

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 7

**CX/FH 09/41/7-Add.1
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Forty-first Session

The Loews Coronado Bay Hotel, San Diego, United States of America

COMMENTS ON THE PROPOSED DRAFT ANNEX ON THE CONTROL MEASURES FOR *VIBRIO PARAHAEMOLYTICUS* AND *VIBRIO VULNIFICUS* IN MOLLUSCS AN SHELLFISH AT STEP 3

COMMENTS SUBMITTED BY

AUSTRALIA, BRAZIL, COSTA RICA, EGYPT, MEXICO, PERU & THE UNITED STATES

AUSTRALIA

ALINORM 09/32/13 Appendix IV is the current version of the proposed draft guidelines on the control of pathogenic *Vibrio* spp. in seafood at step 3. An outcome of the 40th session was an agreement to convene a physical working group (lead by Japan) to develop a draft annex specifically for molluscan shellfish. The document CX/FH 09/41/7 is the proposed draft annex for comment and consideration at the CCFH 41st session.

General comments

Australia acknowledges the work of the physical working group on the development of the proposed annex to the guideline document. The physical working group has identified a number of key points and recommendations, including a change to the title of the draft annexes to specifically name 'bivalve molluscs' rather than the generic 'molluscan shellfish'. The working group did note in their meeting summary that the groups' terms of reference did not include changes to the guideline document. In the current version, the guideline document only refers to the annex as a footnote at paragraph. 65. The physical working group suggested moving paragraphs 29 -31 to the annex. Other paragraphs may also be better placed in the annex. It is strongly suggested that the content of both the guideline document and the annex are considered together to ensure that both documents are consistent and appropriately referenced.

The annex contains many references to monitoring, modelling and risk. There is a need to have standard microbiological methods e.g. ISO methods for *Vibrio* spp. in order begin to establish the levels of *Vibrio* spp. in seafood. However, in relation to monitoring, standard microbiological methods are not adequate to assess risk to consumers. Molecular techniques are required to identify specific virulence factors and genes. The predictive tool being developed by the United States to assess the risk posed by *V. parahaemolyticus* and *V. vulnificus* in seafood is welcomed.

Specific comments for CX/FH 09/41/7

Text in document	Comment	Suggested text
CX/FH 09/41/7 Title "... in molluscan shellfish at step 3"	Agree with physical working group comment that the title of the annex should be changed to reflect the focus on bivalve molluscs specifically.	Proposed draft annex on the control of <i>Vibrio parahaemolyticus</i> and <i>Vibrio vulnificus</i> in bivalve molluscs
CX/FH 09/41/7 Physical working group report parag. 11	Agree with physical working group recommendation to convene an expert consultation panel to conduct validation of the predictive models used to develop the FAO/WHO risk assessments. The growth rate models used in Table 1 are a case in point.	Remove Table 1
CX/FH 09/41/7 Annex parag. 5	The current scope of the annex and guideline is from primary production through to final consumption. Australia's comment in CX/FH 08/40/8 – Add. 1 was that code would be more focussed if the scope was between primary production to retail .	
CX/FH 09/41/7 Annex parag. 10 lines 6 - 8	The comment that <i>V.p</i> grows faster and at lower temperatures than <i>V.v</i> (Table 1) is based on very limited information and does not considered potentially important factors such as strain-to-strain differences. The use of these growth rates in a 'predictive tool' will require detail evaluation and validation. See working group recommendation on the validation of predictive models. Agree with physical working group recommendation on convening a expert consultation group to valid models	
CX/FH 09/41/7 Annex para. 13	In relation to ballast water, national organisations such as	

	the Australian Maritime Safety Authority (www.amsa.gov.au) or the International Maritime Organization (www.imo.org) have guidelines for the exchange of ballast water. The IMO refers to exchange of ballast water 200 nautical miles off-shore in depths greater than 200 metres.	
CX/FH 09/41/7 Annex para. 18, Dot point 1	The guidance on the development of an appropriate level of protection for <i>Vibrio</i> spp. in bivalve molluscs would be welcomed.	

BRAZIL

Brazil congratulates the drafting group led by Japan for the advances obtained and the efforts to grant an objective approach to the document. Continuing the revision of the document, the alterations in the items described below are suggested.

Report of the physical working group

TABLE (page 2, paragraph 8)

Consideration should be given to more clearly defining the proposed new category “*raw after post-harvest processing*”, as the definition to raw bivalve molluscs in the CODEX STAN 292-2008 states that “Raw bivalve molluscs processed for direct consumption or for further processing are products that were alive immediately prior to the commencement of processing and comply with Section I-2.2 relating to harvesting, purification and relaying. They have been shucked and/or frozen and/or processed to reduce or limit target organisms while essentially retaining the sensory characteristics of live bivalve molluscs. Raw bivalve molluscs are marketed in a frozen or chilled state.” In our understanding, the proposal new category is already covered in the Standard for Live and Raw Bivalve Molluscs (CODEX STAN 292-2008).

It is suggested to rephrase the table Status at consumption and control characteristics of two food categories, Part I and Part II, designated for Sections III – X in Annex to improve clarity, excluding the column “*raw*” and deleting “*after post-harvest processing*” in the third column. Moreover, these categories should be harmonized with the ones approved by Codex Committee for Fish and Fishery Products.

Status at consumption and control characteristics of two food categories, part I and Part II, designated for Section III-X in Annex

Characteristics of control by:	Part I			Part II	
	Status of food at consumption:			Status of food at consumption:	
	Live	Raw	Raw after post-harvest processing	Partially treated ¹ primarily by consumer	Partially treated ¹ primarily by business operator
Producer					
Primary production control ²	+	+	+	+	+
Business operators³					
Post-harvesting processing ⁴	-	-	+	-	-
Time and temperature control	+	+	+	+	+

Adequate partial treatment before consumption ⁵	-	=	-	+/-	+
[Proportional time/temperature control] ⁶	-	=	-	+/-	+

Consumer

Additional treatment before consumption	-	=	-	+	-
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APPENDIX II –Part I**3.3 Handling, storage and transport (paragraph 19, page 13)**

We would like to request clarification regarding the requirement to handle separately live or untreated raw in this step, as harvesting is conducted in the same growing area. It is suggested that the sentence should be reviewed to cover bivalve molluscs that are distinct lots numbers, microbiological cross-contamination and/or be more restrictive to handling, storage and transport of bivalve molluscs that intended to be consumed raw.

If the sentence were maintained we suggest the term “~~or untreated raw~~” be deleted.

Bivalve molluscs destined to be consumed live (~~or untreated raw~~) should be handled separately from those destined for post-harvest processing or other treatment.

5.2.1 Time and temperature control (paragraph 24, page 14)

It is suggested to rewording the following paragraph:

24. Refer to Section 4.1 of the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003). Temperature control to reduce the temperature to the point that *V. parahaemolyticus* and *V. vulnificus* do not grow should be used and maintained [after harvesting or after relaying/depuration, where applicable, and during processing [operation] [and subsequently until consumption] ~~[during the entire food chain] [during the entire food production/preparation chain]~~.

5.2.2 Specific process steps (paragraph 25, page 14)

We would like to request clarification regarding the requirement to distribute separately live or untreated raw from post-harvesting processing or other treatment. This provision is to avoid microbiological cross-contamination. It is suggested also the inclusion of a new section to cover cross-contamination to rephrase the wording on paragraph 19 and 25.

Bivalve molluscs destined to be consumed live or (~~untreated raw~~) should be distributed separately from those submitted to post-harvest processing or other treatment to avoid cross-contamination.

or

Bivalve molluscs destined to be consumed live or raw should be handling, storage, transported and distributed separately from those untreated/not processed to avoid cross- contamination.

APPENDIX II –Part II**3.2 Hygienic Production of Food Sources (paragraph 39, page 15)**

It is suggested to delete “untreated raw” from the paragraph below, as CODEX STAN 292-2008 and CAC/RCP 52-2003 establish two category of bivalve molluscs, live or raw (after post-harvesting processing).

The controls described in Section III (PRIMARY PRODUCTION) of PART I should be implemented. The combination of measures of the treatment and those described in Section III of this part should achieve at least an equivalent level of protection to the level of protection provided for bivalve molluscs in Section III of PART I. Bivalve molluscs destined for partial treatment should be handled separately from those to be consumed live or [raw] , ~~untreated raw or after post-harvest processing.~~

3.3 Handling, storage and transport (paragraph 41, page 15)

It is suggested to delete “untreated raw” from the paragraph below, as CODEX STAN 292-2008 and CAC/RCP 52-2003 establish two categories of bivalve molluscs, live or raw (after post-harvesting processing).

The controls described in Section III (PRIMARY PRODUCTION) of PART I should be implemented. The combination of measures of the treatment and those described in Section III of this part should achieve at least an equivalent level of protection to the level of protection provided for bivalve molluscs in Section III of PART I. Bivalve molluscs destined for partial treatment should be handled and distributed separately from those to be consumed live or [raw], ~~untreated raw or after post-harvest processing.~~

COSTA RICA

Costa Rica thanks the Codex Committee on Food Hygiene for the opportunity to comment on the document prepared by the physical working group led by Japan. Costa Rica's comments are listed below:

1- On line 11 [line 9 in the English version of the document] of the introduction to appendix II of the document, Costa Rica suggests the following phrasing: *“In many countries, bivalve molluscs are often kept at room temperature for long periods, which results in postharvest proliferation of these pathogens and this contributes in large part to their risk, according to recently completed FAO/WHO risk assessments for both pathogens2.”* [Translator's note: this recommended change appears to apply ONLY to the phrasing of the Spanish translation, there is no substantive change.]

2- In **SECTION II – OBJECTIVES**. Line 5, Costa Rica proposes correcting the sentence in the following way: *“Controls for these pathogens are similar but differ to the extent that characteristics of growth and survival differ.”* [Translator's note: Again, this comment appears to be a correction of the phrasing of the Spanish translation only. No substantive change.”]

3-Regarding the third bullet of paragraph 14, ships are often at sea several hours and the temperature can exceed 5°C, even 10°C, increasing the risk that these pathogens may grow. Given that, Costa Rica proposes that the temperature be less than 10°C for *Vibrio parahaemolyticus* and *Vibrio vulnificus*.

4-Regarding paragraph 23, Costa Rica thinks that what constitutes validation of pressurization and moderate heating treatments should be clarified.

5- Costa Rica underscores the importance of keeping the phrasing of paragraphs 19 and 25 as is in the proposed draft.

6- In paragraph 30 Costa Rica proposed changing the sentence as follows:

In addition, programs for consumer information should be oriented toward the nutritional benefits of these products, but also toward providing warnings of the risks and dangers of becoming ill from *Vibrio* pathogens (see para. 106 of the Proposed Draft *Code of Hygienic Practice for Pathogenic Vibrio spp. in Seafood* (at Step 3)), to help consumers make informed choices about purchase, storage, shelf-life labelling and appropriate consumption of a live and raw bivalve molluscs, taking into consideration the specific regional conditions and consumption habits.

7- In regards to point 5.2.4, paragraph 48, Costa Rica considers that recommendations should be suggested to prevent or avoid cross contamination between bivalve mollusks before and after partial treatment. We do not think that this paragraph is related to paragraph 85 of the Draft *Code of Hygienic Practices for Pathogenic Vibrio spp. in Seafood* (at step 3).

8- Costa Rica thinks that the contributions of the document are very good, and supports the document moving on to step 5.

EGYPT

The Proposed draft should consider the health risks associated with *vibrio. parahaemolyticus* and *vibrio.vulnificus* in different shellfish species.

- The methods to monitor pathogenic *vibrio.parahaemolyticus* and *vibrio.vulnificus* in paragraph 12-15 should be scientifically validated.

- EOS agrees with the working group that the forthcoming CCFH 41st session should encourage FAO and WHO to provide member countries with technical assistance to improve their capacity of labore in detecting *vibrio.spp*.

MEXICO

Mexico reiterates its commitment to the Codex Alimentarius and is thankful for the opportunity to comment on the document Proposed Draft Annex on the control measure for *Vibrio parahaemolyticus* and *Vibrio vulnificus* in molluscan shellfish, at Step 3 of the Process:

General comments:

- The document is complete and specific on the points that it covers.
- It is still considered debatable that equal importance is given to the “consumer control (partially treated primarily by consumer and Additional partial treatment before consumption)” and to the actions carried out by processors.
- The characteristics of each of the processes other than thermal (for example, acid treatment, recommending the type of acid and in what concentration) need to be included in the definition of “partially treated.”
- Change the units to ppm, as ppt (g/l) was used.

	Location	Comment
1.	SECTION III – PRIMARY PRODUCTION 3.1 ENVIRONMENTAL HIGIENE Paragraph 12	Although we know that the work group did not establish the recommended maximum levels of these organisms in the product, which was originally one of the reasons that this work was created and separated from the topic of the Codex Committee on Fish and Fishery Products, it can be pointed out that the countries should, could or it would be advisable to establish regulatory limits based on the results of sampling and available epidemiological analyses.
2.	3.3 HANDLING, STORAGE AND TRANSPORT	The <u>control temperature</u> must be appropriately indicated, which for these organisms would be 10°C or lower
3.	5.2.1 Control of time and temperature Paragraph 24	We think that control of time and temperature should be proposed <u>from harvest to final distribution</u> , even considering the individual characteristics of said activity in each country. In this regard, we think it is advisable to appropriately cite the control temperature where appropriate in the document, which for the case of these organisms would be 10°C or less.

PERU

The following changes or additions are proposed:

- The following could be taken into account in the introduction:

Some species are primarily associated with gastrointestinal illness (*V. cholerae* and *V. parahaemolyticus*), while others may cause non-intestinal illness, such as septicemia (*V. vulnificus*). In tropical and temperate climate regions, the *Vibrio spp.* that cause illness are naturally present in the marine, coastal and estuarine (brackish) environments, and are very abundant in estuaries. It has also been shown that in several parts of the world there is a positive correlation between water temperature and the numbers of *Vibrio*. On the other hand, according to data presented by the

United States and Denmark in the recent 40th Meeting of the Food Hygiene Committee, there is a positive correlation between water temperature and the numbers of isolated *Vibrio* that are pathogenic to humans, and between water temperature and the number of reported human infections. This correlation is especially conspicuous in the case of *V. parahaemolyticus* and *V. vulnificus*.

- In number 11, it should be taken into account that the factors that affect the prevalence of pathogenic *V. parahaemolyticus* in the environment are temperature, like, for example, the Rate of development of *V. parahaemolyticus* in oysters at temperatures other than 26°C, making temperature the potential variable.

UNITED STATES

General Comments

The United States generally supports the efforts of the Working Group with regard to the control measures that have been developed for bivalve molluscs intended to be consumed live and raw. The United States also supports the recommendations in the report with regard to further development and application of risk assessment procedures (“calculators”) using region specific data. The United States is available to demonstrate the utility of risk assessment calculations for *V. parahaemolyticus* and *V. vulnificus* at the CCFH meeting in San Diego as requested by the Working Group during their meeting in Kyoto, Japan in June 2009. The United States believes that this presentation would be most appropriate for the base document working group meeting on Sunday November 15, 2009 but is open to other suggestions.

However, the United States has significant concerns about the current structure of the Annex. In particular, we believe that by dividing the document into two parts, the Working Group has effectively created a new category of bivalve molluscs that are intended to be “partially treated” or further processed by consumers in order to eliminate hazards that are likely to be present. In particular, the document includes requirements for the consumer (see page 10, paragraph 5 and page 17, paragraph 54 under Section 9.3 Labeling). The United States believes this requirement is not appropriate because Codex guidelines and standards are intended to provide guidance to governments and industry with the goal of providing safe food *to* consumers and promoting fair trade practices. Placing the burden of delivering a final control measure on the consumer is not appropriate for Codex guidelines and standards.

Furthermore, the application of the General Principles for Food Hygiene, including the HACCP Annex, which apply to the products produced under these guidelines, properly places the burden on the processor to determine whether a hazard is reasonably likely to occur and when it is, to apply appropriate control measures to eliminate, prevent or reduce it to an acceptable level. Relying on the consumer to control hazards that are reasonably likely to occur is not appropriate when implementing HACCP principles.

There is also the question of enforceability – the United States is not aware of any government or industry organization that has the authority or the ability to verify that this final control measure has been adequately applied at the consumer level.

Finally, the United States is concerned about the confusion that may be created for consumers as the packaging and appearance of raw bivalve molluscs with less stringent treatment will be difficult for consumers to distinguish from those that have been produced and processed to minimize the hazard from these pathogens. Consumers may have the expectation that these products are safe to consume raw without further treatment. Even if consumers actually read the label and recognize the need for additional “partial treatment” prior to consumption, they quite possibly lack the knowledge and equipment to assure that they have adequately reduced or eliminated the hazard.

Specific Comments

Page 3 - Irradiation should be included as an example of post harvest processing in footnote 4. The table indicates that post harvest processed product will not be alive. While that may be true for the treatments currently identified, it is not the case for irradiated product.

Page 4 - paragraph 9, page 11 - paragraph 6 and page 13 - paragraph 23 should include irradiation as an example of post harvest processing and should indicate that irradiated shellfish are still alive after treatment.