codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 6 **CX/FFP 06/28/6**

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

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PROPOSED DRAFT STANDARD FOR LIVE AND RAW BIVALVE MOLLUSCS GOVERNMENT COMMENTS AT STEP 3

PART I - COMMENTS IN REPLY TO CL 2005/14-FFP
(Canada, European Community, New Zealand)

CANADA

General Comments

Canada generally supports the approach outlined in the standard for live and non-viable bivalve molluscs as a basis for further discussion. We recognize that there are fundamental issues that will require further discussion by the Committee.

Canada notes that "*non-viable bivalve molluscs*" include products that are "*processed to eliminate target pathogens while retaining the sensory characteristics of live products*." (See Section 1 - Scope, 1st paragraph). We favour this description because it helps clarify that canned or cooked bivalve molluscs would not be covered by this standard. Canada suggests that this document should be checked to ensure that the clause "**while retaining the sensory characteristics of live products**" is appended to each instance that "*processed to eliminate target pathogen*" is referenced in this document. Alternatively, "*non-viable bivalve molluscs*" could be defined at the beginning, or at an appropriate place of the document and this term can be used throughout the text.

Canada notes that the terms "*products*" and "*final products*" were used interchangeably to describe "*bivalve molluscs*". We believe that these terms should be standardized and suggest that the term "*bivalve molluscs*" should be used. If agreed, a document check should be performed to affect this change.

Specific Comments

SECTION 1 - SCOPE

> Add new 2nd sentence (**in bold faced text**) as follows: "This standard applies to live bivalve molluscs and non-viable bivalve molluscs that have been shucked and/or frozen and/or processed to eliminate target organisms while retaining the sensory characteristics of live products. **Non-viable bivalve molluscs are marketed either in a frozen or fresh state.** These bivalve molluscs may be intended for direct consumption or further processing. In the case of scallops, adductor muscle is excluded"

Reason: The Canadian proposal clarifies that "*non-viable bivalve molluscs*" include products that are commercially marketed in a fresh state and frozen state. For example, shucked bivalve molluscs meat can be sold in both the fresh or frozen form.

PART I – LIVE BIVALVE MOLLUSCS

SECTION 3 - ESSENTIAL COMPOSITION AND QUALITY FACTORS

I-3.2 Other Ingredients

Revise to read: "**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.**"

Reason: Some Codex Frozen Fish Standards contain a standard for water used for glazing (e.g. Codex Standard for Quick Frozen Fish Fillets (Codex Stan 190-1995)). For consistency, Canada recommends that a similar approach should be applied for water used for manufacturing ice.

SECTION I-5 HYGIENE & HANDLING

Add the following adopted Codex text as new sub-section:

"**I - 5.X 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, Rev 4-2003), and the Code of Practice for Fish and Fishery Products *(reference to be provided)***"

Reason: The Canadian proposed text is consistent with the food hygiene text stipulated in the CAC Procedural Manual (14th edition, pp 95).

I-5.2

Revise to read: "Live bivalve molluscs should possess visual characteristics associated with freshness and viability, including shells free of dirt, and an adequate response to percussion ~~normal amounts of intravalvular fluid~~ as determined by product specialists familiar with the species."

Reason: Canada recommends deleting the assessment for viability based on "*normal amounts of intravalvular liquid"* since this is a subjective criterion. Our proposal would align this provision with the definition for "*dead or damaged product*" in the Defectives section [1] (i.e. the definition does not contain a criterion for "*normal amounts of intravalvular liquid"*)

I-5.3(i)

Delete text: "*Bivalve mollusc shall be free from micro-organisms or substances originating from microorganisms in amounts which may present a hazard to health in accordance with standards established by the CAC.*"

Add the following adopted Codex text as new sub-section:

"**I – 5.X 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).**"

[1] Section 8.6 - Dead or Damaged Product states that "*dead product is characterized by no response to percussion*."

Reason: The Canadian proposed text is consistent with the food hygiene text stipulated in the CAC Procedural Manual (14th edition, pp 95).

I-5.3(ii)

Revise to read: ~~AND/~~ OR ~~– for discussion~~

Reason: Canada is of the view that it is not possible to apply both standards and would prefer 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."

SECTION I-6 LABELLING

I-6.1

Revise to read: "The name of the food to be declared on the label shall be [the name of the species of bivalve molluscs] [the common or usual name of the species of bivalve molluscs] ~~according to the law, customs or practice in the country in which the product is to be distributed~~ **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**"

Reason: The Canadian proposed text is consistent with the adopted text of a number of existing Codex Fish Standards and the decision of the CCFFP to retain the reference to "*law and custom*" in the name of the food labeling provision. (Alinorm 05/28/18, para 8).

I-6.5.1

Revise to read: "For live bivalve molluscs, the product shall declare the **harvest location and** the date of minimum durability, harvest date or packing date or a statement to this effect."

Reason: Canada is of the view that the harvest location should be declared on the label of live bivalve molluscs intended for retail sale. As consumption of bivalve molluscs with accumulated biotoxins can result in the rapid onset of severe illness or death in humans, this information is required to permit the immediate closure of implicated harvest areas and to effect immediate and prompt recall of affected products from those areas.

I - 6.5.3

Delete text: "*I-6.5.3 [Every package containing purified bivalve molluscs must be provided with a label certifying that all molluscs have been purified.]*"

Reason: Canada would like to seek clarification on the purpose for the labelling of purified bivalve molluscs (i.e. for consumer information or for batch identification). We are of the view that Section I-2.2 - Process Definition and Section I-5.3 (i) sufficiently address purification and microbiological criteria respectively and therefore the labelling provision I-6.5.3 is unnecessary.

Section I-2.2 - Process Definition 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.

SECTION I - 7 SAMPLING, EXAMINATION AND ANALYSIS

Delete: "*I-7.4 Sample Preparation*"

Reason: Canada questions the need for this provision because there is no requirement associated with it.

SECTION I - 8 DEFINITION OF DEFECTIVES

Move "*I-8.2*" and "*I-8.3*" as new provisions in Section II-8 (Definition of Defectives for non-viable bivalve molluscs):

"*I-8.2 Odour/Flavour: Bivalve molluscs affected by persistent and distinct objectionable odours or flavours indicative of decomposition or rancidity*."

"*I-8.3 Texture: Textural breakdown of the flesh, indicative of decomposition, characterized by muscle structure which is mushy or paste-like*."

Reason: Canada notes the "*odour/flavour*" and "*texture*" provisions apply only to non-viable bivalve molluscs since these products are dead and therefore prone to spoilage. We believe that defect specifications for live bivalve molluscs should comply with Section I-8.4 Dead or Damaged Product.

PART II – NON-VIABLE BIVALVE MOLLUSCS

SECTION 2 - DESCRIPTION

II - 2.1 - Product Definition

Revise to read: "Non-viable bivalve molluscs processed for direct consumption or further processing are products that ~~are no longer alive immediately prior to consumption but~~ were alive immediately prior to commencement of **processing, comply with Section I-2.2 and have been shucked and/or frozen and/or processed to eliminate target organisms while retaining the sensory characteristics of live products. Non-viable bivalve molluscs are marketed either in a frozen or fresh state.** Presentation may or may not include the shell."

Reason: Canada suggests that this section should be revised to:

- limit it to live bivalve molluscs for processing. The clause regarding the bivalve molluscs being alive prior to consumption has been appropriately addressed in I-2.1 Product Definition (Live Bivalve Molluscs)

- incorporate our earlier comments regarding the need to clarify that canned or cooked bivalve molluscs would not be covered by this standard and include products that are commercially marketed in a fresh state

II - 2.2 - Process Definition

Delete 1st sentence: "*Non-viable bivalve molluscs processed for direct consumption or further processing are ones that meet the process definition for live bivalve molluscs and in addition have been shucked and/or frozen and/or processed to eliminate target organisms.*"

Reason: There appears to be repetition with Section II – 2.1 Product Definition.

Add as new paragraph: "**Fresh bivalve molluscs shall, after any suitable preparation, receive no preservation treatment other than chilling**."

Reason: If the Working Group/Committee accepts the Canadian proposal in the "Product Definition" section to include bivalve molluscs that are marketed in a fresh state, our proposal defines the process to obtain a raw fresh product.

II – 3.2 - Glazing (for frozen bivalve molluscs)

Revise to read: "**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.**"

Reason: The standard for water used in glazing should be consistent with existing Codex Frozen Fish Standards (e.g. Codex Standard for Quick Frozen Fish Fillets (Codex Stan 190-1995)).

II - 6.5.1

Delete text: "*6.5.3 [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: Canada has reservations regarding the use of safety claims because it is not clear how these claims can be substantiated. Safety claim declarations on labels could also be construed by the consumer to mean that bivalve molluscs using such claims are "better and safer" products because they have undergone a specific process to eliminate or reduce the hazard.

EUROPEAN COMMUNITY

The European Community (EC) thanks the United States for their efficient involvement in this matter and supports the text in general, but would however like to propose the following amendments on the draft standard at Step 3 of the Codex Procedure:

I-5. HYGIENE AND HANDLING

(ii) [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 **specified in ISO 16649-3** or any other method equivalent.] AND/OR – for discussion
[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.]

I-6.5 Other Labelling Requirements

I-6.5.1 For live bivalve molluscs this product shall declare the date of minimum durability, harvest date or packing date or a statement to this effect **or the entry "these animals must be alive when sold".**

II-5. HYGIENE AND HANDLING

II-5.2 Bivalve molluscs should possess visual characteristics associated with freshness, including, where relevant, shells free of dirt **~~. and normal amounts of intravalvular liquid as determined by products specialists familiar with the species.~~**

II-6.5 Other Labelling Requirements

Refer to I-6.5 Other Labelling Requirements **a part the entry "these animals must be alive when sold**"

II-6.5.2 [Every package containing **processed ~~purified~~** bivalve molluscs must be provided with a label certifying that all molluscs have been **processed to eliminate target organism ~~puriefied.~~**].

NEW ZEALAND

General Comment on Re-formatting

New Zealand generally supports the re-formatting of the document as circulated. This appropriately clarifies that the standard applies to two classes of product. Live bivalve molluscs and non-viable (dead) bivalve molluscs still in an essentially raw form.

Scope

New Zealand supports the scope of the proposed draft standard.

I - 5.1

New Zealand believes the appropriate wording for this sentence is "The final product shall be free from any foreign material that presents a hazard to human health".

I – 5.2 Live Bivalve Molluscs

New Zealand would either like to see a definition for "percussion" inserted or the word replaced by simpler language. Normally we would describe this as "shellfish will close by themselves when tapped" or similar wording. (Also I- 8.4)

I- 5.3 (ii)

New Zealand considers that the levels prescribed are rather impractical, considering the limitations of the MPN method. We therefore propose that the levels be set per gram as follows:

Eschericia coli	n = 5	c=1	m = 2.3	M = 7
Faecal coliforms	n = 5	c = 1	m = 3.0	M = 10

This recognises both the innate imprecision of the MPN method and that individual shellfish may bio-accumulate indicator organisms at different rates. New Zealand is not aware of any research that demonstrates a linkage between these sorts of levels in the context of the above sampling plan and any increased risk to human health that would justify the more restrictive levels stipulated in the draft document. These levels are utilised in the New Zealand monitoring programme and have been found to work very well to ensure public health and safety is protected.

I - 5.3 (v)

New Zealand requests removal of the first paragraph in this section. New Zealand's experience with the use of mouse bioassay for determination of Diarrhetic Shellfish Poison (DSP) is such that it is very clear that use of mouse bioassay produces too many false positive results from substances that are not DSP toxins. Generally these substances are not harmful to humans, eg free fatty acids. Others, for example, Neurotoxic Shellfish Poison (NSP) are more appropriately tested for using other methods of analysis specific to the toxin being tested for. We also anticipate that by the next meeting of CCFFP an LCMS method for saxitoxins will be approved by AOAC. We note that it is highly undesirable for Codex to promote the use of animal testing methods when there are more accurate and specific test methods available.

There should be uniformity in units used for expressing levels of marine biotoxins in shellfish – we suggest mg/kg would be suitable.

We submit that only reference methods should be listed in this standard. We note that other methods may be very suitable to screen samples and these could be elaborated on further in the draft Code of Practice section on bivalve shellfish.

New Zealand reserves its right to comment on this section further once all documentation relating to the report of the WHO/FAO expert consultation on marine biotoxins has been considered by our biotoxin experts.

I - 7.6

New Zealand is aware that there are a wide variety of methods in use for analysis for *E.coli* and faecal coliforms. In the absence of an exhaustive comparative study of such methods to base a recommended method on, we suggest that the method be simply stated as the method or methods as approved by the official agency having jurisdiction.

The final sentence of this section should be moved to the Code of Practice if appropriate to retain as it does not appear to be an appropriate part of a standard.

I -7.7

New Zealand reserves its right to comment on this section further once all documentation relating to the report of the WHO/FAO expert consultation on marine biotoxins has been considered by our biotoxin experts.

II - 2.2 Process Definition

New Zealand believes that the first paragraph of this definition contains too much detail and could be significantly improved by retaining the first sentence and moving the remainder of the paragraph to the Code of Practice to form the basis of an advisory section on frozen shellfish.

II - 3.2 Glazing (For frozen bivalve molluscs)

“Clean” water is not defined. We suggest that replacing the word “clean” with the word “potable” would clarify this section and is consistent with the standard for fish fillets.

II - 5.2

We suggest that this section could be improved by rewording as follows:

“Bivalve molluscs should meet the requirements of I-5.2 prior to shucking, freezing, or processing to eliminate target organisms. After shucking, freezing or processing to eliminate target organisms they should retain visual characteristics associated with freshness, including where relevant, shells free of dirt and normal amounts of intravalvular liquid as determined by product specialists familiar with the species.”

II - 6.5.2

New Zealand does not understand why it is necessary for packages containing purified bivalve molluscs to have a label certifying that all molluscs have been purified. We see no purpose for such a label. We also note that there are no similar requirements proposed for labelling treated contaminated product such as post harvest treated and relayed product.

II - 7.5.2

It is not clear what the purpose of this section is. The scope of the standard is for bivalve molluscs suitable for direct consumption or further processing.

This section appears unnecessary unless the scope of the standard includes products that require cooking by the consumer though we would note that cooking of shellfish is generally minimal and would not be likely to reach the temperatures specified in this section. We are therefore unsure as to whether there is any value in retaining this section in this standard.

PART II COMMENTS IN REPLY TO CL 2006/7-FFP
(Australia, Brazil, Canada, European Community, Japan, Peru)

AUSTRALIA

1. SCOPE

For the last sentence in Para 1, Australia suggests:

This standard does not apply to scallops when the final product is the adductor muscle only.

PART I - LIVE BIVALVE MOLLUSCS

I-2.2 Process Definition

Australia suggests:

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

Reason: relaying and depuration are both "purification" measures, notwithstanding that the former occurs in the natural environment and the latter in a controlled/artificial environment.

I-3.1 Bivalve molluscs

Second sentence, Australia suggests:

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

Reason: there are characteristics other than visual ones which may indicate acceptability of molluscs.

I-3.2 Other Ingredients

Title of section, Australia suggests:

1.3.2 Ice for packing

I-5. HYGIENE AND HANDLING

Australia suggests that all text in section I-5.2 be deleted and replaced by the following:

Bivalve molluscs shall comply with standards for micro-organisms, toxins and other deleterious substances which may present a hazard to human health, as prescribed by, and when examined using testing methods approved by, the official agency having jurisdiction. As far as practicable, criteria established by the Codex Alimentarius Commission shall be considered when prescribing applicable standards and test methods.

Example 1: Live bivalve molluscs shall not exceed the maximum permissible level of the designated micro-organism when tested in accordance with an MPN method specified in ISO 16649-3, or equivalent:

Escherichia coli*/g n=5 c=1 m=2.3 M=7*

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.

Example 2: Live bivalve molluscs must not contain Salmonella *in 25g flesh.*

Example 3: In the edible parts of live bivalve molluscs, Paralytic Shellfish Poison must not exceed 80 µg/100g saxitoxin equivalent.

Example 4: The edible parts of bivalve molluscs must not contain lead exceeding 2mg/kg.

Reason: standards may differ between countries in accordance with local environmental factors, species, testing capabilities and consumer dietary intake, and the relevant competent authority should therefore be able to prescribe limits in accordance with relevant risk assessment procedures. Additionally, Codex 'horizontal' Committees such as CCFH and CCFAC are responsible for setting microbiological and contaminant standards within the appropriate and consistent risk assessment profile.

BRAZIL

PART I – LIVE BIVALVE MOLLUSCS
1.2.3. PRESENTATION –
Brazil asks for clarification about the term "any presentation".
Reason: we think there is no other presentation for this kind of product.

1-6. LABELLING
We suggest deleting: "the name of the species of bivalve molluscs".
Reason: the name of the species of bivalve molluscs is not necessary for the most of the consumers.

CANADA

General Comments

Canada generally supports the approach of this standard but recognizes that there are fundamental issues which require further discussion by the Committee.

Many of the Canadian comments noted below stem from recommendations made by the Codex Working Group meeting[1] held in Ottawa, Canada (April 2006) wherein the 'Report of the joint FAO/IOC/WHO ad hoc Expert Consultation on Biotoxins in Bivalve Molluscs' was reviewed and assessed in terms of advancing work on the current draft standard.

Specific Comments

PART 1 - LIVE BIVALVE MOLLUSCS

SECTION I-5 HYGIENE & HANDLING

I-5.2 (iii)

Canada would like to seek further clarification regarding the intent of the requirement for viruses (specified as *"…must not contain enteric pathogenic viruses in 10 grams of flesh"*), and would suggest there is a need for CCFFP to discuss possible implications of such a requirement.

Canada suggests the following revisions (i.e. for paragraphs (iv) - (ix)) as per the recommendations made by the aforementioned Codex Working Group meeting (April, 2006). These relate to the identification of marine biotoxin groups and the corresponding action levels.

I-5.2 (iv)

> *In the edible parts of live bivalve molluscs (the whole part or any part intended to be eaten separately) the total* ***~~Paralytic Shellfish Poisoning (PSP)~~ content of biotoxins from the saxitoxin (STX) group*** *must not exceed* ***0.8 milligrams ~~microgrammes~~*** *of saxitoxin (2HCL) equivalent per* ***kilogram ~~100 g~~*** *of mollusc flesh*

I-5.2 (v)

> *In the edible parts of live bivalve molluscs (the whole part or any part intended to be eaten separately)* ***the total content of biotoxins from the okadaic acid (OA) group ~~there must not be a positive result for the Diarrhetic Shellfish Poison (DSP) and the maximum level of Okadaic acid, Dinophysistoxins and Pectenotoxins together,~~*** *must not exceed* ***0.****16* ***milligrams ~~microgrammes~~*** *of okadaic equivalents per* ***kilogram ~~100g.~~ of mollusc flesh.***

I-5.2 (vi)

> *In the edible parts of live bivalve molluscs (the whole part or any part intended to be eaten separately)* ***the total content of biotoxins from the domoic acid (DA) group ~~the content of Amnesic~~***

[1] 'Report of the Working Group Meeting to Assess the Advice From the Joint FAO/WHO/IOC *Ad Hoc* Expert Consultation on Biotoxins in Bivalve Molluscs', Ottawa, Ontario, April 2006

~~***Shellfish Poisoning (ASP)***~~ *must not exceed* ***20 milligrams*** ~~***2000 microgrammes***~~ *of domoic acid per* ***kilogram*** ~~***100g***~~ *of mollusc flesh.*

I-5.2 (vii)

In the edible parts of live bivalve molluscs (the whole part or any part intended to be eaten separately) ***the total content of biotoxins from the brevetoxin group*** ~~***the total Neurotoxic Shellfish Poison (NSP) content***~~ *must not exceed 20 mouse units* ***or equivalent****.*

I-5.2 (viii)

In the edible part of live bivalve molluscs (the whole part or any part intended to be eaten separately) the ***total content of biotoxins from the*** ~~***level of***~~ *Azaspiracid (AZA****P****)* ***group*** *must not exceed* ~~***16 microgrammes per 100g.***~~ ***0.16 miligrams per kilogram****.*

I-5.2 (ix)

~~***In the edible part of live bivalve molluscs (the whole part or any part intended to be eaten separately) the level of Yessotoxins must not exceed 100 microgrammes per 100g.***~~

SECTION I-7 SAMPLING, EXAMINATION AND ANALYSES

Canada suggests that the following wording be added, as per recommendation 19.2 made by the Codex Working Group on biotoxins in bivalve molluscs.

I-7.1 Sampling

(i) …

(ii) ***The portion of the shellfish analysed should be the portion considered edible. This is generally the whole tissue. Where whole-tissue analysis is not possible or practical, the most contaminated tissue (e.g. the digestive gland) may be dissected and analysed and the results converted to an edible tissue basis. The conversion factor should be supported by data based on weights of dissected parts and the extent of transfer of toxin into other tissues.***

I-7.5 Determination of Biotoxins

Canada suggests inclusion of the following draft table as a replacement for the current text. This follows the recommendations made by the Codex Working Group regarding appropriate methodologies for recognition by Codex. Note that the content of this table is conditional on CCFFP submission to, and endorsement by, CCMAS.

Provision	***Methodology[1]***	***Principle***	***Type***
Saxitoxin Group	*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	*bioassay*	*III*
Azaspiracid Group	*	*LC-MS* [2]	*II*
	*	*bioassay*	*III*

[1:] *All methods subject to endorsement by CCMAS*

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

** Official /recognized method title to be identified*

PART II RAW BIVALVE MOLLUSCS

SECTION 6 - LABELLING

II-6.4.2 and II-6.4.3

Canada would like to seek further clarification regarding the intent and/or possible implications of the following two provisions.

> *6.4.2: Every package containing bivalve molluscs that have been processed to reduce or limit target organisms must be provides with a label certifying that all molluscs have been processed to reduce the target organisms to levels acceptable to the official agency having jurisdiction.*
>
> *6.4.3: Safety claims made for bivalve molluscs processed to reduce or limit target organisms should be specific to the target organism that have been reduced or limited and the ability to reliably achieve the appropriate reduction in the target organism(s) shall be validated by a study approved by the official agent having jurisdiction.*

EUROPEAN COMMUNITY

The European Community and its 25 Member States (ECMS) appreciate the opportunity to address the Codex Alimentarius Commission's request for comments on the Proposed Draft Standard for Live and Raw Molluscs Processed for Direct Consumption or for Further Processing and would like to suggest the following amendments.

I-5.2. Hygiene and handling

sub-paragraph (ii)

Reference to faecal coliforms

The ECMS are still of the opinion that the detection of faecal coliforms does not provide a reliable indication of a pathogenic risk. Studies have shown that, although *E.coli* merely give an indication that can only be used to keep an eye on the situation, they correlate better with the presence of pathogens than faecal coliforms taken together.

I-7.4, last sub-paragraph would need to be amended accordingly:

"In the absence of routine virus testing and the establishment of virological standards, an assessment of the risk from viruses should be based on E.coli counts …"

Sub-paragraph (iii)

Virus criterion

It seems too early to establish a criterion of "no enteric pathogenic viruses in 10g flesh" at a time when the work to establish the routine methods for analysing viruses (norovirus, hepatite A virus, etc.) has not yet

been brought to a successful conclusion, and this sub-paragraph contradicts the last sub-paragraph of point I-7.4: *"In the absence of routine virus testing and the establishment of virological standards …*".

I-6.1. the name of the food

Scientific name

It is necessary for the common name and the scientific name of the species to be declared.

The scientific name makes it possible to supplement the information provided to the consumer and to carry out the necessary checks.

The second wording of the first paragraph could be chosen and paragraph I-6.1.2 could be reworded as follows:

I-6.1 "The name of the food to be declared on the label shall be the common or usual name of the species of bivalve molluscs in accordance with the law and custom of the country in which the food is sold and in a manner not to mislead the consumer.

…

I-6.1.2. In addition to the specified labelling designations above the scientific name of the species of the bivalve molluscs shall be added:

I-6.4.labelling of containers

This chapter should cover the cases of the transactions before and after transition through a shipping centre.

Moreover, what is already stated in other paragraphs of I-6 should not be repeated and the omitted points should be included.

This labelling information must be available at each stage of the marketing of the produce and, where appropriate, on accompanying documents.

In the light of the comments set out above, the proposed new wording of point I-6.4 is as follows:

I-6.4 Labelling of Containers

Information shall specify ~~in the containers and the accompanying documents~~ :

** in accompanying documents (all states before packaging) :*

- *~~The~~ name of the food as described in I-6.1 ;*
- *lot identification ~~(if purified (depurated))~~ ;*
- *type of harvest (caught or farmed) ;*
- *~~harvesting~~ location of the production area and its health status ;*
- *date of harvesting ~~or~~ ;*
- *if purified or relayed, duration and date of completion of processing ;*
- *~~the~~ name, ~~and~~ address and, where appropriate, authorization or registration number of producers or purifier ;*
- *destination of the lot ;*
- *storage instructions, as appropriate*

** on the container (all states after packaging) :*

- *name of the food as described in I-6.1 ;*
- *type of harvest (caught or farmed) ;*
- *harvesting location ;*
- *name, address and, where appropriate, authorization or registration number of packer ;*
- *date of packaging, comprising at least the day and the month ;*
- *lot identification, if different of date of packaging ;*

- *storage instructions, as appropriate ;*
- *date of minimum durability, or a statement to this effect, or declare "these animals must be live when sold" at the discretion of the country where the product will be sold.*

~~I-6.4.1 In lieu of harvest date or date of purification, labelling for live bivalve molluscs may declare the date of minimum durability, or a statement to this effect, or declare "these animals must be live when sold" at the discretion of the country where the product will be sold.~~

I-7.4. METHODS OF ANALYSIS OF ESCHERICHIA COLI AND FAECAL COLIFORMS IN SHELLFISH MEAT

References for analysis methods

The reference to scientific publications is insufficient for describing any routine method, since publication does not imply validation of the method presented.

Moreover, the references to the analysis methods mentioned are old. The only references must be references to standards corresponding to validated methods.

Accordingly, the Donovan *et al*. method (1998) has an ISO reference, which is::

ISO/TS 16649-3 standard - Enumeration of beta glucuronidase-positive Escherichia coli in live bivalve molluscs.

It should be incorporated in its entirety into this document, including into I-5.2 (ii)

Sanitary survey

The conduct of a "*sanitary shoreline survey*" in the absence of routine virus testing and of virological standards is too vague: need to specify what the expression actually covers in terms of analytical requirements. The current wording provides considerable scope for wrong interpretation.

II-2.2. PROCESS DEFINITION

References for systems of processing

The second paragraph appears to be too vague. Moreover, it does not specify any process for limiting "target organisms" ("pathogenic micro-organisms"), nor does it refer to the techniques used, whereas the previous paragraph provides details of freezing.

II-.3.3. other ingredients

References to packing materials

It seems not relevant to include packing materials here.
However, the reference to packing materials could be included in section *"II-2.3 Presentation"* and in "*I-2.3. Presentation"*

II-6 LABELLING

References to systems of processing

Add a paragraph because the products processed as described in this standard are not currently marketed in Europe. In order to avoid any misrepresentation, consumers must be clearly informed of the processing applied to the shellfish, especially when they are sold in their shell.

"II-6.2 a process declaration

Raw bivalve molluscs shall be labelled with a mention of the process in order not to mislead the consumer."

II-6.4. LABELLING OF CONTAINERS

Additional information

Provision should be made for labelling to contain additional information on the basis of the proposal set out in point I-6.4.

General comment on biotoxins

No comments have been made on the section concerning marine biotoxins pending the inclusion of the results of the working party concerned.

JAPAN

In response to CL 2006/7-FFP, we would like to submit the following comments.

- I-5.2 (ii)

  Japan suggests that microbiological criteria on *Vibrio parahaemolyticus* and *Vibrio vulnificus*, which are the major causes of food poisoning associated with bivalve molluscs, should be included in the proposed draft standard. In order to establish microbiological criteria in *Vibrio* for this standard, Japan suggests that the CCFFP should request FAO and WHO to convene the joint Expert Consultation, namely JEMRA, to provide scientific advice which CCFFP can use as a basis for establishing microbiological criteria.

- I-5.2 (iii)

  In accordance with the principle for the establishment of Codex standards, Japan believes that the draft standards of *Salmonella* and enteric pathogenic viruses should be established on the basis of the outcomes of the microbiological risk assessment provided by FAO and WHO through the joint Expert Consultation (namely JEMRA). Therefore, until the Committee receives the scientific advice on *Salmonella* and future advice to be provided on viruses, this paragraph should be put in square brackets.

- I-5.2 (v)

  The FAO/IOC/WHO Expert Consultation (2004) concluded that there is no evidence of adverse effects of Pectenotoxins in humans. The report of the Working Group meeting of 10-13 April 2006 recommended on the basis of the above conclusion that Pectenotoxins should not be regulated. Japan, therefore, suggests that the CCFFP should respect this recommendation and that "Pectenotoxins" should be removed from this paragraph.

- I-5.2 (vii)

  Japan suggests that the word "Neurotoxic Shellfish Poison (NSP)" should be replaced by "Brevetoxin group". Although the Working Group met in April 2006 recommended the draft action level on the basis of the knowledge resulting from the existing history of regulatory programs (US, Mexico and New Zealand) and the absence of human illness in commercially harvested shellfish where these programs are implemented, the FAO/IOC/WHO Expert Consultation (2004) had not recommended any draft standard due to the lack of sufficient data. Therefore Japan suggests that the CCFFP should request FAO/IOC/WHO to reconsider the outcome from the Expert Consultation by critically reviewing additional data from those countries, and that this paragraph should be put in square brackets until the Committee receives further scientific advice from FAO/IOC/WHO.

- I-5.2 (viii)

  "AZP" is supposed to be the abbreviation of "Azaspiracid". Therefore, this should be corrected to "AZA".

  The WG recommended the draft standard of AZA on the basis of the risk assessment of Food Safety Authority of Ireland. However, the FAO/IOC/WHO Expert Consultation had drawn another conclusion using the same outbreak data, and the recommended action level from the WG had been established considering the detection limit of mouse bioassay, which can not be considered as being based on the risk assessment as stated in the Codex principle. Therefore, Japan suggests that the CCFFP should request FAO/IOC/WHO to reconsider the recommended action level, and that this paragraph should be put in square brackets until the Committee receives further scientific advice from FAO/IOC/WHO.

- I-5.2 (ix)

  Notwithstanding necessity of risk management, the WG recommend not to identify the Codex standard of Yessotoxin for the lack of evidence of adverse effects in human in spite of the fact that the FAO/IOC/WHO Expert Consultation recommended the Guidance level of 12 mg/kg in shellfish meat based on the provisional Acute Reference Dose of 50μg/kg body weight and 250 g consumption. Therefore, the draft standard of 100μg/100g can not be justified scientifically. Japan believes that the

action level should not be established at this stage. Japan also suggests that the CCFFP should recommend Member States and Organization to enhance the continuous and active data generation (especially voluntary feeding study) and data collection which could be fed into the risk assessment conducted by FAO/IOC/WHO, and that this paragraph should be put in square brackets until the Committee receives the further scientific advice from FAO/IOC/WHO.

PERU (English versión)

1. SCOPE

Peru is of the opinion that gasteropods, echinoderms and tunicates that have not been depurated should also be considered

Part 1 Live Bivalve Molluscs

1.6 Labelling

1.6.11 Peru is of the opinion that the term “depurated mollusc” should be considered, when they come from depuration centres, as required

Peru agrees with the other aspects mentioned in Part I

PART II–RAW BIVALVE BIVALVE MOLLUSCS

II.2.2 PROCESS DEFINITION

Peru is of the opinion that it should be included that the process should be carried out in an establishment that allows sanitary conditions that ensure food safety.

Peru agrees with the other aspects mentioned in Part II

PERU (version en español)

1. SCOPE

Perú opina que debe considerarse asimismo a los gasterópodos, equinodermos y tunicados, no depurados.

PART I –LIVE BIVALVE MOLLUSCS

1.6 LABELLING

I.6.1.1 Perú opina que debería considerarse el término “molusco depurado”, cuando estos provengan de centros de depuración, en caso lo requiera.

Perú está de acuerdo en los demás aspectos señalados en la Parte I.

PART II–RAW BIVALVE MOLLUSCS

II.2.2 PROCESS DEFINITION

Perú opina que debería incluirse, que el proceso debe realizarse en un establecimiento que permita condiciones sanitarias que garanticen la inocuidad de los alimentos.

Perú está de acuerdo en los demás aspectos señalados en la Parte II.