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**Agenda Item 3** **CX/FFP 14/33/5 Add.2**
**ORIGINAL LANGUAGE ONLY**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX COMMITTEE ON FISH AND FISHERY PRODUCTS**

**Thirty-third Session**

**Bergen, Norway**

**17 – 21 February 2014**

# DRAFT PERFORMANCE CRITERIA FOR REFERENCE AND CONFIRMATORY METHODS FOR MARINE BIOTOXINS (SECTION I-8.6 DETERMINATION OF BIOTOXINS) IN THE STANDARD FOR LIVE AND RAW BIVALVE MOLLUSCS
**(At Step 6 of the Procedure)**

Comments submitted by Costa Rica, European Union and Norway

## COSTA RICA

Costa Rica agradece la oportunidad de poder expresar los comentarios al documento **CL 2013/16-FFP** anteproyecto de criterios de rendimiento para los métodos de referencia y confirmación para biotoxinas marinas.

**Justificación:**

Costa Rica no emite comentarios en relación a las peticiones establecidas en dicha circular.

## EU

The European Union (EU) would like to thank Norway for their comments and recommendations to the 33rd Session of the CCFFP on the draft performance criteria for reference and confirmatory methods for marine biotoxins in the standard for raw and live bivalve molluscs included in document CX/FFP 14/33/5.

In general, the EU supports the Norwegian proposal since most critical points have been carefully evaluated and comments and opinions from different sources have also been taken into consideration and included in their comments. The EU appreciates the inclusion of data derived from the work of the EURLMB through the EU NRLs Network, in particular data from PT schemes for PSTs, as well as Method Performance criteria for LPTs and Domoic Acid from the EURLMB Standard Operating Procedures.

The EU considers that the Norwegian proposal is a good starting point for discussions at the CCFFP 33. However, there are some issues that might need further discussion particularly the ones related to TEF. The EU is of the opinion that there is an urgent need for harmonization of TEFs and in this respect the EU supports the Norwegian views that updated TEFs are required and oral toxicity should be taken into consideration. Given that new data will be available soon the EU considers that these data should be considered as soon as they are available. The inclusion of oral toxicity values is in the EU's opinion the most appropriate approach and therefore these data need to be included as soon as they are available.

For Lipophilic Toxins the EU supports the criteria proposed by Norway following the results of the Interlaboratory validation study of the EU-Harmonised Standard Operating Procedure for determination of Lipophilic Marine biotoxins in molluscs by LC-MS/MS.

**NORWAY**

**Compliance in results between chemical and biological methods**

*Does the MBA method (AOAC 959.08) perform equivalent to the HPLC method (AOAC 2005.06) for the determination of total toxicity (µg STXdiHCl eq/kg)?*

For checking compliance in results obtained by the HPLC method and the MBA method, results from proficiency testing schemes, arranged by the European Union Reference Laboratory on Marine Biotoxins (EURLMB) in 2010-2013 have been obtained. The statistical evaluations of the results have been carried out by EURLMB according to ISO Guide 13528:2005.

The results for the assigned values of the results obtained by AOAC 2005.06 (HPLC method) and AOAC 959.08 (MBA) are given in the table below:

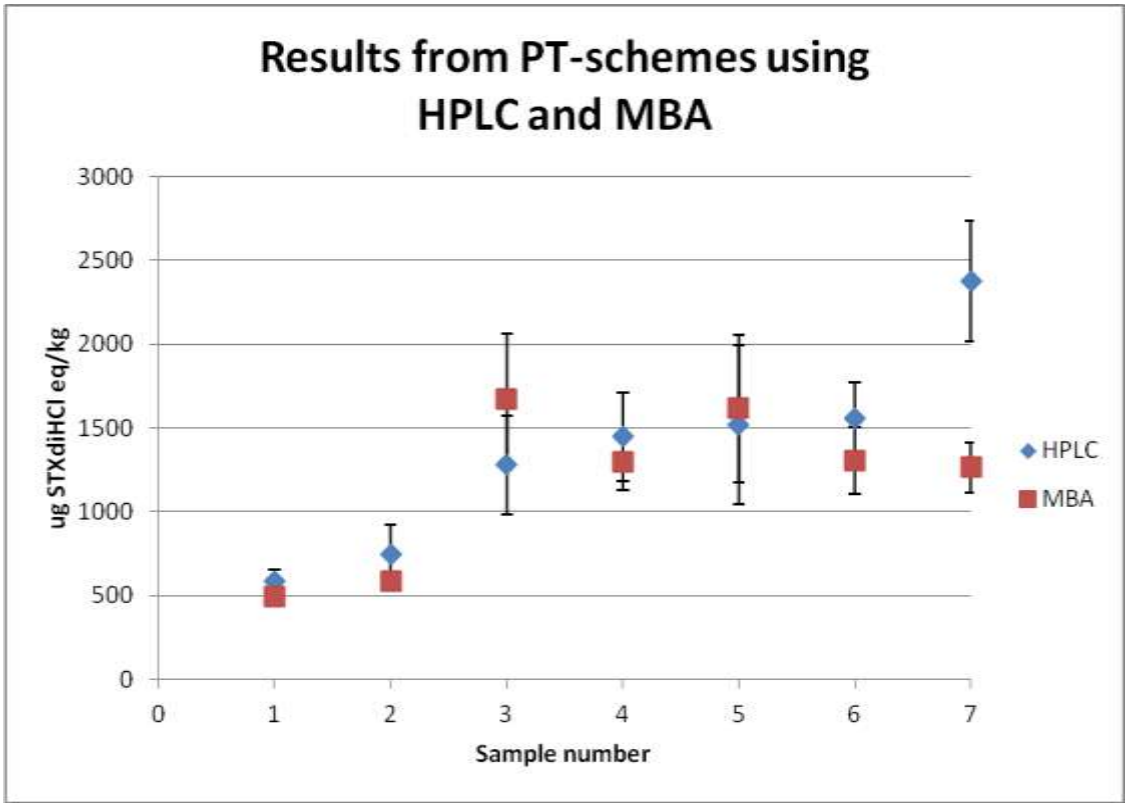
| **Sample code EURLMB** | **Origin** | **Matrix** | **Toxic profile** | **AOAC 2005.06* µg STXdiHCl eq/kg n=no of labs u= uncertainty** | **AOAC 959.08 µg STXdiHCl eq/kg n=no of labs u= uncertainty** |
|---|---|---|---|---|---|
| 10/P/01 (5) | Portugal | Clams *Donax trunculus* | *Gymnodinium catenatum* Dc GTX2,3; C1,2; dcSTX; GTX5; dcNEO;GTX6 | 1518 n=13 u=238 | 1616 n=20 u=220 |
| 10/P/02 (2) | Norway | Mussels *Mytilus edulis* | *Alexandrium sp.* GTX2,3;STX;NEO traces | 747 n=11 u=89 | 587 n=20 u=27 |
| 11/P/01 (6) | Norway | Mussels *Mytilus edulis* | *Alexandrium sp.* GTX2,3;STX | 1561 n=10 u=107 | 1304 n=19 u=101 |
| 11/P/02 (4) | Norway | Mussels *Mytilus edulis* | *Alexandrium sp.* GTX2,3;STX; GTX1,4 traces; NEO traces, dcSTX traces | 1447 n=10 u=132 | 1297 n=20 u=83 |
| 12/P/01 (7) | Portugal | Clams *Venerupis pullastra* | *Gymnodinium catenatum* dcGTX2,3; dcSTX; dcNEO | 2376 n=14 u=179 | 1263 n=13 u=73 |
| 13/P/02 (1) | Spain | Mussels *Mytilus edulis* | *Alexandrium sp.* GTX2,3;STX traces; GTX1,4 | 584 n=15 u=37 | 492 n=22 u=25 |
| 13/P/03 (3) | Portugal | Cockle *Cerastoderma edule* | *Gymnodinium catenatum* dc GTX2,3; C1,2; dcSTX; GTX5; dcNEO;GTX6; C3,4 | 1278 n=12 u=149 | 1670 n=24 u=195 |

*EFSA TEFs WERE USED FOR CALCULATIONS

(Source for the table: B.Ben Gigirey et al.)

The number of participating laboratories is sufficient to evaluate the results statistically.

For checking the compliance in the results of the two methods, the results have been sorted in increasing concentration based on the AOAC 2005.06 method (the sample code in parentheses). The obtained results including 2 times the uncertainty of the assigned values are plotted in the figure below. The plot shows that, except for the highest concentration (sample 7), the results are overlapping. For sample 7, there is a statistical difference in the results obtained by the two methods; the assessment of the results obtained by the MBA method would however also lead to rejection of the samples against the maximum permitted limit (ML).


Results from PT-schemes using HPLC and MBA
ug STXdiHCl eq/kg
3000
2500
2000
1500
1000
500
0
0
1
2
3
4
5
6
7
Sample number
HPLC
MBA