, crustaceans and echinoderms) of the *General Standard for Food Additives*

(CODEX STAN 192-1995).

For raw frozen molluscs any antioxidant listed in food category 09.2.1 (Frozen fish, fish fillets, and fish products, including molluscs, crustaceans, and echinoderms) of the *General Standard for Food Additives* (CODEX STAN 192-1995).

**2.5 Contaminants**

Raw bivalve molluscs should meet the requirements of 1.5.

**2.6 Hygiene**

Raw bivalve molluscs should meet the requirements of 1.6.

**2.7 Labelling**

In addition to the provisions of the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985) the following specific provisions apply:

**2.7.1 *The Name of the Food***

The name of the food to be declared on the label shall 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.

There shall appear on the label, reference to the presentation provided for in Section 2.2.3-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.

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.

**2.7.2 *Content Declaration***

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

**2.7.3 *Storage Instructions***

The label shall specify the conditions for storage and/or temperature that will maintain the food safety and characteristics of the product during transportation, storage and distribution including date of minimum durability and for date of shucking.

**2.7.4 *Labelling of Non-retail Containers***

Refer to 1.7.4 Labelling of Non-retail Containers.

Every package containing bivalve molluscs that have been processed to reduce or limit target organisms must be provided with a label certifying that all molluscs have been processed to reduce the target organism to levels acceptable to the official agency having jurisdiction.

Safety claims for bivalve molluscs processed to reduce or limit target organisms should be specific to the target organisms that have been reduced or limited as described in the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

**2.8. Sampling, examination and analysis**

**2.8.1 *Sampling***

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.

**2.8.2 *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 2.8.3 through 2.8.7, and *Guidelines for the Sensory Evaluation of Fish and Shellfish in Laboratories* (CAC/GL 31-1999).

**2.8.3 *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 2.8.3.1 through 2.8.3.5.

*2.8.3.1 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.

*2.8.3.2 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.

*2.8.3.3 Determination of Net Weight of Products Covered by Glaze*

AOAC official method 963.18, Net Contents of Frozen Seafoods.

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.

*2.8.3.4 Determination of Drained Weight*

In the case of shucked bivalve molluscs, the drained weight shall be determined according to AOAC official method 953.11.

**2.8.4 *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.

**2.8.5 *Sample Preparation***

*2.8.5.1 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 ºC). 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.

**2.8.6 *Methods of Analysis of Escherichia coli***

Refer to 1.8.4 Methods of Analysis of *Escherichia coli*

**2.8.7 *Determination of Biotoxins***

Refer to 1.8.5 Determination of Biotoxins

**2.9 Definition of defectives**

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

**2.9.1 *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.

**2.9.2 *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.

**2.9.3 *Odour/Flavour***

Persistent and distinct objectionable odours or flavours indicative of decomposition or rancidity.

### 2.9.4 *Texture*

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

## 2.10 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 2.9 does not exceed the acceptance number (c) of the appropriate sampling plan in the *General Guidelines on Sampling* (CAC/GL 50-2004);

(ii) the total number of sample units not meeting the count designation as defined in Section II-2.3 does not exceed the acceptance number (c) of the appropriate sampling plan in the *General Guidelines on Sampling* (CAC/GL 50-2004);

(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, Contaminants, Hygiene and Labelling requirements of Sections 2.4, 2.5, 2.6 and 2.7 are met.