

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

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HEALTH
ORGANIZATION



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Agenda Item 13

CX/FFP 08/29/11

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FISH AND FISHERY PRODUCTS

**Twenty-ninth Session
Trondheim, Norway, 18 - 23 February 2008**

PROPOSED DRAFT STANDARD FOR FRESH/LIVE AND FROZEN ABALONE (*HALIOTIS* SPP.) (Prepared by South Africa)

The 28th Session of the Committee on Fish and Fishery Products agreed to undertake new work on the elaboration of a Proposed Draft Standard for Fresh/Live and Frozen Abalone, subject to the approval of the Commission. It was agreed that South Africa with assistance of interested countries would prepare a Proposed Draft Standard for consideration by the next session (ALINORM 07/30/18, paras 131-133). This new work was approved by the 30th Session of the Codex Alimentarius Commission while also endorsing the recommendation of the Executive Committee that the Committee on Fish and Fishery Products consider broadening the scope of the standard to include other gastropods (ALINORM 07/30/REP, para. 100, Appendix VII).

South Africa prepared a first draft of the proposed standard and sent it for comment to countries that had indicated an interest to assist in drafting the document as indicated in [Annex 1](#).

The Proposed Draft Standard, as presented in [Annex 2](#) is hereby circulated for comments at Step 3 and consideration by the Committee.

Governments and international organizations wishing to provide comments should do so in writing, preferably by email, to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme – FAO, Viale delle Terme di Caracalla - 00153 Rome, Italy, Fax: +39 (06) 5705 4593, E-mail: codex@fao.org, with a copy to Codex Contact Point, Norwegian Food Control Authority, P.O. Box 8187 Dep. 0034 Oslo, Norway, Fax: +47.74.11.32.01, E-mail: ccffp@mattilsynet.no, **before 15 November 2007**.

EXPLANATION OF THE PROPOSED DRAFT CODEX STANDARD FOR LIVE/RAW AND FROZEN ABALONE (*HALIOTIS* SPP.)¹

BACKGROUND

The draft has been prepared with the view to have a structure and format of text in conformity with some other Codex Standards (i.e., the Draft for Live and Raw Bivalve Molluscs). The draft was circulated for comments to the countries that indicated an interest in assisting South Africa with the work. Comments were received from New Zealand, Australia and Mexico.

Scope of the document

The recommendation of the 30th Session of the Commission, namely, that consideration be given by the CCFFP to expand the scope to include other gastropods, has been noted. However, the scope of the proposed draft standard is focused on abalone (Genus *Haliotis*) based on the fact that at this point, only information for abalone is available. It would be difficult to include other gastropods if their processing or the hazards associated with them are different to that of *Haliotis* and clarification is sought in this regard.

Inclusion of sections I-5.3, I-7.4 and I-7.5

These sections are included for the following reasons:

1. There is a possibility that live abalone may be eaten raw, so abalone raised in contaminated waters may have micro-organisms that could be hazardous to consumers, including certain pathogenic viruses.
2. The South Africa experience is that gutting and proper cleaning of abalone clear the meat of any remaining Paralytic Shellfish Poisons (PSPs) where these have been isolated in affected animals. No other types of shellfish poisons have been isolated from abalone in South Africa. It is however possible that people consume uncleaned live or raw abalone and the PSPs may be a risk. The experience of other countries will be sought for the rationale to prescribe tests for all other shellfish poisons known to affect bivalves.

¹ Prepared by South Africa

ANNEX 2

**PROPOSED DRAFT STANDARD FOR LIVE ABALONE AND FOR RAW FROZEN ABALONE
FOR DIRECT CONSUMPTION OR FOR FURTHER PROCESSING****1. SCOPE**

This standard applies to live abalone and/or raw frozen abalone of the genus *Haliotis* that have been frozen whole or shucked, viscera, epithelium and mucous removed and 'beak' retained and then frozen while essentially retaining the sensory characteristics of live abalone. Both live and raw abalone may be intended for direct consumption or further processing

Part I below applies to live abalone, while Part II applies to raw frozen abalone.

PART I – LIVE ABALONE**I-2. DESCRIPTION****I-2.1. Product definition**

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

I-2.2 Process Definition

Live abalone are harvested alive from a harvesting area or farm approved by the official agency having jurisdiction, to supply abalone for direct human consumption and may be purged in clean sea water and/or drained prior to packaging for direct human consumption or for further processing as in II-2.2.

I-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 abalone may be packed by weight, count, count per unit of weight, volume or per package.

I-3. ESSENTIAL COMPOSITION AND QUALITY FACTORS**I-3.1. Abalone**

The abalone must be alive and possess organoleptic characteristics associated with freshness, and freedom from taint or extraneous matter, as determined by specialists familiar with the species concerned.

I-3.2. Water for Purging

Sea water for purging shall be of the required cleanliness to ensure that abalone comply with the requirements in I-5.3.

I-3.3. Ice for Packing

If ice is used for packing, the water used for the manufacture of ice shall be of potable quality or shall be clean sea-water. Potable water is fresh water fit for human consumption. Standards for potability shall not be less than those contained in the latest edition of the WHO "International Guidelines for Drinking Water Quality." Clean sea-water is sea-water which meets the same microbiological standards as potable water and is free from objectionable substances.

I-3.4. Final Product

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

I-4. FOOD ADDITIVES

Food additives are not permitted in live abalone.

I-5. HYGIENE AND HANDLING

I-5.1. It is recommended that the products covered by provisions of this standard be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969) and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice.

I-5.2 The products should comply with any microbiological criteria established in accordance with the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).

I-5.3 Live abalone shall not contain numbers of faecal coliforms or *E.coli* bacteria in excess of testing regimes as follows:

- i. Live abalone shall not exceed the maximum permissible level of the designated microorganism when tested in accordance with the MPN method specified in ISO 16649-3 or equivalent. In an analysis involving five (5) samples, none may contain more than 330 *E.coli* per 100g, and not more than one (1) of the five (5) samples may contain between 230 and 330 *E.coli* per 100g.

Escherichia coli/g n=5 c=1 m=2.3 M=3.3

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.

- ii. Live abalone must not contain more than 330 faecal coliforms per 100g. In an analysis involving five (5) samples, none may contain more than 330 faecal coliforms per 100g; and if more than two (2) of the five (5) contain between 230 and 330 faecal coliforms per 100g, the five samples must be analyzed for *E.coli*. In that analysis, no sample may contain more than 330 *E.coli* per 100g, and not more than one (1) of the five (5) samples may contain between 230 and 330 *E.coli* per 100g.

Faecal coliforms/g n=5 c=2 m=2.3 M=3.3

Escherichia coli/g n=5 c=1 m=2.3 M=3.3

- iii. Live abalone must not contain *Salmonella* in 25g flesh and *Vibrio parahaemolyticus* in 100g/flesh.
- iv. As abalone are not filter feeders they are not usually associated with the concentration of biotoxins. However, they may be exposed to microalgal blooms resulting in product surface or gut contamination and hence biotoxin standards should be set.

(iv)-1 In the edible parts of live abalone (the whole part or any part intended to be eaten separately) the total content of biotoxins from the saxitoxin (STX) group must not exceed 0.8 milligrams of saxitoxin (2HCL) equivalent per kilogram of abalone flesh.

(iv)-2 In the edible parts of live abalone (the whole part or any part intended to be eaten separately), the total content of biotoxins from the okadaic acid (OA) group must not exceed 0.16 milligrams of okadaic acid per kilogram of abalone flesh.

(iv)-3 In the edible parts of abalone (the whole part or any part intended to be eaten separately) the total content of biotoxins from the domoic acid (DA) group must not exceed 20 milligrams of domoic acid per kilogram of abalone flesh.

(iv)-4 In the edible parts of abalone (the whole or any part intended to be eaten separately) the total content of biotoxins from the brevetoxin group must not exceed 20 mouse units or equivalent.

(iv)-5 in the edible parts of abalone (the whole or any part intended to be eaten separately) the total content of biotoxins from the Azaspiracid (AZP) group must not exceed 0.16 milligrams per kilogram.

I-5.4 When tested by appropriate methods of sampling and examination prescribed by the Codex Alimentarius Commission, the product shall not contain any other substances in amounts which may represent a hazard to health in accordance with standards established by the Codex Alimentarius Commission.

I-6. LABELLING

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

I-6.1. 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 abalone 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.

I-6.1.1 There shall appear on the label, reference to the presentation (provided for in Section I-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.

I-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.

I-6.2. Content Declaration

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

I-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.

I-6.4. Labelling of Non-retail Containers

At a minimum, labelling for live abalone shall contain information adequate to:

- (i) Clearly identify the product for consumers
- (ii) Identify all traceability/product tracing information that might be needed in the event of a food safety problem, e.g., information about geographic origin, date of harvesting, as well as identification of the despatch centre or other establishment from which they were shipped
- (iii) Establish durability or shelf life

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.

I-7. SAMPLING, EXAMINATION AND ANALYSIS

I-7.1. Sampling

- (i) Sampling of lots for examination of the product shall be in accordance with the Codex General Guidelines on Sampling (CAC/GL 50-2004).
- (ii) The portion of the shellfish to be analysed shall be the portion considered edible.

I-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 I-7.3 through I-7.5, and "Guidelines for the Sensory Evaluation of Fish and Shellfish in Laboratories" (CAC/GL 31-1999).

I-7.3. Determination of Count per Unit Weight or Volume

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

I-7.4. Methods of Analysis of *Escherichia coli* and Faecal Coliforms in Shellfish Meats

Recommended Procedures for the Examination of Seawater and Shellfish 4th ed. 1970. The American Public Health Association, Washington, DC (for faecal coliforms in meats), or other validated methods as

accepted by the competent authority. The ISO/TS 16649-3 standard — Enumeration of beta glucuronidase-positive *Escherichia coli* in live abalone.

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 surveys.

I-7.5. Determination of Biotoxins

The majority of the currently available methods do not meet all Codex criteria for reference methods (Type II). There are a number of chemical methods, instrumental methods and functional assays currently in use.

These are listed in the table below.

<i>Provision</i>	<i>Methodology</i>	<i>Principle</i>	<i>Type</i>
Saxitoxin Group	AOAC Lawrence LC-FL method	LC-FL	II
	AOAC International Mouse Bioassay	Bioassay	III
	*	Receptor Binding Assay	III
	*	Immunochemical	III
	*	LC-MS ²	III
Okadaic Acid Group	*	LC-MS ²	II
	*	Bioassay ²	III
	*	PP2A ²	III
	*	LC-FL	III
	*	ELISA ²	III
Domoic Acid Group	Quilliam LC-UVD method	LC-UV	II
	*	ELISA	III
	*	LC-MS	III
	*	LFIC ²	III
Brevetoxin Group	*	LC-MS ²	II
	*	ELIZA ²	III
	APHA mouse bioassay ¹	Bioassay	III
Azaspiracid Group	*	LC-MS ²	II
	*	Bioassay	III

¹When using the MBA for detecting lipophilic marine biotoxins, false positives may occur due to the presence of other substances such as YTX, PTX and CI which are not known to cause human illness. When false positives are suspected, confirmatory testing, using an internationally validated method, can be carried out in order to identify the type(s) of marine biotoxins present.

²Further method development (e.g. interlaboratory validation, CRM availability) needed prior to submission for endorsement by CCMAS.

*Official/recognized method title to be identified.

I-8. DEFINITION OF DEFECTIVES

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

I-8.1. Foreign Matter

The presence in the sample unit of any matter which has not been derived from abalone, 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.

I-8.1. Dead or Damaged Product

Dead abalone is characterized by lack of muscle movement when touched and/or complete muscle stiffness due to the rigor mortis process setting in after death of the animal. Animals damaged to the extent that they can no longer function biologically, are considered to be defective. The product is rejected if more than 5% of the units in the sample are dead or damaged.

I-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 I-8 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-7.3 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, Hygiene and Labelling requirements of Sections I-4, I-5 and I-6 are met.

PART II – RAW FROZEN ABALONE**II-2. DESCRIPTION****II-2.1. Product Definition**

Raw frozen abalone processed for direct consumption or for further processing are products that were alive immediately prior to the commencement of processing and comply with Section I-2.2 relating to harvesting. They have been frozen whole or shucked, viscera, epithelium and mucous removed and “beak” retained and then frozen while essentially retaining the sensory characteristics of live abalone.

II-2.2. Process Definition

The product is harvested as in I-2.2 and after suitable preparation is subjected to a freezing process complying with the conditions laid down hereafter.

The freezing process shall be carried out in appropriate equipment in such a way that the range of maximum ice crystallization is passed quickly. The quick freezing process shall not be regarded as complete unless and until the product temperature has reached -18°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.

II-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 abalone may be packed by weight, count, count per unit of weight, volume or per package.

II-3. ESSENTIAL COMPOSITION AND QUALITY FACTORS**II-3.1. Raw Frozen Abalone**

Raw abalone shall be of a quality fit for human consumption.

II-3.2. Glazing

If glazed, the water used for glazing or preparing glazing solutions shall be of potable quality or shall be clean sea-water. Potable water is fresh-water fit for human consumption. Standards of potability shall not be less than those contained in the latest edition of the WHO “International Guidelines for Drinking Water Quality.” Clean sea-water is sea-water which meets the same microbiological standards as potable water and is free from objectionable substances.

II-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.

II-3.4. Final Product

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

II-4. FOOD ADDITIVES

Only the use of the following additives is permitted in raw abalone.

Antioxidants

For raw frozen abalone 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).

II-5. HYGIENE AND HANDLING

II-5.1. It is recommended that the products covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969), the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003).

II-5.2 The products should comply with any microbiological criteria established in accordance with the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).

II-5.3 Abalone should meet the requirements of I-5.2 to I-5.4 prior to freezing or shucking, viscera, epithelium and mucous removal and retention of the “beak” followed by freezing. After processing they should retain visual characteristics associated with freshness, including, where relevant, shells free of dirt.

II-6. LABELLING

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

II-6.1. 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 abalone 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.

II-6.1.1 There shall appear on the label, reference to the presentation (provided for in Section II-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.

II-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 county in which the product will be distributed.

II-6.2. Content Declaration

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

II-6.3. Storage Instructions

The label shall include terms to indicate that the product shall be stored at a temperature of -18°C or colder.

II-6.4. Labelling of non-retail containers

Refer to I-6.4 Labelling of Non-retail Containers.

II-7. SAMPLING, EXAMINATION AND ANALYSIS**II-7.1. Sampling**

- (i) Sampling of lots for examination of the product shall be in accordance with the Codex General Guidelines on Sampling (CAC/GL 50-2004).
- (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.

II-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 II-7.3 through II-7.7, and Guidelines for the Sensory Evaluation of Fish and Shellfish in Laboratories” (CAC/GL 31-1999).

II-7.3. Determination of Net Weight

The net weight of all sample units shall be determined by the procedures described or mentioned in sections II-7.3.1 through II-7.3.3.

II-7.3.1 Determination of Net Weight

- (i) Weigh the unopened container;
- (ii) Open the container and remove the contents;
- (iii) Dry the empty container and weigh.
- (iv) Subtract the weight of the empty container from the weight of the unopened container.

The resultant figure will be the total net weight.

II-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.

II-7.3.3 Determination of Net Weight of Frozen Products Covered by Glaze

AOAC official method 963.18, Net Contents of Frozen Seafoods.

II-7.4. DETERMINATION OF COUNT PER UNIT WEIGHT OR VOLUME

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

II-7.5. SAMPLE PREPARATION

II-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 abalone, until no hard core or ice crystals are left.

II-7.6. Methods of Analysis of *Escherichia coli* and Faecal Coliforms in Shellfish Meats

Refer to I-7.4 Methods of Analysis of *Escherichia coli* and Faecal Coliforms in Shellfish Meats

II-7.7. Determination of Biotoxins

Refer to I-7.5 Determination of Biotoxins

II-8. DEFINITION OF DEFECTIVES

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

II-8.1. Deep Dehydration

Greater than 10% of the weight of the abalone in the sample unit 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 abalone.

II-8.2. Foreign Matter

The presence in the sample unit of any matter which has not been derived from abalone, 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.

II-8.3. Odour/Flavour

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

II-8.4. Texture

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

II-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 II-8 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;

the Food Additives, Hygiene and Labelling requirements of Sections II-4, II-5 and II-6 are met.