codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 6 **CX/FFP 06/28/6-Add.1**

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

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

(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[1])

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[2] 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.

[1] The list of participants is provided in Annex 1.
[2] The report is available at: ftp://ftp.fao.org/es/esn/food/biotoxin_report_en.pdf

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.[3]

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

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

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. 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

3. 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: <u>Approach Taken</u>

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: <u>General Considerations on Analytical Methodology</u>

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: <u>Replies to Specific Questions Posed by the CCFFP</u>

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

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Annex 2 *(available in English only*)

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

Annex 3 *(available in English only)*

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 the

adequate 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.