

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 6

CX/FFP 05/27/7

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

Twenty-seventh Session
Cape Town, South Africa
28 February – 4 March 2005

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

NEW ZEALAND

1. Scope and Title

New Zealand believes that the title of this standard should be: “Codex Standard for Bivalve Molluscs” without qualification in the title.

This is because the standard appropriately appears to cover live, processed raw, processed and canned bivalve molluscs. Inclusion of processed raw products will permit the standard to cover all products that are essentially uncooked and hence subject to microbiological contamination risk from the waters in which they are grown. Broader application of the standard will also ensure a consistent standard of shellfish material to be subjected to further processing internationally.

New Zealand believes scallops should be included within the scope of the standard except for scallop adductor muscle only. Areas where the traded product is scallop gonad or adductor muscle with gonad only attached should not need classification as the microbiological contaminants are largely removed with the removal of the viscera but chemical and marine biotoxin monitoring should be undertaken.

Accordingly New Zealand suggests the following statement of scope for Bivalve Molluscs to be covered by this standard to replace the first sentence under scope:

“This standard applies to live, processed raw, processed and canned bivalve molluscs excluding scallop adductor muscle only products, intended for direct human consumption or further processing.”

2.1 Product Definition

New Zealand suggests insertion of the following definition:

Bivalve Mollusc: Means all shellfish of the Phylum Mollusca, Class Bivalvia excluding scallop (Family Pectinidae) adductor muscle only.

This definition then permits simplification of text under 2.2 Process Definition. (See comments below)

New Zealand supports removal of the square brackets in both paragraphs of this section. The inclusion of post-harvest treated product within this standard is an important development in improving the safety of traded product. While the current application of this technology is towards management of *Vibrio vulnificus* the potential application of such technology is significant to manage more widespread pathogens such as noroviruses and salmonella. Therefore to exclude the use of such technology within such a standard is unwise as any country could potentially find new methods of removing pathogenic organisms from raw shellfish and should be free to implement these provided they introduce no new hazards to the product.

2.2 Process Definition

New Zealand believes that the definitions in the draft text need further elaboration to improve clarity and proposes replacement with the following definitions.

“Live Bivalve Molluscs means Bivalve Molluscs harvested alive for direct human consumption from an approved growing area and/or from another appropriately classified area followed by an approved purification process.”

The details of growing area classification and purification processes can then be developed within the code of practice without being unnecessarily constrained by wording in the standard.

“Frozen Bivalve Molluscs shall be derived from Live Bivalve Molluscs that have been frozen to -18°C at the thermal centre”

The remaining text in the draft definition of frozen should be transferred to the Code of Practice to form the basis of an advisory section on frozen shellfish, which could be further developed as section 7.7.3.

“Processed Bivalve Molluscs shall be derived from Live Bivalve Molluscs that have undergone a form of processing for sale. This may be in addition to freezing.”

“Canned Bivalve Molluscs shall be derived from:

- Live Bivalve Molluscs; or
- Bivalve Molluscs that meet the requirements for Live Bivalve Molluscs except for the microbiological requirements where this is approved; or
- Processed Bivalve Molluscs; and

shall be packed in hermetically sealed containers and shall have received a processing treatment sufficient to ensure commercial sterility.”

Such wording will make it clear that shellfish for canning still need to meet requirements relating to chemical and marine biotoxin contamination but not necessarily microbiological contamination. It may be appropriate to utilise canning technology to eliminate some forms of microbiological contamination.

New Zealand proposes a new definition be inserted for:

“Approved means Approved by the official agency having jurisdiction.”

3.1 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. The word is also used in 5.2.

3.2 Glazing

It is inappropriate to refer to definitions in a code of practice in a standard. If the definition is required in the standard then it should appear in the standard, not in a subsidiary document. In this paragraph we suggest that replacing the word “clean” with the word “potable” would resolve any confusion without requiring a new definition to be inserted. This is consistent with the standard for fish fillets.

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”.

5.3 (ii)

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

| | | | | |
|------------------------|-------|-------|---------|--------|
| <i>Eschericia coli</i> | 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 bioaccumulate 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.

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. Furthermore it is highly undesirable for Codex to promote the use of animal testing methods when there are more accurate and specific test methods available.

New Zealand reserves its right to comment on this section further once the results of the WHO/FAO expert consultation on marine biotoxins are available.

6.5.2

New Zealand prefers the wording "For all bivalve molluscs, identification of the processing establishment approved by the official agency with the jurisdiction for the production of the product."

6.5.4

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.

7.5.2

It is not clear what the purpose of this section is in relation to live, processed raw and ready to eat products. It might be appropriate for sensory evaluation of 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.

7.6

New Zealand is aware that there 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 is not appear to be an appropriate part of a standard.

7.7

New Zealand reserves its right to comment on this section later once the results of the WHO/FAO expert consultation on marine biotoxins are available.

UNITED STATES

In response to CL 2003/37-FFP, October 2003, the United States respectfully submits the following comments on the Proposed Draft Standard for Live and [Raw] Bivalve Molluscs at Step 3. Recommended additional language within sentences is highlighted in bold for the convenience of the reader.

TITLE and 1. SCOPE, remove brackets from "raw"

Reason: The most logical scope for this standard is through the point when the product can be immediately consumed and/or when it is ready for further processing. The standard would not only include "live" bivalve molluscs, but also shucked and post harvest treated bivalve molluscs, which are both considered "raw." The other less desirable choices are: (1) a standard that includes live, raw and processed; and (2) a standard that only includes live. Choice (1) would be cumbersome and would overlap with existing standards for processed products. Choice (2) would require that other standards be amended to add shucking, post harvest treatment, and related activities.

1. SCOPE, change the word “adductal” to “**adductor**”

Reason: Editorial

2.1 Product Definition, remove brackets from the second sentence and revise to read:

“Raw bivalve molluscs are products that are no longer alive **because of post harvest treatment**, shucking, or freezing, **but that essentially retain** the sensory characteristics of live products.”

Reason: To clarify the definition of raw bivalve molluscs, which the U.S. believes should be included in the scope of this standard.

2.2 Process Definition, 1st paragraph, revise to read:

“Live bivalve molluscs shall be organisms which are harvested alive from a growing area **approved for direct human consumption** or from another appropriately classified growing area followed by an approved purification (**deuration**) **or relaying** process. The approval mentioned in this subsection must be given by the official agency having jurisdiction.”

Reason: To clarify the types of growing areas from which live bivalve molluscs may be harvested. Also, the language we are proposing would not include the reference in the current draft to “natural container (raft, float or tank)” relating to relaying and possibly to deuration. 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.

2.2 Process Definition, 2nd paragraph,

- add a new first sentence to read:

“Raw product is one that meets the process definition for live bivalve molluscs and in addition is one that has been post harvest treated, and/or shucked, and/or frozen prior to direct consumption or further processing.”

- combine next two 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: The proposed new first sentence is necessary to clearly define “raw product.” 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, the latter language in the first sentence about live molluscs would be deleted. The other important point here is to define the freezing process for raw bivalve molluscs, both in-shell and shucked, so the proposed revision retains and emphasizes that point.

2.2 Process Definition, 3rd through 5th paragraphs (sentences), delete

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.

2.2 Process Definition, last paragraph, remove brackets and revise to read:

“Where raw bivalve molluscs are post harvest treated, the treatment shall assure elimination, reduction or limitation of target organisms to the satisfaction of the official agency having jurisdiction.”

Reason: To clarify the purpose of the post harvest treatment process.

3.1 Live Bivalve Molluscs,

- change the title to “Live **and Raw** Bivalve Molluscs”

- revise the first sentence to read “Bivalve molluscs intended for direct consumption or intended to be processed shall be of a quality fit for human consumption.”

- delete the second sentence

Reason: The U.S. is suggesting that the brackets be removed from the word “raw” in the title and scope of this standard so, Section 3 should apply to both live and raw as well. All live and raw products should be of a quality fit for human consumption, but raw bivalve molluscs do not have to be alive immediately prior to

consumption. The second sentence may be deleted because it is redundant with the language in subsection 5.2.

4. FOOD ADDITIVES,

Comment: The U.S. is examining this section and may submit comments at a later date. Comments may be effected by the Committee's decisions on the scope of the document.

5. HYGIENE AND HANDLING, 5.3(i), revise to read: “**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: The concept that live bivalve molluscs should be free from microorganisms and viruses should not just apply to live bivalve molluscs but to all bivalve molluscs that may be directly consumed (live and raw). Also, to clarify that bivalve molluscs should be free of viruses as well as microorganisms. Finally, to delete the idea that these products should be free from substances originating from viruses. We are not aware of such substances.

5. HYGIENE AND HANDLING, 5.3(ii),

Comment: 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 paragraphs without brackets. One way to do that would be to draft a more general paragraph and retain the current bracketed paragraphs as allowable examples. Under this approach, we recommend that the section begin with text to read, “**Bivalve molluscs should not contain excessive numbers of fecal coliforms or E. coli bacteria. Two examples of testing regimes to ensure that the numbers are not excessive are as follows:**” Brackets from the two paragraphs in 5.3(ii) should be removed and the paragraphs then listed as the examples. The word “live” should be removed from the first sentence of each paragraph.

5. HYGIENE AND HANDLING, 5.3(iii), delete the brackets and 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. HYGIENE AND HANDLING, 5.3(iv) to (ix), maintain brackets

Reason: The U.S. agrees with the CCFFP's decision to keep these subsections in brackets until more information on risk assessment from the Joint FAO/WHO Expert Consultation becomes available.

5. HYGIENE AND HANDLING, 5.3(v), move “there must not be a positive result” from the end of the sentence and insert it before the word “using.”

Reason: Clarity.

5. HYGIENE AND HANDLING, 5.3, after 5.3(ix), delete “(Note – comments on methodology is transferred to Section 7.)”

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.

6.1.2, revise sentence 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 in which the product will be distributed.”

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, 1st sentence, revise to read: “**Bivalve molluscs in the shell** shall be labeled by weight, count, count per unit weight, or volume as appropriate to the product.”

Reason: These measurements apply to live and post harvest treated shell-on products.

6.2 Content Declaration, 2nd sentence, delete and replace with the following: “**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. Add another sentence to the last paragraph to read as follows: “**Information may also contain lot identification.**”

Reason: Since harvesting location, date of harvest and date of processing are required, lot identification is a redundancy and may be listed as optional information in the last paragraph.

6.5 Other Labelling Requirements, Suggest changing this title to read: “**Additional Retail Labelling Requirements.**”

Reason: This section includes labeling 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.

6.5.2, delete all bracketed language and revise the sentence to read as follows: “**This product shall declare the identity** of the establishment approved by the...”

Reason: This requirement would not be limited to a specific type of product so, the examples in brackets should be deleted.

6.5.3, remove brackets and revise to read: “Safety claims, **if any**, should be specific to the target organisms or other hazards that have been eliminated, reduced, or limited.”

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 or post harvest treatment process should not exceed what the purification or post harvest treatment process is designed to accomplish.

6.5.4, delete this subsection

Reason: The U.S. does not know why the consumer would need this information. This may be important to EU countries due to the emphasis placed on depuration, but this is not true in other countries. Whether the consumer must be told something on the label depends on if the consumer would be misled in the absence of that information. This does not seem to apply to depuration, which most consumers have never even heard of. If the decision is made to retain this sentence, then the U.S. would suggest changing the word “must” to “may.”

7.3.5 Determination of Drained Weight, add the following sentence: “**In the case of shucked bivalve molluscs, the drained weight should be determined according to AOAC official method 953.11.**”

Reason: This procedure applies to drained liquid from shucked oysters, but will work for clams as well.

7.5.2 Cooking Methods,

Comment: 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 analysis is adequately covered in 7.2, “Sensory and Physical Examination.”

7.6 MPN Method For Analyses of E.Coli/Faecal Coliforms, change the title to “7.6 Methods of analysis of *Escherichia coli* and faecal coliforms in shellfish meats,” retain the last two paragraphs, but delete the remaining text and insert the following text at the beginning:

“**Recommended Procedures for the Examination of Seawater and Shellfish 4th ed. 1970. The American Public Health Association, Washington, DC (for faecal coliforms in meats), or other validated methods as accepted by the competent authority. The MUG method in Rippey, S.R., L.A. Chandler, and W.D. Watkins. 1987.J. Food. Prot. 50:685-690, and also available in the FDA Bacteriological Analytical Manual, Flurometric method for enumeration of *Escherichia coli* in molluscan shellfish (<http://www.cfsan.fda.gov/~comm/microbio.html>) and Donavan, *et al.*1988.**

Modification of the standard UK method for the enumeration of *Escherichia coli* in live bivalve mollusks. Communicable Disease and Public health1:188-196 are currently used in shellfish programs.”

Reason: The change in the title clarifies that the methods of analysis for *Escherihcia coli* and faecal coliforms are not the same. There is no official U.S. or international method for *Escherihcia coli* in shellfish meats. This change provides suggested methods that are in use for *E. coli* and faecal coliforms. Any adopted method must be validated and adopted at the discretion of the shellfish authority.

7.7 Determination of Biotoxins, suggest putting brackets around this entire subsection

Reason: This subsection should remain in brackets until more information on risk assessment from the Joint FAO/WHO Expert Consultation becomes available.

8.6 Dead or Damaged Product, renumber as 8.5; replace “exceed” with “exceeds” in the last sentence

Reason: To use the correct number and for clarity.