codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 4 **CX/FFP 08/29/4-Add.1**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FISH AND FISHERY PRODUCTS
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DRAFT STANDARD FOR LIVE AND RAW BIVALVE MOLLUSCS
COMMENTS AT STEP 6
(European Community)

The European Community (EC) notes that the Codex Committee on Food Hygiene (CCFH) did not endorse the hygiene provisions of the Proposed Draft Standard for Live and Raw Bivalve Molluscs at its 38th Session.

The EC is 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 gives 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.

The following detailed EC comments are provided in preparation for the next session of the CCFFP.

PART I — Live bivalve molluscs

Point I.3.2 ICE FOR PACKING

As with the proposed draft Code of Practice for Fish and Fishery Products (point 2.3), imposing the same microbiological criteria for **clean seawater** as for potable water is problematic. Seawater does contain micro-organisms (cf. the conformity criteria for *E. coli* and faecal coliforms in live bivalve molluscs) and operators can determine the quality of the water by monitoring their own water supply, just as the risk of pathogens in production areas can be assessed by monitoring the production areas.

The criterion "**free from objectionable substances**" also needs to be clarified.

For reasons of functionality, please indicate precise **references** to the appropriate paragraphs of the latest edition of the **WHO Guidelines** for verifying the quality of clean seawater on the basis of a risk analysis according to the cleanliness of the seawater, in particular the monitoring criteria and associated reference methods in accordance with the Codex principles (CAC/GL 21-1997). The controls must be realistic in the light of the potential health risk in order to avoid discouraging the use of clean seawater because of the cost of compulsory analyses, where these are not essential.

Point I.5. HYGIENE AND HANDLING

Point I.5.3: Irrespective of the type of analysis (microbiological, biotoxins), it should be indicated that these apply only to the edible parts, particularly given that this is stated in section I.7.1 on sampling.

> *Live bivalve molluscs shall not contain* ***in the edible parts (the whole part or any part intended to be eaten separately)*** *numbers of faecal coliforms or E. coli bacteria in excess of testing regimes as follows:*

Point I.5.3(i): It is important to specify the **unit of measurement** for the maximum limits for *E. coli* because the sampling specifications (next line) refer to *Escherichia coli*/g, following the example of the ISO MPN test methods, which also express the quantity in terms of a number per gramme. It should be noted, however, that Regulation (EC) No 2073/2005 expresses the standard for bivalve molluscs in terms of *E. coli per* 100 g of flesh and intra-valvular liquid.

Point I.5.3(ii): Not only should the "**330 faecal coliforms**" criterion be removed in favour of the *E. coli* indicator, but there is little point statistically in introducing a second "**330 *E. coli***" limit after the initial analysis of the "faecal coliforms" because of the high degree of imprecision in the counting process using the Most Probable Number (MPN) technique. The theoretical confidence interval is higher than a logarithmic unit, excluding the uncertainty of measurement to be determined by the laboratory, in particular for values close to the method's threshold. Furthermore, there is no ISO method for the simultaneous analysis of faecal coliforms and *E. coli* for bivalve molluscs.

Point I.5.3(iii): At this stage we do not have the knowledge or methods to propose a limit value for *Vibrio parahaemolyticus* based solely on the bacteria count per gramme of flesh, particularly given that only a small minority of *Vibrio parahaemolyticus* (those coding for haemolysins) are pathogenic. It is not possible with current detection methods to routinely distinguish pathogenic from non-pathogenic *Vibrio parahaemolyticus* or, consequently, to set a criterion according to the principles set out in document Codex CAC/GL 21-1997.

> *(iii) Live bivalve molluscs must not contain Salmonella in 25 g flesh* ~~***and Vibrio parahaemolyticus 100MPN/g flesh.***~~

NB: In an opinion of 19 and 20 September 2001, the European Commission's Scientific Committee on Veterinary Measures relating to Public Health (SCVMPH) concluded that the scientific data currently available did not support setting specific criteria for pathogenic *V. parahaemolyticus* in seafood, while recommending establishing codes of practice to ensure that good hygiene practices have been applied.

Point I.5.3(vii):

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

Reference should be made to the Codex standards for contaminants, which must be complied with by all bivalve molluscs placed on the market.

Point I.6. LABELLING

Point I.6.4(1): Consumers are not concerned at this stage: non-retail containers.

To be consistent with the Proposed draft Code of Practice for Fish and Fishery Products (Live and Raw Bivalve Molluscs, Lobsters and Crabs and relevant Definitions), point 7.9 documentation, the point I.6.4 has to be modified :

i) Clearly identify the product ~~***for consumers***~~ ***by its common and scientific name*** ~~***as stated in 1.6.1…***~~

Point I.7. SAMPLING, EXAMINATION AND ANALYSES

Not all the analysis methods for determining the various pathogens are indicated (for example, the method for determining *Salmonella* is not mentioned).

Point I.7.4: Delete "**faecal coliforms**" from the title, as the only faecal contamination indicator that can be used for products placed on the market is *Escherichia coli.*

I.7.4. Methods of Analysis of Escherichia coli ~~***and faecal coliforms***~~ *in shellfish meats*

1st paragraph of point I.7.4: The references for certain analytical methods are imprecise, very old and refer here to water and bivalve molluscs (Examination of Seawater and Shellfish, 4th ed. 1970), and faecal coliforms in meat (APHA, Washington DC), whereas the products being placed on the market are live bivalve molluscs.

*Recommended Procedures… … . The ISO/TS 16649-**3*** ~~***standard – Enumeration of beta glucuronidase-positive Escherichia coli in live bivalve molluscs.***~~ ***- Horizontal method for the enumeration of beta-glucuronidase-positive Escherichia coli - Part 3: Most probable number technique using 5-bromo-4-chloro-3-indolyl-beta-D-glucuronide or other validated methods in accordance with the protocol set out in ISO 16140 or other internationally accepted similar protocol***

Table in paragraph I.7.5: The ELISA method for determining Domoic Acid toxins has been validated by the AOAC and should therefore be indicated as a type III method.

Footnote [1] to the table in paragraph I.7.5: Specify the names of the toxins as well as their abbreviations, as they have not been referred to earlier in the document.

When using the MBA for detecting lipophilic marine biotoxins, false positives may occur due to the presence of other substances such as YTX ***(Yessotoxins)****, PTX* ***(Pectenotoxins)*** *and CI* ***(Cyclic Imines)****, which are not known to cause human illness. When false positives are suspected, confirmatory testing, using an internationally validated method, can be carried out in order to identify the type(s) of marine biotoxins present.*

Point I.8. DEFINITION OF DEFECTIVES

Point I.8.2: If over 5% of the shellfish are found to be dead or damaged, the entire batch must be rejected and not just the sample.

~~***Sample***~~ ***Batch*** *shall be rejected if dead or damaged bivalve molluscs exceed 5% by count.*

PART II — Raw bivalve molluscs

As a general point, the above observations concerning part I on labelling, analysis methods, sampling, etc. must also be included in this part.

Point II.3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

Same comment as before (comment ~~**02**~~**34**) concerning clean seawater.

Point II.3.2: As in paragraph I-3.2, specify in the last sentence the appropriate references for verifying the quality of clean seawater in accordance with the Codex principles (CAC/GL 21-1997) to ensure that clean seawater can be used while avoiding imposing stricter conditions in real terms than those for potable drinking water.

Point II.5. HYGIENE AND HANDLING

The wording of sections II.5.2 and II.5.3 raises the question of which organisms are targeted by the treatment methods recommended. In section II.5.3, for example, bivalve molluscs must comply with the criteria of I.5.2 (*E. coli*, *Salmonella* and biotoxins) both before and after treatment: so what is the point of treatment?

It would therefore be appropriate to indicate which germs can successfully be treated using these methods (vibrio? virus?) and to specify in this part the points of control to verify that the procedure used is being properly implemented.

Point II.5.2: Numbering error.

> *II.5.2. 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).*

Point II.5.3: Numbering error in the reference to the microbiological and biotoxin criteria.

> *II-5.3 Bivalve molluscs should meet the requirements of* ~~***I-5.2***~~ ***I-5.3*** *prior to shucking, freezing, or processing to reduce target organisms. After shucking, freezing or processing to reduce target organisms, they should retain visual characteristics associated with freshness, including, where relevant, shells free of dirt.*

Point II.6. LABELLING

Point II.6.3: (Although a provision on the use-by date is already included in the general standard, reference should still be made to the minimum durability date, given the specific format of this standard in two parts).

> *The label shall specify the conditions for storage and/or temperature that will maintain the quality during transportation, storage and distribution****, including the date of minimum durability****.*

Point II.6. LABELLING

Point II.7.5.1: Numbering unnecessary, given that there are no other headings under point II.7.5.

Point II.7. SAMPLING, EXAMINATION AND ANALYSES

Same comment as above (comment ~~**15**~~**46**) concerning faecal coliforms.