codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 7 **CX/FFP 03/8**

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

Twenty-sixth Session
Ålesund, Norway, 13 - 17 October 2003

PROPOSED DRAFT STANDARD FOR LIVE AND PROCESSED BIVALVE MOLLUSCS GOVERNMENT COMMENTS AT STEP 3 (Canada, New Zealand, United States of America)

CANADA

General Comment

Canada generally supports this document but recognizes that there are specific issues in this standard which require further discussion by the Committee.

Specific Comments

SECTION 2 - DESCRIPTION

Section 2.1 - Product Definition

1. Canada believes the range of products described under "processed bivalve molluscs" in this proposed draft standard is too broad. We suggest the Committee discuss the purpose(s) and scope of this standard and review the products to be included. There are advantages to limiting the product range. In discussing this approach, the following should be considered:

1.1) The proposed draft standard will need to be follow the "Format for Codex Committee Standards"[1]. This would mean that each bivalve mollusc product (e.g. smoked, marinated, breaded, etc.) will need to be adequately and specifically described and hygienic and defective specifications along with their sampling and methods of analysis will need to be elaborated. The bivalve molluscs standard will become lengthy and could become complicated to use. Existing Codex fish standards currently only cover one product/process type. A simpler standard with a narrower scope will improve the standard's user-friendliness.

1.2) The proposed draft standard has elaborated hygiene and handling requirements for live and raw bivalve molluscs. Given that raw shucked bivalve mollusc meats will be used in the processing of other bivalve molluscs products, it should be presumed that further processed products would be safe

[1] Codex Alimentarius Commission Procedural Manual, 12th Edition pp 78 - 81.

for human consumption provided that the human health hazard issues specific to the process itself, are adequately controlled.

In summary, Canada would prefer a bivalve molluscs standard that is food safety based and limited to live bivalve molluscs and their raw products.

2. In reference to post harvest treated bivalve molluscs, Canada is of the opinion that Codex standards should allow flexibility for other possible risk management options provided that these methods are technically feasible and scientifically validated. We would agree in principle that post harvest treated bivalve molluscs should be included in this standard and welcome further discussion on this matter.

SECTION 5 - HYGIENE & HANDLING

Section 5.3

3. For ease of reference, consideration should be given to standardizing or limiting the units expressed for the biotoxin tolerances listed in this section. Canada proposes the toxin standards be expressed as follows: 80 µg/100g for PSP, 0.16 µg/g for DSP, 20 µg/g for ASP, 16 µg/100g for AZP, and 1 µg/g for Yessotoxin.

5.3(I)

4. Section 5.3(I) which states: "*Live bivalve molluscs shall be free from micro-organisms or substances originating from micro-organisms or viruses in amounts which may present a hazard to health in accordance with standards established by the CAC*", is not consistent with the food hygiene text adopted at the 23rd Session of the Codex Alimentarius Commission (CAC) and as contained in the 12th edition of the CAC Procedural Manual (pp 85 - 86). Canada recommends replacing the proposed text in Section 5.3(I) with adopted Codex text as follows: "**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)**."

5.3(ii)

5. Canada prefers option two which states: "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."

5.3(v) & 7.7

6. Canada would like clarification concerning the two separate proposed references for DSP (i.e. DSP and DSP toxin). It is unclear whether bivalve molluscs must comply with both provisions or that one provision could replace the other. This information will also help clarify Section 7.7 concerning the determination of DSP. Furthermore, it is not clear if Section 7.7 - Determination of Biotoxins recognizes chemical methods (HPLC) for DSP testing as "authorized", "approved" or "acceptable".

7. Canada notes that the proposed draft standard references that the DSP toxin testing is performed on the whole part or any part intended to be eaten separately. However, in some countries, DSP toxin testing is performed only on the digestive tissue only. The DSP limit values are different. Because the sampling for the two approaches is fundamentally different, it makes it difficult to compare the degree of similarity between two tolerances. Consideration should be given to a more universal expression of the DSP standard which recognizes different, yet equivalent, approaches for testing**.**

SECTION 6 - LABELLING

6.1

8. Current Codex Standards for fish and fishery products do not require the designation of scientific name for the name of the food. Canada is of the view that this standard should remain consistent with the adopted text of existing Codex norms. We would therefore support retaining the clause**". . . common or usual name of the species. . ."** and deleting the text in square brackets regarding **".** . *name of the species.* ."

6.5.4

9. Concerning the provision: "*Every package containing purified bivalve molluscs must be provided with a label certifying that all molluscs have been purified*," Canada would like to seek clarification on the purpose for the labelling of purified bivalve molluscs (i.e. consumer information or batch identification). We wish to note that Section 2.2 - Process Definition, paragraph 1, has laid down purification requirements of live bivalve molluscs. It stipulates that purification is an approved process given by the official agency having jurisdiction. This food safety management approach is designed to reduce microbiological hazards to acceptable levels thus minimizing the health risks to consumers. If this labelling provision is for consumer information, Canada is of the view that Section 2.2 - Process Definition, paragraph 1, sufficiently addresses purification and therefore would recommend that consideration be given to delete the labelling requirement.

SECTION 7 - SAMPLING, EXAMINATION AND ANALYSIS

Section 7.1 - Sampling

10. It is recommended that additional work in this subsection is necessary to address sampling and elaborate sampling plan(s) to be employed for biochemical toxin analysis of loose bulk packaged shell stock.

NEW ZEALAND

The New Zealand Government would like to make the following comments:

1. In 2.2, Process definition, it is unclear whether canned bivalve molluscs are required to meet the requirements for live bivalve molluscs. Looking at 2.1 and 3.1, it seems that they should, so this should be clearly stated in 2.2.
2. In 3.2 it would be better if "clean water" was also defined here - the Code differentiates between "clean water" and clean (sea) water.
3. In 5.3.i, apart from the CODEX Committee on Fish and Fishery products, would there be some other Committee that might set the levels? If it is this Committee, then the levels should be included in this document.
4. In 5.3.ii, the levels prescribed are rather impractical, considering the MPN method. We therefore propose that the levels per gram be

   Eschericia coli n = 5 c=1 m = 2.3 M = 7

   Faecal coliforms n = 5 c = 1 m = 3.0 M = 10
5. In 5.3iv, add at the end 'with a 24 hour observation time" - This addresses the issue of some countries running short observation times to limit the ability to detect some of the biotoxins.
6. It is unclear why purified bivalve molluscs must be labelled as such - when there are no similar requirements for labelling treated contaminated product such as post harvest treated and relayed product.
7. In 7.6 - suggest that as there are such a variety of methods in use, the method be simply stated as the method in current use by the official agency having jurisdiction.
8. In 7.7 - suggest that at the end, delete 'for use' and add "by the official agency having jurisdiction".

UNITED STATES

In response to CL 2002/20-FFP (Item 6), June 2002, Proposed Draft Standard for Live and Processed Bivalve Molluscs, Step 3, Appendix VII, the United States wishes to submit the following comments. Attached to these comments is a draft showing how the standard would look if the comments were adopted.

TITLE

The United States suggests changing the title to “Draft Standard for Live and Raw Bivalve Molluscs”.

Reason: During the 25th Session the United States indicated that it could support a standard that included both live and all processed forms of molluscan shellfish. The United States is now persuaded, especially by comments from Canada, that the better approach may be to limit the scope to live and raw bivalve molluscs. It is important to ensure that molluscan shellfish for human consumption, whether processed or not, meet basic standards. A Codex standard for live and raw bivalve mollusks can focus on those basic matters without being unwieldy. Additional matters relating to processed bivalve molluscs can be covered in standards for specific types of processed products, e.g., canned. For this reason, most of the United States comments in this document reflect changes necessary to narrow the scope of the standard to live and raw bivalve only.

1. SCOPE

1st paragraph: change to read: “This standard applies to live bivalve mollusks and their raw products including scallop with viscera and/or gonads attached.”

Reason: see reason above, plus clarity concerning the inclusion of viscera and gonads in scallops that could pose the same public health hazards as other bivalve molluscan shellfish.

2nd paragraph: delete [Traceability]

Reason: "Product tracing" or "trace back" has become the language used in place of "traceability" by other U.S. Codex committees.

2. DESCRIPTION

2.1 Product Definition.

1st paragraph, delete 3rd through 5th sentences about processed products. Add, at the end, the following new sentence: "Raw bivalve molluscs are products that are no longer alive immediately prior to consumption but were alive immediately prior to shucking, freezing or other treatment that did not eliminate the sensory characteristics of live products."

Reason: sentences 3-5 are recommended for deletion because processed products would be outside the scope of the standard. A sentence for the purpose of defining "raw" bivalve molluscs is recommended for inclusion because the scope of the standard would include "raw" in addition to "live." "Raw" bivalve molluscs would include molluscs that have undergone treatments that are lethal to the shellfish (e.g. shucking and freezing) but that maintain the properties expected of raw shellfish.

2nd paragraph (bracketed), delete.

Reason: The United States originally proposed this language in order to clarify that products that have undergone "post harvest treatment" need not be limited to those that have undergone depuration. In recent years new forms of post harvest treatment have become available, primarily targeted toward the naturally occurring pathogen *Vibrio vulnificus.* It is important to note that these new forms of post harvest treatment also appear to be effective against *Vibrio parahaemolyticus.* Short of water closure, the United States is not aware of any control strategy that would be effective against these pathogens. As we know, water closure can cause significant economic hardship while denying products to consumers. It should be regarded as a control of last resort. Some other delegations expressed reservations, however, about including these post harvest treatments in the standard, primarily based on the concern that these treatments could be used inappropriately as a replacement for traditional controls such as water classification. The United States agrees with those delegations that water classification is and should remain an essential element of any system of safety controls for molluscan shellfish. The United States has never envisioned post harvest treatments as a replacement for water classification or any of the other classic components of a safety control system. But the United States also believes that depuration need not remain the only recognized post harvest treatment as progress makes new treatments available, especially when the only alternative control for a particular hazard is to close waters and shut down harvest. However, as an acknowledgement of the concerns that have been expressed by the other delegations, and in the spirit of compromise, the United States is willing to drop the language in brackets here, since the product definition of "raw bivalve molluscs" in the first paragraph would encompass products that have received any form of post harvest treatment so long as the result is a product that has retained the sensory characteristics of a live mollusc.

2.2 Process Definition

1st paragraph: Revise to read: "Live and raw bivalve mollusks shall be organisms that are harvested alive from an approved growing area and/or from another appropriately classified growing area. Where appropriate, and especially where harvesting is from an area that is not fully approved for direct consumption, this harvesting may be followed by an approved relaying procedure for further purification or by depuration or other post harvest treatment by an approved purification center. The classification and approval mentioned in this subsection must be given by the official agency having jurisdiction. Relaying, depuration and other forms of post harvest treatment shall assure the purification, i.e., elimination, reduction, or limitation of target organisms or other hazards to the satisfaction of the of the official agency having jurisdiction."

Reason: In keeping with the proposed scope of the document, this language would provide a process definition for both "raw" and "live," not just for "live." It would define stages at which bivalves can be harvested and/or purified for raw consumption based on officially approved water classifications and purification procedures: 1) harvest from fully approved waters for raw consumption without need for any

further purification; 2) move from waters that are not fully approved for harvest for direct raw consumption but are not heavily polluted so the product can be relayed to purify in fully approved waters; 3) move to an approved centre or centres to purify by depuration and/or other form of post harvest treatment. Note that the language now accommodates movement to post harvest treatment from fully approved waters, not just from "another appropriately classified growing area." The flexibility to do this may enable waters to stay open where post harvest treatment can eliminate a hazard, such as a naturally occurring pathogen, that traditional water classification strategies are unable to solve, even where the water has been fully approved in the traditional sense. The economic harm and the loss to consumers caused by water closure should be a last resort. Also, by requiring that shellfish that receive post harvest treatment must first be harvested from approved or otherwise appropriately classified waters, the proposed language would reinforce that post harvest treatment is not a substitute for a traditional water classification program.

[Note: The language we are proposing would not include the reference in the current draft the reference to "natural container (raft, float or tank)" relating to relaying and possibly to depuration. The reasons for the proposed deletion are: (1) the language appears to imply that relaying must involve a "natural container;" however, relaying may also involve depositing shellfish in a location on the ocean bottom; and (2) it is not clear what is meant by a "natural" container.]

2nd paragraph, combine the first and 2nd sentences to read: "Where raw bivalve molluscs are frozen, 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 remainder of the paragraph would remain as currently drafted.

Reason: So long as it is clear that frozen bivalve molluscs must be those that meet the definition of "raw" bivalve molluscs (as stated in the suggested revision, above) it should not also be necessary to state that frozen bivalve molluscs must be derived from organisms that meet the requirements for live molluscs. Consequently, that latter language about live molluscs would be deleted. The other important point here to define the freezing process for raw bivalve molluscs, both in-shell and shucked, so the proposed revision retains and emphasizes that point.

Remainder of 2.2: delete, including the bracketed paragraph about post harvest treatment.

Reason: There would be no need to provide process definitions for canned or other processed market forms if the scope of this standard is limited to live and raw product. The bracketed paragraph about post harvest treatment would not be necessary because that topic would be adequately addressed in 2.1 and 2.2, 1st paragraph. The bracketed paragraph would also not be necessary because the paragraphs we are recommending for deletion all involve processed market forms. Shellfish that have received only depuration or other forms of post harvest treatment should not be considered as having been further processed. Depuration or other post harvest treatment should be considered as a purification treatment and the product is considered raw, with the characteristics of raw.

4. FOOD ADDITIVES

1st paragraph: revise to read: "Only the use of the following additives is permitted in raw bivalve molluscs."

Reason: This suggested revision would replace the word "processed" with the word "raw" in keeping with the recommendation that the scope of this standard include "raw" but not "processed" products.

Antioxidants

Paragraphs 1, 4 & 5: delete

Reason: This standard as suggested would not include "processed" product such as marinated, battered, smoked, dried, etc.

Current 2nd paragraph (would become 1st paragraph per the recommendation above): Revise to read: "For raw, fresh, shucked bivalve molluscs…"

Reason: To identify that this material applies to "raw," but not to "live" product per the recommended scope of the standard; to identify that it applies to raw product that is fresh, shucked.

Current 3rd paragraph (would become 2nd paragraph per the recommendation above): Revise to read: "For raw, frozen, shucked bivalve molluscs…"

Reason: To identify that this material applies to "raw," but not to "live" product per the recommended scope of the standard; to identify that it applies to raw product that is frozen, shucked.

Sequestrant

Change to read: "For raw fresh or frozen bivalve molluscs any sequestrant listed…"

Reason: to change this sentence to refer to "raw" products rather than to "canned" products, in keeping with the recommended change in the scope of the standard.

5. HYGIENE AND HANDLING

5.1: Add a second sentence to read: "This includes bacterial and viral pathogens and toxins."

Reason: clarity

5.3(i): Revise to read: "Live bivalve molluscs shall be free from micro-organisms and viruses or substances originating from micro-organisms in amounts which may present a hazard to health in accordance with standards established by the CAC."

Reason: To clarify that live bivalve molluscs should be free from viruses as well as from micro-organisms; and to delete the idea that these products should be free from substances originating from viruses. We are not aware of such substances.

5.3(ii): The United States prefers the second bracketed paragraph over the first bracketed paragraph because it reflects U.S. practice. The United States accepts, however, that both bracketed paragraphs are not substantially different from one another and are not likely to produce substantially different public health outcomes. Thus, if Codex were to select one bracketed paragraph over another, the result could be unnecessarily burdensome to countries that follow the standard reflected in the deleted paragraph. In this instance, therefore, the Committee may want to retain both bracketed paragraphs. One way to do that would be to draft a more general paragraph and retain the current bracketed paragraphs as allowable examples.

5.3(iii): add the following to the end of the sentence: "and must not contain enteric pathogenic viruses in 10 g flesh."

Reason: Need a value for the level of acceptable viruses.

5.3 at the end: Delete: (*Note – comments on methodology is transferred to Section 7.)*

5.4: delete the 2nd and 4th bullets.

Reason: In keeping with the recommendation that the standard apply to "live" and "raw" only, the bullets for canned and low acid and acidified low acid canned foods should be deleted.

6. LABELLING

6.1: **The Name of the Food**: Delete bracketed language "[the name of the species of bivalve mollusks]" and delete the remaining brackets. The sentence would then read: "The name of the product as declared on the label shall be the common or usual name of the species of bivalve mollusks according to the law, custom or practice in the country in which the product is to be distributed."

Reason: The common or usual name adequately satisfies consumer's need to understand the nature of the product. It is unlikely that consumers would recognize the Latin names.

(NOTE: The United States notes that the codex labeling Committee may be considering whether the word "custom" should continue to be used in codex standards. Thus, this language may have to be revisited in light of any decisions on the subject by the labeling committee.)

6.1.2: Change 1st paragraph to read: "In addition to the specified labeling designations above, the common or usual trade names of the specific variety (e.g. Kumomoto oysters) may be added so long as it is not misleading to the consumer in the country…"

Reason: "Usual or common" was changed to "common or usual" to be consistent with 6.1 plus an example "(e.g., Kumomoto oysters)" was added to demonstrate the meaning of 6.1.2 .

6.2: **Content Declaration:** 2nd sentence, revise to read: "Raw fresh or frozen shucked bivalve molluscs shall have a net weight declaration in accordance with Codex General Standard for labelling of Prepackaged Foods."

Reason: In keeping with the recommendation about the scope of the standard.

6.4: **Labelling of Non-Retail containers (for bulk transport of live and raw shucked bivalve mollusks):** Delete, 2nd bullet "lot identification" and delete "lot identification, and" in the last sentence.

Reason: since harvesting location, date of harvest and date of processing are required, lot identification is a redundancy.

6.5: **Other Labelling Requirements**

Suggest changing this title to read: **Additional Retail Labelling Requirements.**

Reason: This section includes labelling requirements that are applicable to retail products in addition to the requirements in Sections 6.1 Name of Product, 6.2 Content Declaration and 6.3 Storage Instructions.

6.5.3 : Revise to read: "Safety claims, if any, should be specific to the organisms or other hazards that have been eliminated, reduced, or limited by a specific control or purification process."

Reason: Safety claims on consumer labeling have not been common in the past but are starting to be used. It is important that any such claims not mislead the consumer. For example, a safety claim made for a product that has undergone a purification process should not exceed what the purification process is designed to accomplish.

7. SAMPLING, EXAMINATION AND ANAYSES

7.3.5: **Determination of Drained Weight:** Delete the material in 7.3.5(i) and renumber paragraphs 7.3.5(ii)-(v) to be 7.3.5(i)-(iv). At the beginning of new paragraph 7.3.5(i) [formerly 7.3.5(ii)], add: "In the case of shucked bivalve molluscs,".

Reason: This revision would changes the determination from canned products to shucked products, in keeping with the recommended scope of the standard. It would provide a methodology for determining drained weight of shucked oysters.

7.5.2: **Cooking Methods:** The U.S. assumes that this section refers to an aspect of sensory analysis. If so, it is not necessary and should be deleted because sensory adequately covered in 7.2, "Sensory and Physical Examination."

8. DEFINITION OF DEFECTIVES

8.5: **Objectionable Matter (Canned Products):** This should be deleted because this standard is suggested for live and raw only.

8.6: **Dead or Damaged Product:** Renumber as 8.5 per the previous comment and, in the last sentence, replace "exceed" with "exceeds" to correct a typographical error.

PROPOSED DRAFT CODEX STANDARD FOR LIVE AND RAW BIVALVE MOLLUSCS

(At Step 3 of the Procedure)

1. SCOPE

This standard applies to live bivalve molluscs and their raw products including scallop with / viscera and/or gonads attached.

Product tracing is an important feature for bivalve molluscs and must be secured.

(The Proposed Draft Standard for Quick Frozen Scallop Muscle Adductor Meat includes scallops without gonads and viscera.)

2. DESCRIPTION

2.1 Product Definition

Bivalve molluscs are organisms from the class bivalvia that are suitable for human consumption.

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 processing, such as shucking, freezing or other treatment that did not eliminate the sensory characteristics of live products.

2.2 Process Definition

Live and raw bivalve molluscs shall be organisms that are harvested alive from an approved growing area and/or from another appropriately classified growing area. Where appropriate, and especially where harvesting is from an area that is not fully approved for direct consumption this harvesting may be followed as appropriate by an approved relaying procedure for further purification or by depuration or other post harvest treatment by an approved purification centre. The classification and relaying, depuration and other forms of post harvest treatment shall assure the purification, i.e, elimination, reduction , or limitation of target organisms or other hazards to the satisfaction of the official agency having jurisdiction.

Whereraw bivalve molluscs are frozen, . 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 -18ºC 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.

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 additivess is permitted in raw bivalve molluscs

Antioxidants

For raw fresh shucked bivalve 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) at levels not to exceed good manufacturing practices (GMP).

For raw frozen shucked bivalve 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) at levels not to exceed good manufacturing practices (GMP).

Sequestrant

For raw fresh or frozen bivalve molluscs any sequestrant listed in Table III 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. This includes bacterial and viral pathogens and toxins.

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 bacteria or substances originating from bacteria, or from viruses, in amounts that 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 discussionLive 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 and must not contain enteric pathogenic viruses in 10 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 exceed16 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.

(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 [draft] recommended International Code of Practice for Fish and Fishery Products];
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- the Recommended International Code of Practice for the Processing and Handling of Quick Frozen Foods (CAC/RCP 8-1976);
- the Draft International Code of Hygienic Practice for the Products of Aquaculture (under elaboration, 1994);
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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 common or usual name of the species of bivalve molluscsaccording 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 common or usual trade names of the specific variety (e.g. Kumomoto oysters) 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.

Raw, shucked fresh or frozen bivalve molluscs shall have a net weight declaration in accordance with *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,
-
- 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, 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 Additional Retail Labelling Requirements

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

6.5.2 Identification of the establishment approved by the official agency with the jurisdiction, for the production of the product.

6.5.3 Safety claims, if any, should be specific to the target organisms or other hazards that have been eliminated, reduced, or limited by a specific control or purification process.

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

(i) In the case of shucked bivalve molluscs, open and tilt the container to distribute the contents on a pre-weighed circular sieve which consists of wire mesh [with square openings of 2.8 mm x 2.8 mm – confirm AOAC mesh size] or [*2.5 mm x 2.5 mm*];

(ii) Incline the sieve at an angle of approximately 17-20 º and allow the bivalve molluscs to drain for two minutes, measured from the time the product is poured into the sieve;

(iii) Weigh the sieve containing the drained bivalve molluscs;

(iv) The weight of drained bivalve molluscs is obtained by subtracting the weight of the sieve and drained product.

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 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.

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 *Eschericia coli* in live bivalve molluscs. Communicable Disease and Public Health 1. 188-196.

In the absence of standard virus testing procedures, an assessment of the risks from viruses must be based on analysis using the methods in currently applied by the official agency having jurisdiction.

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.

8.5 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 exceeds 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.