codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 7 **CX/FFP 02/7-Add.1**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FISH AND FISHERY PRODUCTS
Twenty-fifth Session
Ålesund, Norway, 3 - 7 June 2002

PROPOSED DRAFT STANDARD FOR LIVE, QUICK FROZEN AND CANNED BIVALVE MOLLUSCS
GOVERNMENT COMMENTS AT STEP 3
(Malaysia, New Zealand, Spain, United States)

MALAYSIA

General Comment

Malaysia would like to seek clarification whether the sections in the standard address all three live, quick frozen and canned bivalve molluscs where applicable.

2. DESCRIPTION

2.1 Product Definition

Malaysia would like to propose the inclusion of the word "dried" and "salted" in the third paragraph of this section as such products are used to prepare canned bivalve molluscs. Therefore, the paragraph should read as follows:

Canned bivalve molluscs are a product prepared from fresh, frozen, cooked, **dried, salted**, smoked or not smoked edible portions of bivalve molluscs to which salt, water and/or edible oils, or other ingredients and packing medium may have been added.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Live Bivalve Molluscs

Malaysia would like to propose the term "bodily fluids" be replaced with the term "intravalvular liquid" for consistency with Section 5.2.

6. LABELLING

6.1 The Name of the Food

6.1.8 Malaysia would like to propose that section 6.1.8 be amended to be more precise, as follows:

The label shall state the identification of the establishment approved for the production of the product.

6.1.9 Malaysia is of the view that it might be more appropriate for subsection 6.1.9 to be placed elsewhere since it is not related to labelling.

NEW ZEALAND

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

1. Scope

New Zealand suggests amending the first line to read:

> "This standard applies to all species of bivalve molluscs, shucked or in the shell; fresh or frozen; whole or in part; and includes scallops except where the product is the adductor muscle only, i.e. without the viscera and roe."

2.1 Product definition

2.2 Process definition

There is a high degree of overlap between these two definition sections. For example, the product definition of "quick frozen bivalve molluscs" indicates that their key characteristic is that they are frozen – which refers to a process. Given that the products are largely defined by the processing that they undergo, New Zealand suggests collapsing these two sections into a single definition section to remove the repetition.

2.1 Product definition

The term "quick" frozen normally refers to a specific time/temperature regime. Unless that regime is defined, the word "quick" should be deleted.

The terms "freezing" and "quick freezing" are both used in the second paragraph. As per our comment on section 2.1, the word "quick" should be deleted.

2.2 Process definition

The terms "potable" and "clean seawater" appear, but these are not defined until section 3.2. New Zealand suggests including the definitions here, where the terms are first used.

Section 5.3

For clarity, subsections (iv), (v) and (vi) should follow the same wording format for describing the whole part or edible part separately, then the shellfish toxin, then the maximum allowable level.

Subsections (iv), (v) and (vi) contain region-specific test methods. New Zealand requests that the phrase "or a method approved by the official agency having jurisdiction" be added to each reference to a test method.

New Zealand suggests adding a new subsection immediately after (vi), as follows:

> ( ) "In the edible parts of bivalve molluscs (the whole or any part edible separately) the total Neurotoxic Shellfish Poison (NSP) content must not exceed 20 mouse units per 100g of edible mollusc using the current American Public Health Association Inc. method or other method approved by the official agency having jurisdiction."

New Zealand suggests that another subsection be added requiring testing for AZP (Azaspiracid) using a method approved by the official agency having jurisdiction.

6.1.3 The name of the food

The terms "blanched", "deshelled" and "heat shocked" all have similar meanings, and are used alternately in different parts of the world. Therefore, we suggest amending section 6.1.3 as follows:

> "6.1.3 Products shall be designated as steamed, cooked, *deshelled/heat shocked/blanched*, frozen, canned as appropriate."

6.3 Storage instructions

For deshelled/heat shocked/blanched product, the temperature for storage should be changed to "-1 to +7^{o}C".

7.7 MPN method for analyses of *E Coli* / faecal coliforms

7.8 Determination of biotoxins

New Zealand wishes to have input into the test methods for these once a proposal is suggested.

SPAIN (English version)

In Section 5 - Hygiene and Handling

As we agree with the text in square brackets, we propose to delete the square brackets.

In section 5.3 (iv) third line "80 microgrammes per 100g" should read "80 microgrammes of saxitoxin equivalent per 100g.."

ESPAÑA (version española)

A la sección 5. Higiene y manipulación.

Por estar de acuerdo con el contenido de los corchetes se propone suprimir los corchetes.

En el apartado 5.3.(iv) tercera línea donde dice: "…80 microgramos por 100 g…", debe decir: "…80 microgramos de saxitoxina equivalente por 100 g…".

UNITED STATES

Section 1, Scope, paragraph 1**,** revise as follows: "This standard applies to live and processed bivalve molluscs. This standard does not apply to fresh or frozen scallop adductor muscle meat (i.e., without viscera and roe).

Reason: As drafted, the standard applies to some processed forms of bivalve molluscs (quick frozen and canned, although it also discusses shucked) but omits all others, presumably because the omitted forms are less significant in international commerce. However, the general principles in this standard apply to all processed forms, e.g., the extent to which they should be obtained from bivalve molluscs that meet the requirements of the standard with regard to hygiene and handling. Consequently, we suggest expanding the scope to include all processed forms.

An alternative approach would be to develop a standard for live and raw product forms, consistent with the comments recently provided by Canada. Other product forms could be covered in a separate standard or standards, as the Committee decides. The United States could support such an approach as an alternative to its own suggestion.

Section 1, Scope, paragraph 2, delete "**traceability**" and substitute "The tracing of products for the purpose of facilitating the withdrawal from the market when a risk to human health has been identified is an important feature…"

Reason: Traceability is a term not agreed to in Codex where the substituted language was agreed to at step 8 by the 3rd session of the ad hoc Task Force on Foods Derived from Biotechnology.

Section 2.1, Definition, paragraph 1, delete in its entirety and substitute the following: "Live bivalve molluscs are products that are alive immediately prior to consumption. Presentation includes the shell. Processed bivalve molluscs are products that are no longer alive immediately prior to consumption but were alive immediately prior to the commencement of processing. Processed bivalve molluscs include, but are not necessarily limited to the following market forms: quick-frozen, post-harvest treated, breaded, smoked, marinated, shucked, cooked-ready-to-eat, and canned. Canned bivalve molluscs may be made from products that have already undergone processing."

Reason: Live bivalve molluscs would not be prepared with a packing medium, salt, water, and /or edible oils etc. by a processor. If the scope of the standard were expanded to include all processed forms, a product definition for processed bivalve molluscs would be appropriate in addition to a product definition for live bivalve molluscs.

Section 1, last paragraph, at the end paragraph add "Post-harvest treated bivalve molluscs are products prepared from live bivalve molluscs that have been treated after harvest to eliminate, reduce, or limit specified target organisms within the product, and to retain the sensory qualities of a live bivalve mollusc."

Reason: Post-harvest treated bivalve molluscs represent a relatively new market form but are expected to gain in importance in international trade as a significant enhancement to safety. The United States recently developed a program to significantly reduce illnesses from *Vibrio* bacteria that takes advantage of post-harvest treatment as a key component of the control strategy. Consequently, there is likely to be a notable transition to post-harvest treatment in the United States.

Section 2.2, Process Definition, paragraph 2, first sentence, after " bivalve molluscs" add ", except as provided below, processed bivalve molluscs shall be derived from organisms that meet all the requirements for live bivalve molluscs." Then start a new sentence " The product shall…"

Reason: If the scope of this document is expanded to include all processed forms of bivalve molluscs, we recommend a blanket statement covering all processed products, rather than a statement for each processed form, e.g., frozen. Exceptions could be made, as proposed below, for processed forms that do not need to be derived from organisms that meet all the requirements for live, i.e., canned and post harvest treated.

Section 2.2, Process Definition, paragraph 2**,** last sentence, after "Frozen bivalve molluscs shall" add "after suitable preparation." The product definition section refers to "quick frozen" but the process definition section refers to "frozen." Should the two be consistent?

Reason: This is a technical edit if the previous suggested revision is adopted.

Section 2.2,Process Definition, paragraph 4, at the end of paragraph add the following: "Post-harvest treated bivalve molluscs shall be organisms that meet the requirements for live bivalve molluscs, either because they are derived from organisms that meet these requirements or because they have received post-harvest treatment, or because of a combination of the two. The post-harvest treatment shall assure the elimination, reduction, or limitation of the target organisms to the satisfaction of the official agency having jurisdiction."

Reason: As with canning, it is not essential that the live bivalve mollusc be in full compliance with all safety requirements at the moment of harvest so long as it is in full compliance after undergoing post-harvest treatment. To ensure that it is in full compliance, it is essential that the post-harvest treatment receive a full validation to the satisfaction of public health authorities before any safety claims may be made for the product.

Section 2.2, Process Definition, last paragraph, at the end of paragraph add the following: "The water used for washing live bivalve molluscs shall be of potable quality or seawater of equal or better bacterial quality than the water from which the shellfish were harvested."

Reason: If the standard is going to describe the circumstances when water must be of adequate quality, it should include the water used for washing live bivalve molluscs. [NOTE: another option would be to include this material in the code of practice rather than in the standard. See Draft Code of Practice Section 7.6.3 Washing, declumping, debyssing and grading.]

Section 3.1, Live Bivalve Molluscs, paragraph 1, and at the end of last sentence add, "as determined by product specialists familiar with the species."

Reason: It might be extremely difficult to quantify in this standard such things as the normal quantity of bodily fluids because of the variation among species. However, the properties specified are commonly used in the trade to establish viability and quality. Consequently, instead of attempting quantification, we recommend that the standard recommend to users of the document that they consult with experts in the trade, as necessary, to determine whether the attributes have been met.

Sections 4, Food Additives, delete in its entirety and substitute the following:

> The use of the following additives is permitted.
>
> Antioxidants
>
> For marinated molluscs and fully preserved (canned molluscs), any antioxidants listed in Table III of the General Standard for Food Additives (CODEX STAN 192-1995).

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

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

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

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

Sequestrant

For canned 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)."

Reason: The U.S. suggests that the CCFFP expand the Food Additive section to allow for the food additives provided for in Codex. Additives are endorsed for use in various foods according to their function. The U.S. knows of no justification for restriction of use for any endorsed food additives in molluscan shellfish products. Use of food additives must be declared on the label. If the Committee decides to limit the scope of this standard to live and raw product forms, the above materials will have to be reviewed for relevance

Sections 5.2, at the end of last sentence add, "as determined by product specialists familiar with the species."

Reason: It might be extremely difficult to quantify in this standard such things as the normal quantity of bodily fluids because of the variation among species. However, the properties specified are commonly used in the trade to establish viability and quality. Consequently, instead of attempting a quantification, we recommend that the standard recommend to users of the document that they consult with experts in the trade, as necessary, to determine whether the attributes have been met.

Section 5.3, item (i), delete in its entirety and substitute the following:

"The product in-commerce shall meet the following standard:

"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."

The molluscs shall meet the following harvest standard.

"At a country's discretion: Live bivalve molluscs must not contain more than 300 fecal coliforms or more than 230 E coli per 100g of mollusc flesh and intravulvar liquid. Determination by the 5 tube, 3 dilution MPN testing method or any other equivalent method. Or

The Live bivalve molluscs shall not have been harvested from waters containing:

(a) A median value greater than 14 fecal coliforms per 100 ml of water and a 90^{th} percentile greater than 43 fecal coliforms per 100 ml of water or greater than 49 fecal coliforms per 100 ml of water. Determination by the 5 tube, 3 dilution or 3 tube, 3 dilution MPN testing method respectively; or

(b) A median value greater than 70 total coliforms per 100 ml of water and a 90^{th} percentile greater than 230 total coliforms per 100 ml of water or greater than 330 total coliforms per 100 ml of

water. Determination by the 5 tube, 3 dilution, or 3 tube, 3 dilution MPN testing method, respectively."

Reason: The current draft incorporates the European standard for shellfish meats. Growing waters are to be closed when this meat standard is exceeded. Other countries, including the United States, operate a water-based system and close waters when certain water standards are exceeded. The two systems are in alignment to the extent that when the European standard of 300 fecal coliforms is found in shellfish meat, it is overwhelmingly likely that the water-based standard in the U.S. and elsewhere would also be exceeded. However, whether waters would be closed in the U.S. and elsewhere when meat levels are significantly below 300 fecal coliforms is a question that the United States is attempting to answer. Thus, because it is not yet known whether the two systems (meat-based vs. water-based) result in closure under identical or near identical circumstances, the United States recommends that, for now, the Codex standard provide both the EU meat-based standard for closure and the water based standard and allow countries to choose between the two.

Sections 5.3, item (ii), delete this item and allow item (iii) below to make the point. It is not clear why the standard should be specific about Salmonella but not specific about other microbial pathogens.

Section 5.3, item (iv), change "or any part edible separately" to "any part intended to be eaten separately."

Reason: It is important that the standard apply to the whole edible portion of a bivalve mollusc or to portions that could be reasonably expected to be eaten separately. The standard should not be interpreted as applying to separate parts of the mollusc that are not ordinarily eaten separately. For example, the siphons of Alaska butter clams, could theoretically be eaten separately and if one were to analyze the siphon, that specific tissue might exceed the standard while the whole edible portion would not. Because siphons are not ordinarily eaten separately, there would be no valid public health reason to reject the clam under these circumstances.

Section 5.3, item (v.), change "or any part edible separately" to "any part intended to be eaten separately." The reason for this revision is the same as above.

Section 5.3, item (vi), delete in its entirety and substitute the following: "In the edible parts of bivalve molluscs (the whole part or any part intended to be eaten separately), the total Amnesiac Shellfish Poison (ASP) content must not exceed 20 microgrammes domoic acid per gram [or 2000 microgrammes domoic acid per 100 g] of mollusc flesh in accordance with the HPLC testing method."

Reason: (a) same as above re "intended to be eaten separately;" (b) change "…Shellfish Poisoning" to "…. Shellfish Poison" to reflect that what is being measured here is the amount of "poison" in the flesh; and (c) to change the level to that established by Canada in the wake of a domoic acid outbreak there in 1987, and subsequently adopted by the United States. That level was established after extensive examination of epidemiological data from a large number of cases and it has worked well over the years. The level of 20 microgrammes per 100 g of flesh in the current draft appears to have been a mathematical error and not an intended change from the 1987 level.

Section 5.3, item (vii.), delete in its entirety and substitute "In the absence of routine virus testing procedures and the establishment of virological standards, an assessment of the risk from viruses must be based of faecal bacteria counts and sanitary shoreline survey."

Reason: Faecal bacteria counts alone do not provide adequate information about the risk from viruses because these bacteria might not be present at unacceptable levels even though viruses are present. A good example is a wastewater treatment facility that treats waste to meet the bacteriological water quality standard but is likely to be discharging viruses. Shoreline sanitary surveys identify these kinds of pollution sources.

Section 6.1, The Name of the Food, first sentence, delete "The name of the product as declared on the label shall be the name of the species of bivalve molluscs" and substitute "The name of the product as declared on the label shall be the common or usual name of the species of bivalve molluscs"

Reason: Requiring the species name here, in addition to allowing the "usual or common trade name" in 6.1.2, could be interpreted to require the Latin name in addition to common or usual name. For purposes of consumer labeling, the common or usual name in use in the country in which the product is to be distributed should be sufficient to ensure that the consumer is not misled or confused.

Section 6.1.1, we are not sure what, exactly, "presentation" refers to. Does "presentation" include the designations in 6.1.3? If so, 6.1.1 and 6.1.3 could be combined.

Section 6.1.2, this section could be deleted if the suggested revision to 6.1, above, is adopted. It would be redundant with 6.1 and no longer be necessary.

Section 6.1.3, do the requirement in this section constitute "presentation?" See our comments on "presentation", Section 6.1.1, above.

Section 6.1.4, delete in its entirety and substitute "For live bivalve molluscs, this product shall declare the date of harvest."

Reason: If there is a problem, harvest date allows the trace back of all bivalve molluscs that have been harvested at the same time as the mollusc(s) that have caused the problem. Harvest date also helps establish when the problem may have occurred in the water. This information can be useful when attempting to determine the cause of a problem. [Finally, the length of the shelf life for live products can be highly variable and, to our knowledge, have not been uniformly established or agreed to.]

Section 6.1.5, delete this section in its entirety.

Reason: The importance of this information is not clear. Labeling information should only be required when the information is essential to the consumer.

Section 6.1.7, delete this section in its entirety.

Reason: This kind of information relates to commercial practices and is not necessary on consumer labels. Consumer information is covered in 6.3, below. The United States has no requirement for this kind of information to be provided by one commercial entity to another in the distribution chain, and does not perceive a need for it.

Section 6.1.8, delete in its entirety and substitute the following: "The label shall contain information that will enable timely identification of the establishment that has produced the product."

Reason: This change should meet the purpose of the provision while still allowing for the name of the manufacturer, packer, or distributor of the product, as allowed by some country requirements.

Section 6.1.9, delete in its entirety and substitute the following: "Identification of the growing area must be kept at the first, or primary establishment involved in the production of the product." Furthermore, this is not a labeling requirement and thus should either be moved to a different section of the standard or relocated into the code of practice for these products.

Reason: For processed products especially, there may be more than one producer in the chain of production. So long as the growing area can be determined from the first producer in the chain, there is no reason to require all producers to store growing area information.

Add the following new section:" 6.1.10 Safety claims made for post-harvest treated bivalve molluscs should be specific to the target organisms that have been eliminated, reduced, or limited by the post-harvest treatment."

Reason: So far, post-harvest treatments have been shown to be effective against some target organisms but not against all microbial pathogens that could inhabit bivalve molluscs. It is important, therefore, that safety claims made for post-harvest treated bivalve molluscs be limited to the target organisms and not imply that the bivalve mollusc has been rendered safer than it actually has.

Section 6.3, Storage Instructions, second paragraph, delete in its entirety and substitute the following: **"**For deshelled bivalve molluscs, the label shall include terms to indicate that the product should be kept refrigerated."

Reason: Consumers understand what is meant by keep refrigerated, or keep frozen; specific temperature information is less useful or understandable to the average consumer.

Section 6.3, Storage Instructions, last paragraph, delete in its entirety and substitute the following: "For frozen bivalve molluscs, the label shall include terms to indicate that the product should be kept frozen."

Reason: Consumers need to keep these products frozen and will understand what that means. Although the product has been initially frozen to -18 C, consumers need not necessarily store at that temperature so long as they keep it frozen.

Section 6.4, Labeling of Non-Retail Containers (for bulk transport of live bivalve molluscs); rename this section to "Labeling of Non-Retail Containers (for bulk transport of live and raw shucked bivalve molluscs"

Reason: The materials in this section apply to both live and raw shucked product. This revision makes the title consistent with the materials.

Section 7.3.3, Determination of Net Weight of Products Covered by Glaze, after "AOAC official method 963.18, Net Contents of Frozen Seafood Products" add the following new paragraph:

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.

Reason: To provide for a correct method to determine the net weight of a frozen block that contains added water. The water trapped inside the block cannot be removed.

Section 7.5, rename this section to "Sample Preparation." Current section "7.5 Procedures for Thawing" should be renumbered 7.5.1, because it is a procedure that is part of sample preparation; and current section "7.6 Cooking Methods" should be renumbered 7.5.2 because it also is a procedure that is part of sample preparation.