PART III

RISK MANAGEMENT OF BIOTOXINS IN BIVALVE MOLLUSCS

Introduction

Part II provided details of the risk assessments of the various biotoxins undertaken by world experts using the most updated information and data collected by the experts, FAO, the International Oceanographic Commission of UNESCO (IOC), and the World Health Organization.

The Codex Committee on Fish and Fishery Products (CCFFP) then looked at the scientific assessments prepared and evaluated options on how best to use the information provided in order to manage the risk of biotoxins in bivalve molluscs.

At its 27th session, held in Cape Town, South Africa (28 February–4 March 2005), the CCFFP established a Working Group (WG), chaired by Canada, that would work between the 27th and 28th sessions to examine the report from the Joint FAO/WHO/IOC Expert Consultation on Biotoxins in Bivalve Molluscs and prepare a discussion paper for consideration by the 28th session of the CCFFP for finalizing management decisions, namely the Code of Practice (CoP) and the Standard for live and raw bivalve molluscs, including the monitoring and surveillance programmes.

The recommendations of the WG were used in the finalization of the CoP and the Standard for live and raw bivalve molluscs adopted by the Codex Alimentarius Commission (CAC), considering the inputs from various Members that attended the various sessions of the CCFFP and the CAC between 2006 and 2008. The detailed reports of the deliberations during those sessions can be consulted at: www.codexalimentarius.net/web/index_en.jsp. The report of the WG and Codex CoP related to processing live and raw bivalve molluscs and the Codex Standard for live and raw bivalve molluscs have been reproduced in the following pages.

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

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FISH AND FISHERY PRODUCTS
Twenty-eighth Session
Beijing, China, 18-22 September 2006

PROPOSED DRAFT STANDARD FOR LIVE AND RAW BIVALVE MOLLUSCS
(Prepared by Canada, with the assistance of Belgium, Chile, the European Community, France, Ireland, Japan, Mexico, New Zealand, Norway, Spain, the Netherlands, Thailand, United Kingdom, United States, Vietnam, and FAO)

BACKGROUND

1) At the 25th session of the Codex Committee on Fish and Fishery Products (CCFFP) (2002), the Committee asked the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) to provide scientific advice on marine biotoxins in conjunction with its work on the Proposed Draft Standard for Live and Processed Bivalve Molluscs.

2) The CCFFP, at its 26th session (2003), made the following more specific requests:

- Provide scientific advice to the CCFFP to enable the establishment of maximum levels in shellfish for shellfish toxins (PSP-, DSP-, ASP-, AZP- and NSP-toxins, and YTXs and PTXs).
- Provide guidance on methods of analysis for each toxin group.
- Provide guidance on monitoring of biotoxin-forming phytoplankton and bivalve molluscs (including sampling methodology).
- Provide information on geographical distribution of biotoxin-forming marine phytoplankton.

3) The FAO, WHO and the Intergovernmental Oceanographic Commission of UNESCO (IOC) held a Joint ad hoc Expert Consultation on Biotoxins in Bivalve Molluscs in Oslo, Norway (2004), which generated a report that addressed the aforementioned requests. The report considers all available data, mainly derived from published and validated studies. Structured marine biotoxin risk assessments (based on prescribed methods) were conducted and were included in the report, along with guidance on methodology. The conclusions should be reconsidered when further published findings become available.

4) At the 27th session of the CCFFP (2005), the Committee agreed to establish a Working Group (WG), chaired by Canada, that would work between the sessions to examine the report from the Joint FAO/WHO/IOC *ad hoc* Expert Consultation on Biotoxins in Bivalve Molluscs and prepare a discussion paper for consideration by the CCFFP with the following terms of reference:

- Assess how the CCFFP might use the expert advice and make recommendations with respect to approaches that the CCFFP could consider to integrate the advice into the Proposed Draft Standard for Live and [Raw] Molluscs and the section of the Code on Live and [Raw] Bivalve Molluscs.
- Identify new questions that the CCFFP may wish to pose to FAO/WHO;
- Identify areas in the report that may need further clarification.
- As appropriate, make recommendations on the validation of methodology (e.g. such as identifying other international organisations that are working in this area).
- As appropriate, make recommendations on possible changes to the Proposed Draft Standard for Live and [Raw] Molluscs and the section of the Code on Live and [Raw] Bivalve Molluscs arising from the expert advice and other issues arising from the deliberations of the WG.

5) The WG met in Ottawa, Canada, April 10-12, 2006, to review the Discussion Paper prepared by Canada, for consideration at the next Session of the CCFFP. This Discussion Paper provides an assessment of the Report of the Joint FAO/WHO/IOC *ad hoc* Expert Consultation on Biotoxins in Bivalve Molluscs and makes recommendations on standards and information to be included in the draft Codex Standard and Code of Practice on Bivalve Molluscs.

RECOMMENDATION

6) The Committee is invited to consider the Working Group analysis and comments, and the resulting recommendations on the standards and information to be included in the draft Codex Standard and Code of Practice on Bivalve Molluscs.

GUIDING PRINCIPLES FOR THE CODEX WORKING GROUP

The following sets out the guiding principles for the deliberation and discussions of the WG:

7) The WG should recommend marine biotoxin levels in a manner that is consistent with the approach taken for setting levels for other naturally occurring toxicants in Codex Standards.

8) Marine biotoxin standards should not be set where there is a lack of evidence of harm to humans, either from human clinical data, epidemiological studies or animal voluntary feeding studies.[1]

9) Codex should not exclude methods of analysis that are currently being explored by the analytical community. This is a rapidly advancing area that is trying to take into account the knowledge/uncertainty around chemical groupings (not single chemical entities), varying oral toxicity, etc.

10) The WG agreed that it would consider the full body of available knowledge of marine biotoxins in making recommendations to CCFFP on action levels. This knowledge is based on the Expert Consultation risk assessments and the performance history of regulatory programs with regard to the level of consumer protection provided by these programs. The WG considered that the performance history complemented and built on the information provided by the Expert Consultation.

WORKING GROUP ANALYSIS, COMMENTS AND RECOMMENDATIONS

REPORT SECTION 1: Introduction

11) **Summary of Analysis from the Expert Consultation**

The expert consultation classified marine biotoxins into eight groups based on chemical structure. They adopted this grouping in the interest of clarity of discussion and to distinguish between multiple toxin types associated with a single poisoning condition (e.g. DSP). This designation of toxins by chemical classifications is considered more appropriate than that based on clinical symptoms.

12) **WG Comment(s)**

The WG is in general agreement with the proposed grouping, but noted that some of these "toxin types" are not known to have produced human illness.

13) **Recommendation(s)**

The WG recommends that the Codex Standard (section 5 – Hygiene and Handling and section 7 – Methods of Analysis and Sampling) identify requirements for the following marine biotoxin groups:

Known human illness

- Saxitoxin (STX) group (PSP)
- Domoic Acid (DA) group (ASP)
- Okadaic Acid (OA) group (DSP)
- Azaspiracid (AZA) group (AZP)
- Brevetoxin group (NSP)

[1] Before regulating, where only intraperitoneal studies exist, these must be complemented by oral studies. Among these, voluntary feeding should take priority over gavage.

1. The work group recommends that the Codex Standard (section 5 – Hygiene and Handling and section 7 – Methods of Analysis and Sampling) should not identify requirements for the following marine biotoxin groups at this time:

   No known human illness
   - Pectenotoxin (PTX) group
   - Yessotoxin (YTX) group
   - Cyclic Imines group

2. Further work is required on the toxins listed in point 2 and additional recommendations will be provided in the discussions of the individual toxins.

REPORT SECTION 2: Approach Taken

14) **Summary of Analysis from the Expert Consultation**

Each risk assessment was completed in a structured and stepwise manner. While all available published data relating to exposure and toxicological effects was considered, there were data limitations (or data gaps) associated with each toxin. This influenced the basis, accuracy and outcome of the assessment.

15) **WG Comment(s)**

The Working Group discussed the need to agree on a common consumption value. However, it was agreed that this subject would be considered during the discussions of specific toxin sections.

16) **Recommendation(s)**

The Working Group did not make any recommendations in this section.

REPORT SECTION 3: General Considerations on Analytical Methodology

17) **Summary of Analysis from the Expert Consultation**

The Expert Consultation discussed the following information:

(i) the limitations of the various mouse bioassays and the importance of an increased role for multi-toxin, quantitative instrumental methods for toxin analysis;
(ii) the importance of the further development of Certified Reference Materials (CRM) to seeing progress in the area of marine biotoxin method development, validation and testing; and
(iii) the importance of thorough, within-lab method validation and QC, especially in light of the lack of inter-laboratory proficiency testing programs.

18) **WG Comment(s)**

The WG supports the statements in the analysis section above.

The WG is recommending that reference methods should be highly specific, highly reproducible, and not prone to false positives or false negatives. They are expected to be definitive and may well result in significant rejections of product so must withstand the most robust legal and scientific scrutiny.

In considering their weaknesses and merits, the various mouse bioassays should be discussed individually since the level of performance and success differs markedly between the official method for PSP by mouse bioassay, the American Public Health Association (APHA) method for brevetoxins and the multiple mouse bioassay "DSP" procedures employed for the other lipophilic toxins like okadaic acids, azaspiracids and others.

19) **Recommendation(s)**

1. Recognizing that the majority of the currently available methods do not meet all Codex criteria for reference methods (Type II), the WG is recommending that CCFFP should consider a variety of biotoxin analytical methods. Wherever possible, reference methods should not be based on animal bioassays. Chemical methods, instrumental methods and functional assays currently in use, and considered to be validated according to Codex standards, should be recommended by CCFFP to the CCMAS for review and designation as Type II or Type III methods.
2. The Codex Standard should include the principles identified in the Expert Consultation (Section 3.3) regarding the portion of shellfish to be analysed.

REPORT SECTION 4: <u>Effects of Processing</u>

20) **Summary of Analysis from the Expert Consultation**

Evisceration and canning of certain bivalve species for the purpose of detoxification is a long established practice (e.g. scallops, clams). It is imperative that these Post Harvest Processing (PHP) practices, along with any other detoxifying processes that may be developed in the future, are coupled with adequate data to demonstrate their effectiveness.

All processed lots should be subjected to final product testing before marketing.

21) **WG Comment(s)**

While in the majority of cases, processing to reduce toxicity to levels below regulatory requirements is ineffective or impractical, there are a few instances (e.g., evisceration of scallops) in which it is possible.

The WG supports the view that the requirement for final product testing should be limited to a verification activity (after the validation phase) to demonstrate that the process, carried out in accordance with good manufacturing practices and HACCP principles, is under control.

22) **Recommendation(s)**

1. The Working Group recommends that the Codex Standard and/or Code should allow for PHP for reducing marine biotoxin levels, but only under conditions where specific and adequate data are available on toxin interconversions, redistributions and PHP levels to ensure product safety.
2. The Working Group recommends that guidance on PHP for reducing marine biotoxin levels should be linked with the Code of Practice for Fish and Fishery Products. The latter document has incorporated the application of good manufacturing practices and HACCP principles.

REPORT SECTION 5: Toxin Group Specific Section

5.1 AZASPIRACIDS (AZA) group

23) Summary of Analysis from the Expert Consultation

It is evident that future priorities for studies on this toxin should focus on (i) CRM development; (ii) toxicity studies using feeding as the administration route; and, (iii) clarifying the species of phytoplankton that produce AZA toxins.

There were limited data available to the Expert Consultation for assessing this toxin group. However, as there are documented cases of adverse effects in humans, the Expert Consultation recommended guidance levels.

24) WG Comment(s)

The WG agrees that the future priorities for proposed studies on Azaspiracids should include: (i) CRM development; (ii) toxicity studies using feeding as the administration route; and (iii) clarifying the species of phytoplankton that produce AZA toxins.

Given the data available to the Expert Consultation, the existing history of regulatory programs and the level of consumer protection provided by those programs, the WG agreed that the current European, NZ, and Norway action level of 0.16 mg/kg should be maintained. The WG is of the view that the action level should be reviewed as additional data become available.

Following the first recorded outbreak of food poisoning linked to Azaspiracids in 1995, the Food Safety Authority of Ireland carried out a risk assessment which suggested a regulatory limit of 0.12 mg/kg. However, the sensitivity of the mouse bioassay was insufficient to detect the toxin at this level. It was subsequently determined that the mouse bioassay threshold for detecting Azaspiracids was 0.16 mg/kg. Consequently, the regulatory limit for this toxin group was set at this level.

The WG discussed the challenges associated with the two methodologies (i.e., mouse bioassay and LC-MS) currently being used, such as the potential for false negatives, interference from other lipophilic substances for the bioassay, and the lack of reference standards for LC-MS. The WG agreed that there is a greater potential for LC-MS challenges to be resolved in the future. In addition, the evidence available from certain regulatory programs (e.g., Ireland, Norway) suggests that LC-MS is more reliable than the mouse bioassay.

The WG discussed the shortcomings of the existing methods and the fact that neither of these methods meets the requirements of a Codex Type II reference method.

25) Recommendation(s)

1. The WG recommends that the Codex standard (section 1.5) should identify an action level for AZA of 0.16 mg/kg.
2. The WG recommends that the Codex standard (section I-7.7) identify LC-MS as a potential reference method (Codex Type II) for the detection of AZA. This is conditional on CRM being developed and inter-laboratory validation. This method should be submitted by CCFFP to the CCMAS for review and designation as soon as sufficient information for its application is available.

3. The WG recommends that the Codex standard identify other methods, such as the mouse bioassay, for use in monitoring programs.

5.2 BREVETOXIN Group

26) **Summary of Analysis from the Expert Consultation**

Priority should be placed on:

i) production of sufficient quantities of metabolic markers of brevetoxin exposure (i.e., the cysteine and /or oxidized cysteine conjugates, and oxidized brevetoxin-2) necessary for calibration of methods.

ii) completion of a single lab validation (SLV) of ELISA and LC-MS methods to be followed by full AOAC Official Methods of Analysis (OMA) inter-laboratory study and review. This is being pursued via collaborations and oversight of the Brevetoxin subgroup, Marine and Freshwater Toxins Taskforce of AOAC.

27) **WG Comment(s)**

The WG concurred with the Expert Consultation's decision that there is currently insufficient evidence to complete the risk assessment on the Brevetoxins.

Despite the Expert Consultation's decision regarding the available evidence for a risk assessment, the WG recognizes the body of 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.

Any new proposed Codex standard should be based on the current Interstate Sanitation Shellfish Conference (ISSC) action level of 20 Mouse Units as defined in the modified APHA mouse bioassay procedure. It is further recommended that the new Codex standards for use with ELISA and LC-MS methodology be determined empirically, using assay comparisons with mouse assay for naturally contaminated shellfish. Although the resulting guidance levels for ELISA and LC-MS will not be the same, both will be determined empirically by comparison to 20 Mouse Units.

28) **Recommendation(s)**

1. The WG recommends that the Codex standard (section I-5) identifies an action level for the Brevetoxins of 20 Mouse Units or equivalent (conditional on the equivalence information becoming available).
2. The WG recommends that the Codex standard (section I-7.7) identify LC-MS as a potential reference method (Codex Type II) for the detection of the Brevetoxins, conditional on inter-laboratory validation.
3. The WG recommends that the Codex standard (section I-7.7) identify ELISA as a potential "alternative approved method" (Codex Type III) for the detection of the Brevetoxins, conditional on inter-laboratory validation.
4. The WG recommends that the Codex standard (section I-7.7) identify the modified APHA mouse bioassay for use as an alternative approved method (Codex Type III).

5.3 CYCLIC IMINES group

29) **Summary of Analysis from the Expert Consultation**

It is important to note that there is no evidence of harmful effects in humans caused by cyclic imines, as seen for other marine biotoxins and that the toxic potential of cyclic imines by oral administration is significantly lower than after intraperitoneal administration. The significance of these toxins to food safety is unclear.

30) **WG Comment(s)**

The WG discussed the oral toxicity of the cyclic imines group, including spirolides. The report by the European Union Toxicology Working Group (October 2005, Annex 2, *available in English only*) provides evidence that spirolides could be toxic to humans and that further studies are required. Further studies are currently underway in New Zealand and in Europe.

31) **Recommendation(s)**

1. Based on the current lack of historical information from regulatory programs regarding human illness and the risk assessment provided by the Expert Consultation, the WG recommends that CCFFP not identify an action level for any of the cyclic imine toxins in the Codex Standard at this time.
2. The WG recommends that Member States undertake further studies of the toxicity of spirolides such that the CCFFP may ask WHO/ FAO to undertake a risk assessment on these toxins.

5.4 DOMOIC ACID (DA) group

32) **Summary of Analysis from the Expert Consultation**

A significant compilation of data was available to the Expert Consultation for this risk assessment. The absence of data on long-term, low dose exposure was noted.

The action levels derived in the report support the current level identified in the draft Codex Standard (20mg/kg).

33) **WG Comment(s)**

1. The WG agreed that the level of 20mg/kg is appropriate.
2. The WG discussed a range of available methods, some of which (e.g., LC-UVD, LC-MS, and ELISA) are undergoing further validation.

34) **Recommendation(s)**

1. The WG recommends that the Codex Standard (section I-5) should identify the action level for domoic acid as 20 mg/kg.
2. The WG recommends that the Codex standard (I-7.7) should identify the range of methods currently available to effectively detect domoic acid, including ELISA, LFIC and LC-UVD methods. These methods should be recommended by CCFFP to the CCMAS for review and designation (with the appropriate supporting data), with an acknowledgment that an LC-UVD method is the preferred candidate for a Type II method.

5.5 OKADAIC ACID (OA) group

35) **Summary of Analysis from the Expert Consultation**

The Expert Consultation's conclusions were based on real cases of human illnesses. Both Japanese and Norwegian data were used.

36) **WG Comment(s)**

The WG discussed the action levels used in various countries and the level of consumer protection which they have provided to date. The current standard, its practical application and demonstrated results indicate that the level of 0.16 mg/kg provides adequate protection for consumers.

The WG noted that the most current procedures, including those to be used in alternative chemical and biochemical methods, include hydrolysis of naturally occurring esters of the OA group. The toxicity of these substances has proven to be significant and in some cases even the dominant fraction of total OA group toxicity. This would result in a more relevant and ultimately more conservative strategy than reduction of the action level.

The WG agreed that, where instrumental methods are used, the hydrolysis of naturally occurring esters should be an essential part of the methodology.

37) **Recommendation(s)**

1. The WG recommends that the Codex standard (section I-5) identify an action level for OA equivalents of 0.16 mg/kg.
2. The WG recommends that the Codex standard (section I-7.7) identify a range of methods available to effectively detect OA, including the mouse bioassay, *in vitro* functional assays (e.g., PP2A-based assays), ELISA, LC-FL and LC-MS methods as potential alternative approved methods (Type III). These methods should be recommended by CCFFP to the CCMAS for review and designation.
3. The WG recommends that Codex standard (section I-7.7) identify LC-MS method as a potential reference method (Type II).

5.6 PECTENOTOXINS (PTX) group

38) **Summary of Analysis from the Expert Consultation**

It is important to note that there is no evidence of adverse effects of PTX in humans and that, as for other marine biotoxins, animal studies reveal a significant reduction in toxicity via oral administration *vs* intraperitoneal administration.

39) **WG Comment(s)**

The WG discussed the results of the Expert Consultation and the lack of evidence of adverse effects in humans in areas where there are ongoing regulatory monitoring programs.

40) **Recommendation(s)**

1. The WG recommends that the Codex standard not identify any action level for the PTX group. At this time, they should not be regulated.
2. The WG recommends that, should data/evidence become available, the potential for adverse health effects of PTX to humans would be reassessed.

5.7 SAXITOXINS (STX) group

41) **Summary of Analysis from the Expert Consultation**

The Expert Consultation acknowledged data quality challenges in completing this risk assessment. While select unpublished studies were included in this evaluation (along with published sources), the experts recommended that further unpublished data be collected and evaluated with an aim to further increase the accuracy of the assessment. The impact/influence of the long-standing enforced tolerance limit of 0.8mg/kg STX.2HCl equiv., established for consumer protection, was also not considered.

42) **WG Comment(s)**

The WG considered the long history of success (nearly 50 years) using an action level of 0.8 mg/kg with the mouse bioassay, with no human illnesses (from commercially harvested product).
The WG discussed available methodology, in particular the fact that the Lawrence LC-FL method had recently undergone inter-laboratory validation and that it could be considered as a Codex Type II method. The WG also discussed the need for other methods that could be used for routine monitoring, such as mouse bioassay, receptor binding assay, etc.

43) **Recommendation(s)**

1. The WG recommends that the Codex standard (section I-5) maintain the action level currently identified for PSP as 0.8 mg/kg STX.2HCl equiv.
2. The WG recommends to CCFFP that the Codex standard (section I-7.7) identify the Lawrence LC-FL method as a potential reference method (Codex Type II) subject to review by CCMAS. The Lawrence LC-FL method was recently approved by AOAC as an official method of analysis.
3. The WG recommends that Codex identify the range of methods currently available to effectively detect saxitoxins, including the mouse bioassay, the receptor binding assay, immunochemical, LC-FL and LC-MS methods for consideration as Type III methods. These methods should be recommended by CCFFP to the CCMAS for review and designation.

5.8 YESSOTOXINS (YTX) group

44) **Summary of Analysis from the Expert Consultation**

There are no reports of human intoxication caused by YTX and, as for other marine biotoxins, data in mice indicate a significant reduction in potency via oral administration compared to intraperitoneal administration.

45) **WG Comment(s)**

The WG discussed the results of the Expert Consultation and the lack of evidence of adverse effects in humans in areas where there are ongoing regulatory monitoring programs.

46) **Recommendation(s)**

1. The WG recommends that the Codex standard not identify an action level for the YTX group. At this time, they should not be regulated.
2. The WG recommends that, should data become available, the toxicological effects of YTX to humans would be reassessed.

REPORT SECTION 6: Monitoring

47) **Summary of Analysis from the Expert Consultation**

The strengths and weaknesses of microalgae monitoring were noted along with issues associated with the use of indicator shellfish species. Key issues regarding sampling protocols were discussed.

48) **WG Comment(s)**

Phytoplankton monitoring should not be identified by Codex as a requirement since potentially toxic phytoplankton levels would never be the decision factor to control shellfish marketing. Nevertheless, the Codex Code of Practice should acknowledge phytoplankton monitoring as a valuable complementary tool that can be used, in combination with the required monitoring of marine biotoxins in shellfish tissue, to optimize program management and resources. It provides complementary information on trends in toxic phytoplankton abundance that may be used as an early warning of impending marine biotoxin accumulation in shellfish and as a guide for determining the frequency of shellfish sampling.

The WG would like to highlight the fact that the guidance mentions using risk evaluation (including historical information) in order to formulate decisions regarding sampling frequency, including in countries where there is demonstrated evidence of little or no toxin presence.

The WG discussed the use of indicator shellfish species in marine biotoxin monitoring programs (i.e., that the assumptions associated with indicator species should be verified for the harvest species and the range of toxins present).

The WG discussed the need for guidance with respect to sampling programs and agreed that a properly designed sampling and monitoring program is a key element in preventing human illness. As a minimum, the WG agreed on the need to include the guidance established by the Expert Consultation in the Codex Code of Practice.

49) **Recommendation(s)**

1. The WG recommends to the CCFFP that the Code of Practice include phytoplankton monitoring as a valuable complementary tool that can be used in combination with the required monitoring of marine biotoxins in shellfish tissue.
2. The WG recommends to the CCFFP that the Code of Practice include the caution identified in the Expert Consultation report (section 6.3): "It is important to note that using indicator shellfish species, the absence of toxicity in indicated species is assumed to imply the absence of toxicity in other species in the growing area. This implication must be verified

for each shellfish species and for each group of toxins before defining a particular shellfish species as an indicator for that growing area".

3. The WG recommends to CCFFP that the guidance provided by the Expert Consultation (Annex 3, *available in English only*) regarding sampling be included in the Codex Code of Practice.
4. The WG recommends that the FAO/WHO be asked to develop a practical manual and training for biotoxin monitoring programs.

REPORT SECTION 7: Replies to Specific Questions Posed by the CCFFP

50) **Summary of Analysis from the Expert Consultation**

The Expert Consultation replied to the questions posed by the CCFFP. In most cases, responses were cross-referenced with information contained in the Expert Consultation report. Two items regarding "new toxins" and the guidance regarding the systematic collection of data/information on human poisoning incidents were further elaborated in the report.

51) **WG Comment(s)**

The WG noted the importance of the guidance regarding "new toxins" and the systematic collection of data/information on human poisoning incidents.

52) **Recommendation(s)**

1. The WG recommends that the Codex Code of Practice include considerations of dealing with new toxins (as per question 2 in the Expert Consultation report, p.28).
2. The WG recommends that the Codex Code of Practice include suggestions regarding the collection and communication of data/ information on human illness from consumption of bivalve molluscs through local/regional, etc. Ministries of Health.
3. Considering the recent detection of palytoxins in bivalve molluscs, the WG recommends that Member States undertake further studies of the toxicity of these compounds such that the CCFFP may ask WHO/ FAO to undertake a risk assessment on the toxins.

OTHER CONSIDERATIONS

53) **Summary of Analysis from the Expert Consultation**

The Expert Consultation has offered 3 different guidance limits associated with three levels of consumption (100g / 250g / 380g) for most toxin groups. Because the consumption amount impacts on the limit, the WG was asked to consider how this information may be applied in the Codex standard. An issue would be which consumption level is the appropriate consumption level for the protection of consumers.

54) **WG Comment(s)**

The WG considered the 3 levels of consumption outlined by the Expert Consultation. Since the WG discussed each individual toxin group and considered the entire body of knowledge, including regulatory history, in developing recommendations on action limits, thorough discussion on specific consumption limits was not needed.

55) **Recommendation(s)**

The WG recommends to CCFFP that Member States undertake additional surveys on the frequency and amounts of shellfish consumption in their respective countries.

Annex 1: List of participants

Annex 2: Report on Toxicology Working Group Meeting, Cesenatico, Italy, 24-25 October 2005

Annex 3: Report of the Joint FAO/IOC/WHO *ad hoc* Expert Consultation on Biotoxins in Bivalve Molluscs. Oslo, Norway, Sept. 26-30, 2004

Guidance on Sampling (Section 6.4 of the Report)

A micro-algal and shellfish sampling protocol over time and space should include theadequate location and number of sampling sites. Sampling frequency must be sufficient to address spatial-temporal changes in micro-algae, toxins in shellfish and to cover the risks of rapid rises in shellfish toxicity.

Spatial Representational Sampling

The selection of sampling stations for both benthic and suspended culture should be based on sites which have historically presented toxicity in the early stages of a toxic event. It is recognised that sampling, generally, cannot be carried out in a statistically valid way without excessive cost. In order to protect public health, the selection of sampling stations should give appropriate coverage of the extent of a toxic event or the likely "worst case scenario" in a growing area. This should be based on expert judgment using the following factors:

- Hydrography, known upwellings, fronts, current patterns and tidal effects.
- Access to sampling stations in all weather conditions during harvesting.
- Desirability of toxin and micro-algal sampling at the same sampling station.
- In addition to primary (routine) stations, the need for secondary (complementary) and offshore stations.
- Existence of in-situ growth (for example, toxic micro-algae from cyst beds).
- The advection of offshore toxic micro-algal blooms into growing areas.

Routine sampling for micro-algae will generally mean taking an integrated sample from the water column. When a toxic event is in progress or developing, targeted, depth-specific sampling should be considered.

Sampling for shellfish grown in suspension, should at least involve an integrated sample composed of shellfish taken from the top, middle and bottom of the lines.

Temporal Representational Sampling

Minimum weekly sampling frequencies are adopted by most monitoring programmes in areas where toxicity is prevalent and where harvesting is taking place or about to take place. Decisions on the frequency of sampling should be based on risk evaluation. Inputs into the decision may include factors such as seasonality (toxicity and / or harvesting), accessibility, historical baseline information, including toxin and micro-algal data, and the effects of environmental factors such as wind, tide and currents. Sampling frequency and the factors that may lead to it being changed should be described in a "Marine Biotoxin Action Plan" for the growing area.

Shellfish Sample Size

There is no internationally agreed sample size for different shellfish species. There may be high variability of toxicity among individual shellfish. The number of shellfish sampled should be sufficient to address this variability. For this reason, the number of shellfish in the sample, rather than the mass of the shellfish flesh should be the determining factor for the sample size. Additionally, the size of the sample should be sufficient to allow the test or tests for which the sample is being taken to be carried out, and the shellfish sampled should be of the size marketed.

2. CODEX CODE OF PRACTICE FOR PROCESSING LIVE AND RAW BIVALVE MOLLUSCS

SECTION 7 – PROCESSING OF LIVE AND RAW BIVALVE MOLLUSCS

In the context of recognizing controls at individual processing steps, this section provides examples of potential hazards and defects and describes technological guidelines that can be used to develop control measures and corrective action. At a particular step, only the hazards and defects that are likely to be introduced or controlled at that step are listed. It should be recognized that in preparing an HACCP and/or DAP plan it is essential to consult Section 5, which provides guidance for the application of the principles of HACCP and DAP analysis. However, within the scope of this Code, it is not possible to give details of critical limits, monitoring, record-keeping and verification for each of the steps as these are specific to particular hazards and defects.

7.1 General remarks, addition to the prerequisite programme

Bivalve molluscs species, such as oysters, mussels, manilla and hard shell clams, can survive for extended periods out of water and can be traded for human consumption as live animals. Other species like cockles can be traded live if carefully handled, but are normally processed. Species not adapted to dry conditions soon die out of water and are best handled as chilled products or processed.

When spawning (following "gonad ripening") occurs, it becomes undesirable and in many instances impracticable to trade them as live animals. Stress can induce spawning.

The main hazard known for the production of bivalve molluscs is microbiological contamination of waters in which they grow, especially when the bivalve molluscs are intended to be eaten live or raw. Because molluscs are filter feeders, they concentrate contaminants to a much higher concentration than the surrounding seawater. The contamination with bacteria and viruses in the growing area is therefore critical for the end-product specification and determines the process requirements for further processing. Gastro-enteritis and other serious diseases such as hepatitis can occur as a result of agricultural runoff and/or sewage contamination like enteric bacterial and/or viral pathogens (norovirus, viruses causing hepatitis) or from natural occurring bacterial pathogens (*Vibrio* spp.). Another hazard is posed by biotoxins. Biotoxins produced by some algae can cause various forms of serious poisoning like diarrhetic

shellfish poisoning (DSP), paralytic shellfish poisoning (PSP), neurotoxic shellfish poisoning (NSP), amnesic shellfish poisoning (ASP) or poisoning caused by azaspiracid (AZP). Chemical substances, such as heavy metals, pesticides and organochlorides, and petrochemical substances may also pose a hazard in certain areas.

To control the hazards, identification and monitoring of growing areas is very important for ensuring the safety of bivalve molluscs. The identification, classification and monitoring of these areas is a responsibility for competent authorities in cooperation with fishers and primary producers. *Escherichia coli*/faecal coliforms or total coliforms may be used as an indicator for the possibility of faecal contamination. If biotoxins are found in the bivalve molluscs flesh in hazardous amounts, the growing area must be closed for harvesting bivalve molluscs until toxicological investigation has made clear that the bivalve mollusc meat is free from hazardous amounts of biotoxins. Harmful chemical substances should not be present in the edible part in such amounts that the calculated dietary intake exceeds the permissible daily intake.

Bivalve molluscs from waters subject to microbiological contamination, as determined by the authority having jurisdiction, can be made safe by relaying in a suitable area or a depuration process to reduce the level of bacteria if the process is continued long enough, or by processing to reduce or limit target organisms. Depuration is a short-term process commonly used to reduce low levels of bacterial contamination, but long-term relaying is required if there is a greater risk of contamination.

Especially when the bivalve molluscs need to undergo relaying or depuration to be eaten live or raw, stress and excessive shocks must be avoided. This is important because these bivalve molluscs should be able to function again during depuration, relaying or conditioning.

7.2 Classification and monitoring of growing areas

Potential hazards: *microbiological contamination, biotoxins, chemical contamination*
Potential defects: *unlikely*
Technical guidance:

There are five different types of important hazards coming from the bivalve molluscs growing environment:

- enteric bacterial pathogens (e.g. *Salmonella* spp.);
- enteric viral pathogens (e.g. norovirus, viruses causing hepatitis);
- naturally occurring bacterial pathogens (e.g. *Vibrio* spp.);
- biotoxins (e.g. okadaic acid group [DSP], saxitoxin group [PSP], brevetoxin group [NSP], domoic acid group [ASP], azaspiracid group [AZP]);
- chemical contaminants (e.g. heavy metals such lead, cadmium and mercury).

7.2.1 Classification of growing areas

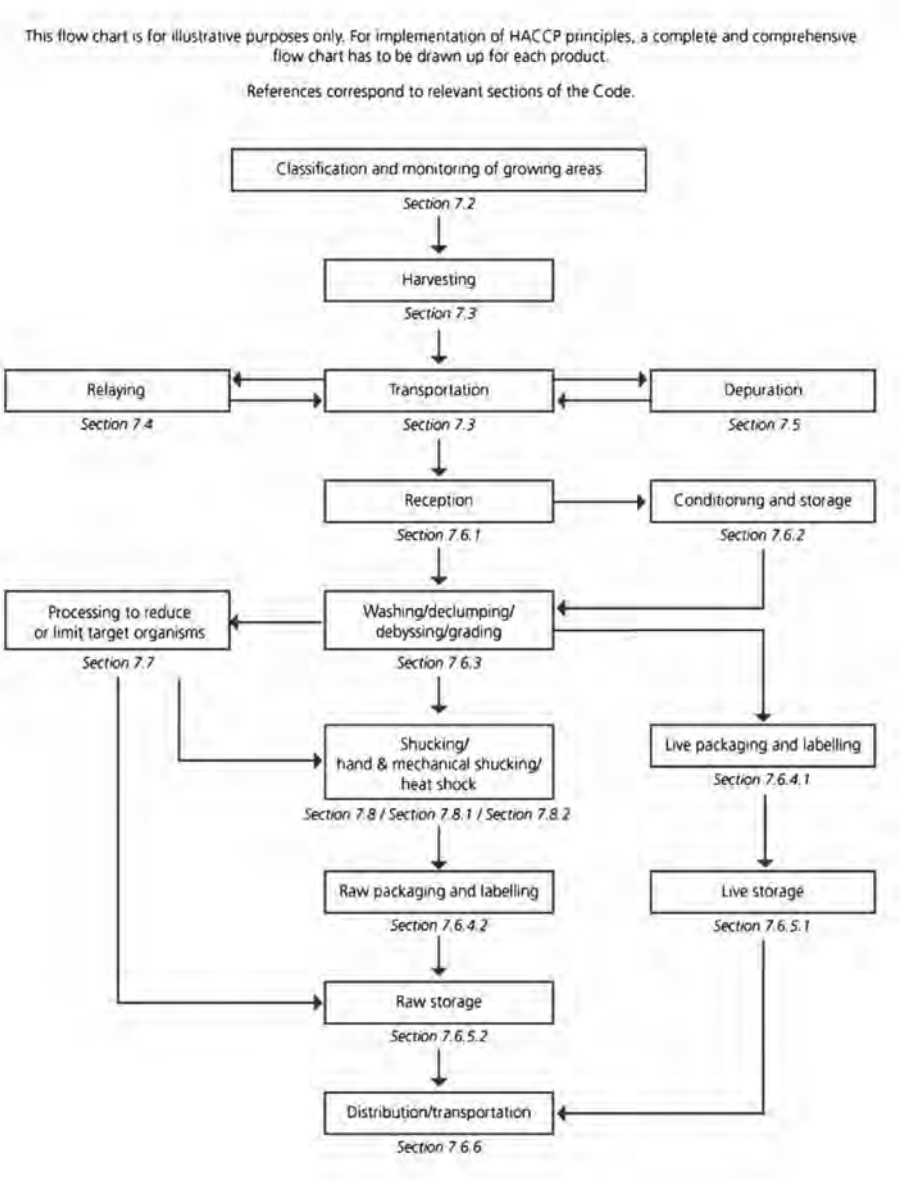
Surveys of the growing area, shoreline and land catchment should be conducted to determine sources of both domestic and industrial pollution that may affect the quality of the growing area water and bivalve molluscs. Sources may include municipal sewage outputs, industrial outputs, mine wastes, geophysical contaminants, domestic animal holding pens, nuclear power plants, refineries or other sources. The need to reschedule hygiene surveys will be determined by population shifts and changes in agricultural and industrial activities in the coastal area. Re-surveys should be conducted at an acceptable frequency and known pollution sources should be re-evaluated on a regular basis to determine any changes to their impact on the growing area.

When pollution sources have been identified and evaluated, sampling stations for water and/or bivalve molluscs and/or sediments should be established and studies conducted to determine the effects of the pollutants on water and bivalve mollusc

quality. The data should be evaluated by the official agency having jurisdiction and growing areas should be classified according to official standards and criteria.

When interpreting growing area data, the official agency having jurisdiction should take into account variations that may affect the level of pollution during the most unfavourable hydrographic and climatic conditions as influenced by rainfall, tides, winds, methods of sewage treatment, population variations and other local factors, as bivalve molluscs respond rapidly to an increase in the number of bacteria or viruses in their environment by accumulating these agents. The agency should also consider that bivalve molluscs have the ability to accumulate toxic chemicals in their tissue in concentrations greater than the levels found in the surrounding water. FAO, WHO or other international or national food standards may be used as a guide to acceptable levels.

FIGURE 7.1
Example of a simplified flow diagram for production of live and raw bivalve molluscs



The official agency having jurisdiction should immediately announce decisions concerning the classification of growing areas to the affected producers and depuration and distribution centres.

When sampling shellfish meats for classification purposes, if the limits of any biological or chemical hazard set in the end-product specification are exceeded, appropriate measures must be taken under the responsibility of the official agency having jurisdiction.

Classified growing areas should be clearly defined by the official agency having jurisdiction as either:

- suitable for harvesting for direct human consumption, relaying in acceptable water or depuration in an approved depuration centre or approved processing to reduce or limit target organisms; or
- non-suitable for growing or harvesting bivalve molluscs.

7.2.2 Monitoring of growing areas

Growing areas should be routinely monitored for changes in water quality and/or bivalve mollusc quality, and substandard areas patrolled to prevent harvesting for purposes other than that established by the official agency.

Biotoxins in bivalve molluscs can be caused by plankton containing toxins. For early warning purposes, where appropriate, it is recommended to have a programme present to monitor growing areas for the species of plankton that can produce toxins and to recognize other environmental signals that a toxic event may be developing.

Harmful chemical substances within bivalve molluscs should not be present in amounts such that the calculated dietary intake exceeds the permissible daily intake. A monitoring system should be present for harmful chemical substances.

When routine monitoring programmes or re-surveys show that the growing area no longer meets the classification criteria, the area should be reclassified or closed for harvesting immediately by the official agency having jurisdiction.

In determining the public health suitability of bivalve mollusc classified growing areas, the official agency having jurisdiction should consider the following actions:

- Classification/reclassification of growing areas by sanitary survey, monitoring of *E. coli*/faecal coliforms or total coliforms at an appropriate frequency based on the risk of contamination, and other sanitary control measures as applicable.
- Classification/reclassification of growing areas by monitoring of pathogens at an appropriate frequency based on the probability of contamination in bivalve mollusc meat (see Section 7.2.2.2).
- Closure/reopening of growing areas by the monitoring of biotoxins in bivalve molluscs alone or in combination with the monitoring of phytoplankton in seawater at an appropriate frequency based on the probability of contamination (see Section 7.2.2.3).
- Control of chemical contaminants.

Under the responsibility of the official agency having jurisdiction, the growing areas providing bivalve molluscs for direct human consumption should meet the following requirements at time of harvest:

- The area is not subject to contamination that may present an actual or potential hazard to human health.
- The bivalve molluscs harvested meet the end-product specification. This can be determined by examination of the molluscan flesh or through adequate monitoring of the water, as appropriate.

Growing areas providing bivalve molluscs for indirect human consumption should be defined in relation to the further procedure of the lot.

7.2.2.1 Escherichia coli/*faecal coliforms/total coliforms*

All growing water and/or molluscan flesh should be monitored for the presence of *E. coli*/faecal coliforms or total coliforms at an appropriate frequency based on the probability and degree of faecal contamination.

Tests for suitable indicator bacteria such as faecal coliforms or *E. coli* or total coliforms should be used to determine the degree of faecal contamination. The effectiveness of indicator bacteria used should be kept under constant review for their reliability as measures for the degree of faecal contamination. If faecal contamination exceeds a certain threshold level, relaying or depuration for a time approved by the official agency having jurisdiction may be allowed.

E. coli/faecal coliforms or total coliforms may be used as an indicator for the presence of faecal contamination. Because these indicators do not correlate well with the presence of viruses, other controls such as shoreline surveys should always be employed.

Other methods such as bacteriophage and viral detection could also be used as indicators when validated analytical methods become available in the future.

7.2.2.2 Pathogen monitoring

Shellfish sanitation programmes rely upon the use of indicator organisms for the presence of contamination rather than upon attempts to monitor for specific pathogens. However, where there has been a shellfish-borne outbreak caused by an identified pathogen such as *Salmonella* and others (*Vibrio* and viruses), monitoring the bivalve molluscs may be appropriate as part of the process of closure/reopening of the affected harvest area. The species, and typically the actual strain, should be known in order to ensure that monitoring is addressing the source of the pathogen. Predetermined acceptance/rejection levels for the pathogen should have been established in order to use such monitoring results for decision-making. Other conditions including the sanitary survey requirements should also have been satisfied as a condition of reopening this area.

7.2.2.3 Marine biotoxin control

Phytoplankton monitoring is a valuable complementary tool that can be used in combination with the required monitoring of marine biotoxins in shellfish tissue to optimize programme management and resources. Growing areas should also be monitored for environmental signals that a toxin event may be occurring, e.g. dead or dying birds, mammals or fish. The risk of blooms of toxic algae may show seasonal variability and areas may also be affected by toxic algae previously unknown in the surrounding sea or coastal waters. These risks should be recognized when drawing up monitoring schedules.

It is important to note that in using indicator shellfish species, the absence of toxicity in indicated species is assumed to imply the absence of toxicity in other species in the growing area. This implication must be verified for each shellfish species and for each group of toxins before defining a particular shellfish species as an indicator for that growing area.

The official agency having jurisdiction should close immediately and effectively patrol affected areas when acceptable levels are exceeded in edible portions of bivalve mollusc meats. These areas should not be opened before toxicological investigation has made clear that the bivalve mollusc meat is free from hazardous amounts of biotoxins.

The official agency having jurisdiction should immediately announce these decisions to the affected producers and depuration and distribution centres.

In establishing sampling programme over space and time, consideration should be given to ensuring adequate location and number of sampling sites. Testing for a

particular biotoxin may not be appropriate when it has been demonstrated that this biotoxin has not been associated with bivalve molluscs in the growing and harvesting areas. Sampling frequency must be sufficient to address spatial–temporal changes in microalgae, toxins in shellfish and to cover the risks of rapid rises in shellfish toxicity.

Spatial representational sampling

The selection of sampling stations for both benthic and suspended culture should be based on sites that have historically presented toxicity in the early stages of a toxic event. It is recognized that sampling, generally, cannot be carried out in a statistically valid way without excessive cost. In order to protect public health, the selection of sampling stations should give appropriate coverage of the extent of a toxic event or the likely "worst case scenario" in a growing area. This should be based on expert judgement using the following factors:

- Hydrography, known upwellings, fronts, current patterns and tidal effects.
- Access to sampling stations in all weather conditions during harvesting.
- Desirability of toxin and microalgal sampling at the same sampling station.
- In addition to primary (routine) stations, the need for secondary (complementary) and offshore stations.
- Existence of *in-situ* growth (e.g. toxic microalgae from cyst beds).
- The advection of offshore toxic microalgal blooms into growing areas.

Routine sampling for microalgae will generally mean taking an integrated sample from the water column. When a toxic event is in progress or developing, targeted, depth-specific sampling should be considered.

Sampling for shellfish grown in suspension should at the least involve an integrated sample composed of shellfish taken from the top, middle and bottom of the lines.

Temporal representational sampling

Minimum weekly sampling frequencies are adopted by most monitoring programmes in areas where toxicity is prevalent and where harvesting is taking place or about to take place. Decisions on the frequency of sampling should be based on risk evaluation. Inputs into the decision may include factors such as seasonality (toxicity and/or harvesting), accessibility, historical baseline information, including toxin and microalgal data, and the effects of environmental factors such as wind, tide and currents.

Sampling frequency and the factors that may lead to it being changed should be described in a "marine biotoxin action plan" for the growing area.

Shellfish sample size

There is no internationally agreed sample size for different shellfish species. There may be high variability of toxicity among individual shellfish. The number of shellfish sampled should be sufficient to address this variability. For this reason, the number of shellfish in the sample, rather than the mass of the shellfish flesh, should be the determining factor for the sample size. In addition, the size of the sample should be sufficient to allow the test(s) for which the sample is being taken to be carried out, and the shellfish sampled should be of the size marketed.

7.2.2.4 Marine biotoxin test methods

Methods suitable for the determination of marine biotoxins are listed in the *Standard for live and raw bivalve molluscs* (CODEX STAN 292 2008). Any methods may be deemed suitable for screening purposes provided they are approved by the competent authority in a country.

7.2.2.5 Chemical contaminants

Growing areas should be monitored for chemical contaminants on a sufficiently frequent basis to provide confidence that any identified sources of chemical contamination are not contaminating the shellfish. Shellfish growing areas where there are no known point sources of likely chemical contamination should only require occasional checks every few years. However, where there are known point sources of specific contamination, shellfish may need to be checked more frequently on a routine basis. There should also be the capacity to sample shellfish reactively if a defined event occurs – for example, a spillage of antifouling paint.

7.3 Harvesting and transportation of live bivalve molluscs

Refer also to Sections 3.1, 3.3, 3.4 and 3.5.

This section applies to the transportation of bivalve molluscs for the purpose of direct human consumption, relaying, depuration, processing to reduce or limit target organisms, or further processing.

Appropriate handling procedures depend on different species, growing area and season.

Potential hazards: *microbiological contamination, biotoxins, chemical contamination*

Potential defects: *physical damage*

Technical guidance:

- Dredges and other harvesting equipment, decks, holds and containers that are contaminated from use in a polluted area should be cleaned and, if applicable, disinfected (sanitized) before being used for bivalve molluscs from an unpolluted area.
- Holds in which bivalve molluscs are held or containers should be so constructed that the bivalve molluscs are held above the floor level and drained so that the bivalve molluscs are not in contact with washdown or bilge water, or shell fluid. Where necessary, a bilge pumping system must be provided.
- Suitable precautions should be taken to protect bivalve molluscs from being contaminated by polluted water, droppings from sea birds, footwear that may have been in contact with faecal matter or by other polluted material. No overboard discharge of waste, including human faecal material, should occur from harvest vessels around shellfish growing areas. No animals should be allowed on harvest vessels.
- Washdown pumps should draw water only from non-contaminated seawater.
- Bivalve molluscs should be harvested from and stored in a growing area or relaying area acceptable to the official agency having jurisdiction.
- On removal from water or during handling and transportation, bivalve molluscs should not be subjected to extremes of heat or cold or sudden variations in temperature. Temperature control is critical in handling live bivalve molluscs. Special equipment, such as insulated containers and refrigeration equipment, should be used if prevailing temperatures and the time involved so require. Bivalve molluscs should not be exposed to full sun or surfaces heated by the sun or come into direct contact with ice and other freezing surfaces, nor should they be held in closed containers with solid carbon dioxide. In most cases, storage above 10 °C (50 °F) or below 2 °C (35 °F) should be avoided.
- Bivalve molluscs should be freed from excessive mud and weed soon after being harvested by washing with clean seawater or potable water under suitable pressure. Wash water should not be allowed to flow over bivalve molluscs already cleaned. The water could be re-circulated if it meets the definition for clean water.

- The interval between harvesting and immersion in water for relaying, storage, conditioning or depuration should be kept as short as possible. This also applies to the interval between final harvesting and handling in a distribution centre.
- If bivalve molluscs are to be re-immersed after harvest, they should be re-immersed in clean seawater.
- Appropriate documentation should be maintained for harvesting and transportation activities.

7.4 Relaying

The requirements for classification and monitoring of growing areas also apply to relaying areas.

Relaying is intended to reduce the level of biological contaminants that may be present in bivalve molluscs that have been harvested from contaminated areas to such levels that the bivalve molluscs will be acceptable for human consumption without further processing. Bivalve molluscs harvested for relaying should only be harvested from areas that are so designated/classified by the official agency having jurisdiction. Relaying methods vary worldwide. Bivalve molluscs may be placed in floats, rafts or directly on the bottom.

Potential hazards: *microbiological contamination, biotoxins, chemical contamination*
Potential defects: *unlikely*
Technical guidance:

- Relaying operations should be strictly supervised by the official agency having jurisdiction to prevent contaminated bivalve molluscs from being diverted directly to the consumer market or from cross-contamination of other bivalve molluscs. Boundaries of relaying areas should be clearly identified by buoys, poles or other fixed means. These areas should be adequately separated from the bivalve molluscs in adjacent waters and suitable control systems should be in place to prevent cross-contamination and commingling.
- Holding time and minimum temperature in the accepted area prior to harvest will be determined by the official agency having jurisdiction according to the degree of contamination before relaying, the temperature of the water, the bivalve molluscs species involved and local geographic or hydrographic conditions to ensure that contamination levels have been adequately reduced.
- Relaying sites could become biotoxic from a bloom, or could become an unexpected a source of environmental pathogens such as *Vibrio* bacteria, and should therefore be monitored as appropriate while they are being used for relaying.
- Bivalve molluscs should be laid out at a density that will permit them to open and undergo natural depuration.
- Appropriate documentation should be maintained for relaying operations.

7.5 Depuration

Refer also to Sections 3.2, 3.3, 3.4 and 3.5.

Depuration is intended to reduce the number of pathogenic micro-organisms that may be present in bivalve molluscs that have been harvested from moderately polluted areas to such levels that the bivalve molluscs will be acceptable for human consumption without further processing. Depuration alone is not suitable for cleansing bivalve molluscs from more heavily contaminated areas or areas subject to contamination by hydrocarbons, heavy metals, pesticides, viruses, vibrios or biotoxins. Bivalve molluscs harvested for depuration should only be harvested from areas that are so designated/classified by the official agency having jurisdiction.

The required conditions vary according to the species of molluscs and the design of the depuration system.

For natural functioning and therefore depuration to occur, it is essential that the molluscs have not been overstressed or damaged during harvesting or handling prior to depuration and should not be in a seasonally weak or spawning condition.

Depuration centres should maintain the same hygiene standards as per Sections 3.2, 3.3, 3.4 and 3.5.

Potential hazards: *microbiological contamination*
Potential defects: *physical damage*
Technical guidance:

- Depuration centres and tanks should be approved by the official agency having jurisdiction.
- Bivalve molluscs subjected to the depuration process should not contain metallic ions, pesticides, industrial wastes or marine biotoxins in such quantities that they represent a health hazard for the consumer.
- Use only shellstock designated as acceptable by the official agency having jurisdiction.
- The process and the equipment, e.g. tanks, used for depuration should be acceptable to the official agency having jurisdiction.
- Dead or damaged bivalve molluscs should be removed before the depuration process, when practicable. Surfaces of shells should be free from mud and soft commensal organisms. If necessary, the bivalve molluscs should be washed with clean seawater before the depuration process.
- The length of the period of depuration should be adapted to the water temperature and physical water quality parameters (clean seawater, salinity, dissolved oxygen and pH levels suitable to permit the bivalve molluscs to function normally), the degree of contamination before depuration and the bivalve mollusc species. Microbiological investigation of process water and of bivalve mollusc meat should be used to assess depuration parameters. It should be taken into account that viruses and *Vibrio* spp. are more persistent during depuration than the indicator bacteria mostly used for microbiological monitoring and that the reducing of the number of indicator bacteria does not always reflect the real situation as regards contamination by viruses and *Vibrio*.
- Water used in depuration tanks should be changed continuously or at suitable intervals or, if recirculated, be treated properly. The flow of water per hour should be sufficient to the amount of bivalve molluscs treated and should depend on the degree of contamination of the bivalve molluscs.
- Bivalve molluscs undergoing depuration should remain immersed in clean seawater until they satisfy the sanitary requirements of the official agency having jurisdiction.
- Bivalve molluscs should be laid out at a density that will permit them to open and undergo natural depuration.
- During the process of depuration, the water temperature should not be allowed to fall below the minimum at which bivalve molluscs remain physiologically active; high water temperatures that adversely affect the pumping rate and the depuration process should be avoided; tanks should be protected from the direct rays of the sun when necessary.
- Equipment in contact with water, i.e. tanks, pumps, pipes or piping, and other equipment should be constructed of non-porous, non-toxic materials. Copper, zinc, lead and their alloys should preferably not be used in tanks, pumps or piping systems used in depuration processing.

- To avoid recontamination of bivalve molluscs undergoing depuration, unpurified bivalve molluscs should not be placed in the same tank as bivalve molluscs that are already undergoing depuration.
- On removal from the depuration system, bivalve molluscs should be washed with running potable water or clean seawater, and handled in the same manner as living bivalve molluscs taken directly from a non-polluted area. Bivalve molluscs that are dead, with broken shells or otherwise unwholesome should be removed.
- Before removing the bivalve molluscs form the tanks, drain the water from the system to avoid re-suspension and re-ingestion. The tanks should be cleaned after each use and disinfected at suitable intervals.
- After depuration, the bivalve molluscs should meet the end-product specification.
- Appropriate documentation should be maintained for depuration.

7.6 Processing of bivalve molluscs in a distribution centre or an establishment

Some countries require that bivalve molluscs that are to be frozen and/or shucked and/or processed to reduce or limit target organisms must first pass through a "distribution centre" from which they exit alive. Other countries allow freezing, shucking and processing to reduce or limit target organisms to occur in establishments that perform the functions of a "distribution centre". Both practices are legitimate and the products from each one should be equally permitted in international trade. Where "distribution centre" activities and processing activities occur under the same roof, care must be taken to ensure adequate separation of activities to prevent cross-contamination or commingling of products.

Distribution centres that prepare live bivalve molluscs suitable for direct consumption and establishments that prepare live and raw bivalve molluscs suitable for direct consumption should maintain the same hygiene standards as per Sections 3.2, 3.3, 3.4 and 3.5.

7.6.1 Reception

Potential hazards: *microbiological, chemical and physical contamination*
Potential defects: *viable parasites, physical damage, foreign matter, dead or dying bivalve molluscs*
Technical guidance:

- Stress and excessive shocks to bivalve molluscs that will be dispatched live from a distribution centre or other establishment must be avoided.
- Distribution centres and other establishments that prepare live bivalve molluscs should only accept bivalve molluscs that meet the end-product specification and that originate directly from approved growing areas or after relaying in an approved relaying area or after depuration in an approved depuration centre or tank.

7.6.2 Conditioning and storage of bivalve molluscs

Refer also to Sections 3.2, 3.3, 3.4 and 3.5.

Potential hazards: *microbiological contamination, chemical contamination, biotoxins*

Potential defects: *physical damage, foreign matter, dead or dying bivalve molluscs*

Technical guidance:

- Conditioning means storage of bivalve molluscs in seawater tanks, basins, floats, rafts or natural sites with the intention to remove mud, sand and slime.
- The process of storing bivalve molluscs in seawater tanks, basins, floats, natural sites or rafts can be used if it is acceptable to the official agency having jurisdiction.
- Only clean seawater should be used in the tanks, floats, natural sites or rafts and should be of an adequate salinity and adequate physical water quality parameters to permit the bivalve molluscs to function normally. Optimal salinity will vary with bivalve mollusc species and with the harvesting area. Water condition has to be of adequate quality for the process. Where natural sites are used for conditioning, these should be classified by the official agency having jurisdiction.
- Before conditioning or storage, bivalve molluscs should be washed to remove mud and soft commensal organisms and dead or damaged bivalve molluscs should be removed when practicable.
- During storage, bivalve molluscs should be laid out at a density and under such conditions that will permit them to open and function normally.
- The oxygen content in the seawater should be maintained at an adequate level at all times.
- The temperature of the water in storage tanks should not be allowed to rise to such levels as to cause weakness in the bivalve molluscs. If ambient temperatures are excessively high, tanks should be placed in a well-ventilated building or away from the direct rays of the sun. The length of the period of conditioning should be adapted to the water temperature.
- Bivalve molluscs should be stored in clean seawater only for such time as they remain sound and active.
- Tanks should be drained, cleaned and disinfected at suitable intervals.
- Recirculating wet storage systems must contain approved water treatment systems.

7.6.3 Washing, declumping, debyssing and grading

Refer also to Sections 3.2, 3.3, 3.4 and 3.5.

Potential hazards: *microbiological contamination, chemical and physical contamination*

Potential defects: *mechanical damage*

Technical guidance:

- All steps in the process, including packaging, should be performed without unnecessary delay and under conditions that will prevent the possibility of contamination, deterioration and the growth of pathogenic and spoilage micro-organisms.
- Damage to shells and stress will shorten the shelf-life of bivalve molluscs and increase the risk of contamination and deterioration. Therefore, bivalve molluscs have to be handled carefully:
  - the number of handlings of bivalve molluscs should be minimized;
  - excessive shocks should be avoided.

- The different process steps should be supervised by technically competent personnel.
- The outsides of the shells should be washed free of mud, and all soft adhering organisms should be removed. Hard adhering organisms should also be removed when possible, care being taken not to chip lips of shells by vigorous washing. Washing should be carried out using pressurized clean (sea)water.
- Bivalve molluscs having formed clumps should be declumped and debyssed as appropriate. The equipment used should be designed and adjusted to minimize the risk of damage to the shells.

7.6.4 Packaging and labelling

Refer also to Sections 3.2, 3.3, 3.4 and 3.5.

All steps in the packaging process should be performed without unnecessary delay and under conditions that will prevent the possibility of contamination, deterioration and the growth of pathogenic and spoilage micro-organisms.

The packaging material should be appropriate for the product to be packaged and for the expected conditions of storage and should not transmit to the product harmful or other objectionable substances or odours and tastes. The packaging material should be sound and should provide appropriate protection from damage and contamination.

7.6.4.1 Packaging and labelling of live bivalve molluscs

Potential hazards: microbiological contamination, physical contamination, chemical contamination

Potential defects: incorrect labelling, presence of damaged or dead bivalve molluscs, foreign matter

Technical guidance:

- Before packaging, bivalve molluscs should undergo visual inspection. Bivalve molluscs that are dead, with broken shells, with adhering soil or otherwise unwholesome should be rejected for human consumption.
- The packaging material should avoid contamination and should be drained.
- Labels should be clearly printed and must comply with the labelling laws of the country where the product is marketed. The packaging material may be used to bear an indication as to how the bivalve molluscs should be kept from the time they were bought at the retailer. It is recommended that the date of packaging be included.
- All packaging material should be stored in a clean and sanitary manner. Product containers should not have been used for any purpose that may lead to contamination of the product. Packaging materials should be inspected immediately before use to ensure that they are in a satisfactory condition and, where necessary, disposed of or cleaned and/or disinfected; when washed, they should be well drained before filling. Only packaging material required for immediate use should be kept in the packing or filling area.

7.6.4.2 Packaging and labelling of raw bivalve molluscs

Potential hazards: microbiological and physical contamination

Potential defects: objectionable matter such as shell pieces; incorrect labelling

Technical guidance:

- Labels should be clearly printed and must comply with the labelling laws of the country where the product is marketed. The packaging material or label may be used as a means to convey appropriate storage instructions to the consumer after retail purchase. It is recommended that the date of packaging be included.

- All packaging material should be stored in a clean and sanitary manner. Only packaging material required for immediate use should be kept in the packing or filling area.
- Shucked and post-harvest treated product should be packed and chilled or frozen as soon as possible.
- Freezing should take place quickly (see Section 8.3). Slow freezing will damage meat.
- If labels on post-harvest treated raw bivalve molluscs make safety claims relating to the post-harvest treatment, the claims should be specific to the target hazard that has been eliminated or reduced.

7.6.5 Storage

7.6.5.1 Storage of live bivalve molluscs

Potential hazards: *microbiological contamination, chemical and physical contamination*
Potential defects: *physical damage*
Technical guidance:

- The end product should be stored under conditions that will preclude contamination with and/or proliferation of micro-organisms. The packaging material of the end product should not have direct contact with the floor but should be placed on a clean, raised surface.
- Storage periods should be kept as short as possible.
- Re-immersion in or spraying with water of live bivalve molluscs must not take place after they have been packaged and have left the distribution centre or establishment except in the case of retail sale at the distribution centre.

7.6.5.2 Storage of raw bivalve molluscs

Potential hazards: *microbiological contamination, chemical and physical contamination*
Potential defects: *physical damage*
Technical guidance:

- Storage periods should be kept as short as possible.
- Damage to packaging of frozen product should be avoided.

7.6.6 Distribution/transportation

7.6.6.1 Distribution of live bivalve molluscs

Refer also to Sections 3.6 and 17.
Potential hazards: *microbiological contamination*
Potential defects: *physical damage*
Technical guidance:

- The product should be dispatched in the sequence of the lot numbers.
- Temperature should be maintained during distribution to control microbial growth.
- Bivalve molluscs intended for human consumption should only be distributed in closed packaging.
- The means of transportation should provide sufficient protection of the bivalve molluscs against damage to the shells from shocks. The bivalve molluscs should not be transported with other products that might contaminate them.

7.6.6.2 Distribution of raw bivalve molluscs

Potential hazards: *microbiological contamination*
Potential defects: *unlikely*
Technical guidance:

- Temperature should be maintained during distribution to control microbial growth.
- The product should be dispatched in the sequence of the lot numbers.
- Transportation should be able to maintain chilled or frozen product for safety and quality.

7.7. Processing to reduce or limit target organisms

Refer also to Sections 3.2, 3.3, 3.4 and 3.5.

Bivalve molluscs processed to reduce or limit target organisms are products prepared from live or raw bivalve molluscs that have been processed after harvest to reduce or limit specified target organisms within the product to levels that are satisfactory to the official agency having jurisdiction. Processing to reduce or limit target micro-organisms is intended to retain the sensory qualities of a live bivalve mollusc. As with all live and raw bivalve molluscs, these bivalve molluscs must meet all microbiological criteria associated with traditional harvest water controls designed to prevent faecal contamination and resulting introduction of enteric pathogens as well as toxins and other contaminants. However, these growing area controls are not designed for control of pathogens that are independent from faecal contamination.

Potential hazards: *microbiological contamination*
Potential defects: *coagulation of meat, defective meat texture, hydrostatic medium forced into the flesh*
Technical guidance:

- Any treatment developed to eliminate or reduce pathogens should be thoroughly validated scientifically to ensure that the process is effective (see the *Guidelines for the validation of food safety control measures* [CAC/GL 69-2008]).
- The control treatments (heat, pressure, etc.) should be closely monitored to ensure that the product does not undergo textural changes in the flesh that are unacceptable to the consumer.
- The treatment parameters established to reduce or limit pathogens should be approved by the official agency having jurisdiction.
- Each establishment that purifies bivalve molluscs with a heat treatment must develop a heat treatment process schedule, acceptable to the official agency having jurisdiction, that addresses such critical factors as the species and size of bivalve molluscs, time of exposure to heat, internal bivalve molluscs temperature, type of heat process used, water/steam to bivalve molluscs ratios, nature of heat equipment, measurement devices and their calibration, post-heating chilling operations, cleaning and sanitizing of heat process equipment.

7.8 Shucking

Shucking is the processing step that removes the edible portion of the mollusc from the shell. It is usually done by hand, mechanically or through heat shock with steam or hot water. This step may expose the product to microbiological or physical contamination.

7.8.1 Hand and mechanical shucking and washing

Physical removal of shellfish meat from the shell will often expose the product to dirt, mud and detritus that should be removed before further processing through washing or other means.

Potential hazards: *physical contamination, microbiological contamination*
Potential defects: *cuts and tears in the flesh, presence of sand and mud*
Technical guidance:

- Care should be taken to eliminate excess mud, detritus and sand from the shucking tables.
- The product should be examined to ensure that cuts and tears are minimized.
- Shucked molluscs should be rinsed or washed to eliminate mud, sand and detritus and to reduce the microbiological level of the products.

7.8.2 Heat shocking of bivalve molluscs followed by packaging

Heat shocking is a method to remove shells from the bivalve molluscs.

Refer also to Sections 3.2, 3.3, 3.4 and 3.5.

Potential hazards: *physical contamination*
Potential defects: *unlikely*
Technical guidance:

- The bivalve molluscs must come from approved growing areas and/or after relaying in an approved relaying area or depuration in an approved depuration centre or tank. Each establishment that heat shucks bivalve molluscs should develop a heat shuck process schedule, acceptable to the official agency having jurisdiction, that addresses such critical factors as the species and size of bivalve molluscs, time of exposure to heat, internal bivalve molluscs temperature, type of heat process used, water/steam to bivalve molluscs ratios, nature of heat equipment, measurement devices and their calibration, post-heating chilling operations, cleaning and sanitizing of heat process equipment.
- All bivalve molluscs should be washed with pressurized potable water or clean seawater and culled for damaged and dead bivalve molluscs prior to heat treatment.
- Before heat shocking, the bivalve molluscs should be inspected to determine whether the bivalve molluscs are alive and not badly damaged.
- Heat shocked bivalve molluscs should be cooled to 7 °C or less within two hours of being heat treated (this time includes the shucking process). This temperature should be maintained during transportation, storage and distribution.
- The heat shocked bivalve molluscs should be packaged as soon as possible. Before packaging, the bivalve molluscs should be examined for objectionable matter such as shell pieces.

7.9 Documentation

The transportation of live bivalve molluscs from a growing area to a distribution centre, depuration centre, relaying area or establishment should be accompanied by documentation for the identification of batches of live bivalve molluscs.

Storage and transportation temperatures should be indicated.

Permanent, legible and dated records of relaying and depuration should be kept concerning each lot. These records should be retained for a period of at least one year.

Depuration centres or tanks and distribution centres and establishments should only accept lots of live bivalve molluscs with documentation issued by or accepted by the official agency having jurisdiction. Where appropriate, this documentation should contain the following information:

- the gatherer's identity and signature;
- the date of harvesting;
- common and/or scientific name and quantity of bivalve molluscs;
- the location of the growing area and the status of this area (suitable for harvesting for direct human consumption, suitable for relaying, suitable for depuration, suitable for approved processing to reduce or limit target organisms);
- for distribution centres and establishments, if appropriate, the date and duration of depuration and the identity and signature of the person responsible;
- for distribution centres and establishments, if appropriate, the date and duration of relaying, the location of the relaying area and the identity and signature of the person responsible.

Complete records of harvest area and date of harvest and length of time of relaying or depuration of each lot should be maintained by the distribution centre or establishment for a period designated by the official agency having jurisdiction.

7.10 Lot identification and recall procedures

Refer also to Section 3.7.

- Each product should have an easy identifiable lot number. This lot number must include an identification code, the number of the establishment that distributes the product, the country of origin and day and month of packaging, in order to facilitate the traceability/product tracing of the product. A record-keeping system should be based on these lot numbers so that individual lots of bivalve molluscs can be traced from the growing area to the end user.

3. CODEX STANDARD FOR LIVE AND RAW BIVALVE MOLLUSCS (CODEX STAN 292-2008)

SCOPE

This standard applies to live bivalve molluscs and to raw bivalve molluscs that 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 either in a frozen or chilled state. Both live and raw bivalve molluscs may be intended for direct consumption or further processing. The standard does not apply to scallops when the final product is the adductor muscle only.

Part I below applies to live bivalve molluscs while Part II applies to raw bivalve molluscs.

PART I – LIVE BIVALVE MOLLUSCS

I-2. DESCRIPTION

I-2.1 Product Definition

Live bivalve molluscs are products that are alive immediately prior to consumption. Presentation includes the shell.

I-2.2 Process Definition

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, e.g. relaying or depuration, prior to human consumption. Both relaying and depuration must be subject to appropriate controls implemented by the official agency having jurisdiction.

I-2.3 PRESENTATION

Any presentation of the product shall be permitted provided that it:

- meets all requirements of this standard; and
- is adequately described on the label to avoid confusing or misleading the consumer.

The bivalve molluscs may be packed by weight, count, count per unit of weight, volume or per package.

I-3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

I-3.1 Bivalve Molluscs

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.

I-3.2 Final Product

Live bivalve molluscs shall meet the requirements of this standard when lots examined in accordance with Section I-10 comply with the provisions set out in Section I-9. Live bivalve molluscs shall be examined by the methods given in Section I-8.

I-4. FOOD ADDITIVES

Food additives are not permitted in live bivalve molluscs.

I-5. CONTAMINANTS

I-5.1 The products covered by this Standard shall comply with the Maximum Levels of the Codex General Standard for Contamination and Toxins in Foods (CODEX STAN 193-1995) and the maximum residue limits for pesticides and/or veterinary drugs established by the CAC.

I-5.2 The following provisions apply to the edible parts of live bivalve mollusc (the whole part or any part intended to be eaten separately).

Name of biotoxin groups	Maximum level/kg of mollusc flesh
Saxitoxin (STX) group	≤0.8 milligrams (2HCL) of saxitoxin equivalent
Okadaic acid (OA) group	≤0.16 milligrams of okadaic equivalent
Domoic acid (DA) group	≤20 milligrams domoic acid
Brevetoxin (BTX) group	≤200 mouse units or equivalent
Azaspiracid (AZP) group	≤0.16 milligrams

I-6. HYGIENE AND HANDLING

I-6.1 It is recommended that the products covered by 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), the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003) and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice.

I-6.2 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).

I-6.3 Growing area monitoring programs, irrespective of the type of indicator bacteria used, must ensure that live bivalve molluscs destined for direct human consumption meet the *E.coli* limit as identified below when tested in accordance with an MPN method specified in ISO 16649-3 or equivalent.

I-6.4 In analysis involving five (5) 100g samples of the edible parts (the whole part or any part intended to be eaten separately), none may contain more than 700 *E. coli* and not more than one (1) of five (5) samples may contain between 230 and 700 *E.coli*, or equivalent as decided by the competent authority having jurisdiction.

Microorganism = *Escherichia coli*	n=5	c=1	m=230	M=700	3 Class Plan

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.

I-6.5 In analysis involving five (5) 25g samples of the edible parts (the whole part or any part intended to be eaten separately), no sample may indicate the presence of *Salmonella* when tested using a method validated against the reference method ISO 6579.

Microorganism = *Salmonella*	n=5	c=0	m=0/25g	2 Class Plan

where n = number of samples that must conform to the criteria; c = the maximum allowable number of defective sample units; m = a microbiological limit which separates good quality from defective quality.

I-6.6 Where the microbiological criteria are not met, actions should be taken as deemed appropriate by the competent authority. In following up, consideration should be given to detention, recall and further processing in a manner to eliminate the hazard from implicated lots. In addition, assessment of the status of harvesting areas and/or establishment controls should be undertaken.

I-7. LABELLING

In addition to the provisions of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985) the following specific provisions apply:

I-7.1 The Name of the Food

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-7.1.1 There shall appear on the label, reference to the presentation provided for in Section I-2.3-Presentation, in close proximity to the name of the product in such descriptive terms that will adequately and fully describe the nature of the presentation of the product to avoid misleading or confusing the consumer.

I-7.1.2 In addition to the specified labelling designations above, the usual or common trade names of the variety may be added so long as it is not misleading to the consumer in the country in which the product will be distributed.

I-7.2 Content Declaration
Live bivalve molluscs shall be labelled by weight, count, count per unit weight, or volume as appropriate to the product.

I-7.3 Storage Instructions
The label shall specify the conditions for storage and/or temperature that will maintain the product safety/viability during transportation, storage and distribution.

I-7.4 Labelling of Non-retail Containers
Labelling for live bivalve molluscs shall contain the following information::

(i) Identification of the product by common and/or scientific names as determined by the competent authority. The country where the product is sold can determine if the scientific name must be indicated on the label.
(ii) Information that might be needed in the event of a food safety problem, including lot identification which could be lot code or date and location of harvest, information about harvest area, date of harvesting, purification or relaying as appropriate, as well as identification of the despatch centre or other establishment from which they were shipped.
(iii) Durability or shelf life.

Date of minimum durability may be replaced by the statement "Bivalves must be alive when sold".

I-8. SAMPLING, EXAMINATION AND ANALYSES

I-8.1 Sampling

(i) Each sample shall contain a sufficient number of bivalve molluscs to ensure that the sample is representative.
(ii) The portion of the bivalve mollusc analysed should be the edible part. 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 adequate data.

I-8.2 Sensory and Physical Examination
Samples taken for sensory and physical examination shall be assessed by persons trained in such examination and in accordance with procedures elaborated in Sections I-7.3 through I-7.5, and Guidelines for the Sensory Evaluation of Fish and Shellfish in Laboratories" (CAC/GL 31-1999).

I-8.3 Determination of Count per Unit Weight or Volume
When declared on the label, the count of bivalve molluscs shall be determined by counting the numbers of bivalve molluscs in the container or a representative sample thereof and dividing the count of bivalve molluscs by the actual weight/volume to determine the count per unit weight or volume.

I-8.4 Method of Analysis of Escherichia coli in bivalve molluscs
The ISO/TS 16649-3 – 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 the ISO 16140 or other internationally accepted similar protocol.

I-8.5 Method of Analysis of Salmonella in bivalve molluscs

The methods to be employed for *Salmonella* should be ISO 6579, or other validated methods that provide equivalent sensitivity, reproducibility and reliability.

I-8.6 Determination of Biotoxins

Provision	Methodology	Principle	Type
Saxitoxin group	AOAC Official Method 2005.06 (Paralytic Shellfish Poisoning Toxins in Shellfish) four matrices and 12 toxins	LC-FL	II

I-9 DEFINITION OF DEFECTIVES

A sample unit shall be considered as defective when it exhibits any of the properties defined below.

I-9.1 Foreign Matter

The presence in the sample unit of any matter which has not been derived from bivalve molluscs, does not pose a threat to human health and is readily recognized without magnification or is present at a level determined by any method including magnification, that indicates non-compliance with good manufacturing and sanitation practices.

I-9.2 Dead or Damaged Product

The presence of dead or damaged product. Dead product is characterised by no response to percussion (i.e. shellfish will close by themselves when tapped). Damaged product includes product that is damaged to the extent that it can no longer function biologically. A sample unit shall be considered defective if dead or damaged bivalve molluscs exceed 5% by count.

I-10 LOT ACCEPTANCE

A lot shall be considered as meeting the requirements of this standard when:

(i) the total number of defectives as classified according to section I-8 does not exceed the acceptance number (c) of the appropriate sampling plan in the General Guidelines on Sampling (CAC/GL 50-2004);
(ii) the total number of sample units not meeting the count designation as defined in section I-7.3 does not exceed the acceptance number (c) of the appropriate sampling plan in the General Guidelines on Sampling (CAC/GL 50-2004);
(iii) the average net weight of all sample units is not less than the declared weight, provided there is no unreasonable shortage in any individual container;
(iv) the Food Additives, Contaminants, Hygiene and Labelling requirements of Sections I-4, I-5, I-6 and I-7 are met.

PART II – RAW BIVALVE MOLLUSCS

II-2 DESCRIPTION

II-2.1 Product Definition

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.

II-2.2 Process Definition
Raw bivalve molluscs must meet the process definition in I-2.2 before they can be processed for direct consumption or further processing.

Bivalve molluscs that have been processed to reduce or limit target organisms while essentially retaining the sensory characteristics of live bivalve molluscs are ones that have been processed to assure reduction or limitation of the target organisms to the satisfaction of the official agency having jurisdiction.

II-2.3 Presentation
Any presentation of the product shall be permitted provided that it:

- meets all requirements of this standard; and
- is adequately described on the label to avoid confusing or misleading the consumer.

The bivalve molluscs may be packed by weight, count, count per unit of weight, volume or per package.

II-3 ESSENTIAL COMPOSITION AND QUALITY FACTORS

II-3.1 Raw Bivalve Molluscs
Raw bivalve molluscs shall be of a quality fit for human consumption.

II-3.2 Ingredients
The packing medium and all other ingredients used shall be of food grade quality and conform to all applicable Codex standards.

II-3.3 Final Product
Raw bivalve molluscs shall meet the requirements of this standard when lots examined in accordance with Section II-9 comply with the provisions set out in Section II-8. Raw bivalve molluscs shall be examined by the methods given in Section II-7.

II-4 FOOD ADDITIVES
Only the use of the following additives is permitted in raw bivalve molluscs.

Antioxidants
For chilled shucked molluscs any antioxidant listed in food category 09.1.2 (Fresh Molluscs, crustaceans and echinoderms) of the General Standard for Food Additives (CODEX STAN 192-1995).

For raw frozen molluscs any antioxidant listed in food category 09.2.1 (Frozen fish, fish fillets, and fish products, including molluscs, crustaceans, and echinoderms) of the General Standard for Food Additives (CODEX STAN 192-1995).

II-5 CONTAMINANTS
Raw bivalve molluscs should meet the requirements of I-5.

II-6 HYGIENE AND HANDLING
Raw bivalve molluscs should meet the requirements of I-6.

II-7 LABELLING
In addition to the provisions of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985) the following specific provisions apply:

II-7.1 The Name of the Food
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.

II-7.1.1 There shall appear on the label, reference to the presentation provided for in Section II-2.3-Presentation in close proximity to the name of the product in such descriptive terms that will adequately and fully describe the nature of the presentation of the product to avoid misleading or confusing the consumer.

II-7.1.2 In addition to the specified labelling designations above, the usual or common trade names of the variety may be added so long as it is not misleading to the consumer in the country in which the product will be distributed.

II-7.2 Content Declaration
Raw bivalve molluscs shall be labelled by weight, count, count per unit weight, or volume as appropriate to the product.

II-7.3 Storage Instructions
The label shall specify the conditions for storage and/or temperature that will maintain the food safety and characteristics of the product during transportation, storage and distribution including date of minimum durability and for date of shucking.

II-7.4 Labelling of Non-retail Containers
Refer to I-6.4 Labelling of Non-retail Containers.

II-7.4.1 Every package containing bivalve molluscs that have been processed to reduce or limit target organisms must be provided with a label certifying that all molluscs have been processed to reduce the target organism to levels acceptable to the official agency having jurisdiction.

II-7.4.2 Safety claims for bivalve molluscs processed to reduce or limit target organisms should be specific to the target organisms that have been reduced or limited as described in the Code of Practice.

II-8. SAMPLING, EXAMINATION AND ANALYSES

II-8.1 Sampling
Sampling of lots for examination of net weight shall be carried out in accordance with an appropriate sampling plan meeting the criteria established by the CAC.

II-8.2 Sensory and Physical Examination
Samples taken for sensory and physical examination shall be assessed by persons trained in such examination and in accordance with procedures elaborated in Sections *II-7.3* through II-7.7, and Guidelines for the Sensory Evaluation of Fish and Shellfish in Laboratories" (CAC/GL 31-1999).

II-8.3 Determination of Net Weight and Drained Weight
The net weight and drained weight of all sample units shall be determined by the procedures described or mentioned in sections II-7.3.1 through II-7.3.5.

II-8.3.1 Determination of Net Weight

(i) Weigh the unopened container.
(ii) Open the container and remove the contents.
(iii) Weigh the empty container, (including the end) after removing excess liquid and adhering meat.
(iv) Subtract the weight of the empty container from the weight of the unopened container.
(v) The resultant figure will be the total net content.

II-8.3.2 Determination of Net Weight of Frozen Products not Covered by Glaze

The net weight (exclusive of packaging material) of each sample unit representing a lot shall be determined in the frozen state.

II-8.3.3 Determination of Net Weight of Products Covered by Glaze

AOAC official method 963.18, Net Contents of Frozen Seafoods.

II-8.3.4 The AOAC official method 963.26 should be used to determine the net weight of products with water added that is inside a "block-frozen" product.

II-8.3.5 Determination of Drained Weight

In the case of shucked bivalve molluscs, the drained weight shall be determined according to AOAC official method 953.11.

II-8.4 Determination of Count per Unit Weight or Volume

When declared on the label, the count of bivalve molluscs shall be determined by counting the numbers of bivalve molluscs in the container or a representative sample thereof and dividing the count of bivalve molluscs by the actual weight/volume to determine the count per unit weight or volume.

II-8.5 Sample Preparation

II-8.5.1 Procedures for Thawing

For frozen product, the sample unit is thawed by enclosing it in a film type bag and immersing in water at room temperature (not greater than 35 °C). The complete thawing of the product is determined by gently squeezing the bag occasionally so as not to damage the texture of the bivalve molluscs, until no hard core or ice crystals are left.

II-8.6 Methods of Analysis of Escherichia coli

Refer to I-8.4 Methods of Analysis of *Escherichia coli.*

II-8.7 Method of Analysis of Salmonella

Refer to I-8.5 Method of Analysis of *Salmonella.*

II-8.8 Determination of Biotoxins

Refer to I-8.6 Determination of Biotoxins.

II-9 DEFINITION OF DEFECTIVES

The sample unit shall be considered as defective when it exhibits any of the properties defined below.

II-9.1 Deep Dehydration (Frozen Products)
Greater than 10% of the weight of the bivalve molluscs in the sample unit or greater than 10% of the surface area of the block exhibits excessive loss of moisture clearly shown as white or abnormal colour on the surface which masks the colour of the flesh and penetrates below the surface, and cannot be easily removed by scraping with a knife or other sharp instrument without unduly affecting the appearance of the bivalve molluscs.

II-9.2 Foreign Matter
The presence in the sample unit of any matter which has not been derived from bivalve molluscs, does not pose a threat to human health and is readily recognized without magnification or is present at a level determined by any method including magnification, that indicates non-compliance with good manufacturing and sanitation practices.

II-9.3 Odour/Flavour
Persistent and distinct objectionable odours or flavours indicative of decomposition or rancidity.

II-9.4 Texture
Textural breakdown of the flesh, indicative of decomposition, characterized by muscle structure that is mushy or paste-like.

II-10 LOT ACCEPTANCE
A lot shall be considered as meeting the requirements of this standard when:

(i) the total number of defectives as classified according to section II-8 does not exceed the acceptance number (c) of the appropriate sampling plan in the General Guidelines on Sampling (CAC/GL 50-2004);
(ii) the total number of sample units not meeting the count designation as defined in section II-2.3 does not exceed the acceptance number (c) of the appropriate sampling plan in the General Guidelines on Sampling (CAC/GL 50-2004);
(iii) the average net weight of all sample units is not less than the declared weight, provided there is no unreasonable shortage in any individual container;
(iv) the Food Additives, Contaminants, Hygiene and Labelling requirements of Sections II-4, II-5, II-6 and II-7 are met.

Biotoxins produced by certain algal species can be accumulated by bivalve molluscs. This constitutes one of the major public health risks that need to be managed during shellfish production. With a view to aiding risk assessment, monitoring and surveillance programmes, this paper provides a range of information about the various biotoxins globally recorded in shellfish: levels detected, toxicological data, methods of analysis for detection and quantification of toxins, and the risk assessment approach for public health management. The complex chemical nature of the toxins, along with several analogues, hampers the development and validation of methods for their detection, for the evaluation of their toxicity and for the development of limits for shellfish safety management. This paper also illustrates the approach taken by the Codex Alimentarius Commission in developing guidelines for bivalve shellfish safety management and for establishing Codex standards for live and raw bivalve molluscs.

ISBN 978-92-5-107003-1 ISSN 2070-7010

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I2356E/1/09.11