



Food and Agriculture
Organization of the
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World Health
Organization

CODEX
ALIMENTARIUS
INTERNATIONAL FOOD STANDARDS

CODEX ALIMENTARIUS
STANDARD

**STANDARD FOR
LIVE AND RAW
BIVALVE MOLLUSCS**
CXs 292-2008



ADOPTED 2008
AMENDED 2026

CXS 292-2008

History of the standard

2026 Amendments

Following the Forty-ninth Session of the Codex Alimentarius Commission in 2026, the titles of Section 8 and Section 17: “Sampling, examination and analysis” were changed to “Methods of analysis and sampling” in accordance with the Codex Alimentarius Commission Procedural Manual; and Section 17.3: “Analysis” was amended by replacing the methods of analysis with a reference to the *Recommended methods of analysis and sampling* (CXS 234-1999).

This publication was reformatted and published in 2026.

2024 Amendments

Following the Forty-seventh Session of the Codex Alimentarius Commission in November 2024, amendments were made in Section 7.4: “Labelling of non-retail containers” by adding a text with a reference to the *General standard for the labelling of non-retail containers of foods* (CXS 346-2021); and Section 8 and Section 17: “Sampling, examination and analysis” were amended by replacing methods of analysis and numeric performance criteria with a reference to the *Recommended methods of analysis and sampling* (CXS 234-1999). Editorial adjustments such as to the numbering of headings have been made to this standard.

Amendments and revisions made prior to 2024:

Revised in 2014 and 2015.

Amended in 2013.

Adopted in 2008.

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 A below applies to live bivalve molluscs while Part B applies to raw bivalve molluscs.

PART A – LIVE BIVALVE MOLLUSCS

2 Description

2.1 Product definition

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

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.

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.

3 Essential composition and quality factors

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.

3.2 Final product

Live bivalve molluscs shall meet the requirements of this standard when lots examined in accordance with Section 10: “Lot acceptance” comply with the provisions set out in Section 9: “Definition of defectives”. Live bivalve molluscs shall be examined by the methods given in Section 8: “Methods of analysis and sampling”.

4 Food additives

Food additives are not permitted in live bivalve molluscs.

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* (CXS 193-1995)ⁱ and the maximum residue limits for pesticides and/or veterinary drugs established by the Codex Alimentarius Commission (CAC).ⁱ

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

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* (CXC 1-1969),² the *Code of practice for fish and fishery products* (CXC 52-2003)³ 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* (CXG 21-1997).⁴

Growing area monitoring programmes, 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 a most probable number (MPN) method specified in ISO 16649-3 or equivalent.

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

Microorganism = <i>Escherichia coli</i>	n=5	c=1	m=230	M=700	3 Class plan
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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.

ⁱ It is recommended to regularly consult CXS 193-1995 for the maximum levels.

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.

7 Labelling

In addition to the provisions of the *General standard for the labelling of pre-packaged foods* (CXS 1-1985),⁵ the following specific provisions apply:

7.1 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 2.3: “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.

7.2 Content declaration

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

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.

7.4 Labelling of non-retail containers

The labelling of non-retail containers should be in accordance with the *General standard for the labelling of non-retail containers of foods* (CXS 346-2021).⁶

In addition, the following should be included:

- 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.
- 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 dispatch centre or other establishment from which they were shipped.
- Durability or shelf life.

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

8 Methods of analysis and sampling

8.1 Sampling

- Each sample shall contain a sufficient number of bivalve molluscs to ensure that the sample is representative.
- The portion of the bivalve molluscs 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.

8.2 Examination

8.2.1 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 the *Recommended methods of analysis and sampling* (CXS 234-1999)⁷ and the *Guidelines for the sensory evaluation of fish and shellfish in laboratories* (CXG 31-1999).⁸

8.3 Analysis

For checking compliance with this standard, the methods of analysis and sampling contained in the *Recommended methods of analysis and sampling* (CXS 234-1999) relevant to the provisions in this standard shall be used.

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.

9 Definition of defectives

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

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.

9.2 Dead or damaged product

The presence of dead or damaged product. Dead product is characterized 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 percent by count.

10 Lot acceptance

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

- the total number of defectives as classified according to Section 9: “Definition of defectives” does not exceed the acceptance number (c) of the appropriate sampling plan in the *General guidelines on sampling* (CXG 50-2004);⁹
- the total number of sample units not meeting the count designation as defined in Section 8.4: “Determination of count per unit weight or volume” does not exceed the acceptance number (c) of the appropriate sampling plan in the *General guidelines on sampling* (CXG 50-2004);
- 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; and
- the food additives, contaminants, hygiene and labelling requirements of Section 4: “Food additives”, Section 5: “Contaminants”, Section 6: “Hygiene” and Section 7: “Labelling” are met.

PART B – RAW BIVALVE MOLLUSCS

11 Description

11.1 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 2.2: “Process definition” 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.

11.2 Process definition

Raw bivalve molluscs must meet the process definition in Section 2.2: “Process definition” 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 those that have been processed to assure reduction or limitation of the target organisms to the satisfaction of the official agency having jurisdiction.

11.3 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.

12 Essential composition and quality factors

12.1 Raw bivalve molluscs

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

12.2 Ingredients

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

12.3 Final product

Raw bivalve molluscs shall meet the requirements of this standard when lots examined in accordance with Section 10: “Lot acceptance” comply with the provisions set out in Section 9: “Definition of defectives”. Raw bivalve molluscs shall be examined by the methods given in Section 8: “Methods of analysis and sampling”.

13 Food additives

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

13.1 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* (CXS 192-1995).¹⁰

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* (CXS 192-1995).

14 Contaminants

Raw bivalve molluscs should meet the requirements of Section 5: “Contaminants”.

15 Hygiene

Raw bivalve molluscs should meet the requirements of Section 6: “Hygiene”.

16 Labelling

In addition to the provisions of the *General standard for the labelling of pre-packaged foods* (CXS 1-1985), the following specific provisions apply:

16.1 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.

The label shall include 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.

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

16.2 Content declaration

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

16.3 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.

16.4 Labelling of non-retail containers

Refer to Section 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* (CXC 52-2003).

17 Methods of analysis and sampling

17.1 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.

17.2 Examination

17.2.1 Sensory and physical examination

Samples taken for sensory and physical examination shall be assessed by persons trained in such examination and in accordance with the *Recommended methods of analysis and sampling* (CXS 234-1999) and the *Guidelines for the sensory evaluation of fish and shellfish in laboratories* (CXG 31-1999).

17.3 Analysis

For checking compliance with this standard, the methods of analysis and sampling contained in the *Recommended methods of analysis and sampling* (CXS 234-1999) relevant to the provisions in this standard shall be used.

17.3.1 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.

18 Definition of defectives

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

18.1 Deep dehydration (frozen products)

Greater than 10 percent of the weight of the bivalve molluscs in the sample unit or greater than 10 percent 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.

18.2 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.

18.3 Odour/flavour

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

18.4 Texture

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

19 Lot acceptance

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

- the total number of defectives as classified according to Section 18: “Definition of defectives” does not exceed the acceptance number (c) of the appropriate sampling plan in the *General guidelines on sampling* (CXG 50-2004);
- the total number of sample units not meeting the count designation as defined in Section 12: “Essential composition and quality factors” does not exceed the acceptance number (c) of the appropriate sampling plan in the *General guidelines on sampling* (CXG 50-2004);
- 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; and
- the food additives, contaminants, hygiene and labelling requirements of Section 13: “Food additives”, Section 14: “Contaminants”, Section 15: “Hygiene” and Section 16: “Labelling” are met.

REFERENCED TEXTS

- 1 *General standard for contaminants and toxins in food and feed* (CXS 193-1995).
- 2 *General principles of food hygiene* (CXC 1-1969).
- 3 *Code of practice for fish and fishery products* (CXC 52-2003).
- 4 *Principles and guidelines for the establishment and application of microbiological criteria for foods* (CXG 21-1997).
- 5 *General standard for the labelling of pre-packaged foods* (CXS 1-1985).
- 6 *General standard for the labelling of non-retail containers of foods* (CXS 346-2021).
- 7 *Recommended methods of analysis and sampling* (CXS 234-1999).
- 8 *Guidelines for the sensory evaluation of fish and shellfish in laboratories* (CXG 31-1999).
- 9 *General guidelines on sampling* (CXG 50-2004).
- 10 *General standard for food additives* (CXS 192-1995).

Codex Alimentarius

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