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**European Union comments**

**CODEX COMMITTEE ON FOOD HYGIENE**

**Fiftieth Session**

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**Agenda Item 6: Revision of the Code of Practice for Fish and Fishery Products (CX/FH 18/50/6)**

***Mixed Competence  
European Union Vote***

The European Union and its Member States (EUMS) would like to thank the work of the EWG led by Japan and the United States of America. The EUMS have the following comments on the revision of the section on sampling, examination and analyses.

The EUMS believe that the criterion of 200 mg of histamine per kg, responding to a pragmatic approach based on the establishment of a three-class attributes plan, should in no way be called into question.

The control of histamine is primarily based on the application of good hygiene practices whose effectiveness can be verified by a three-class attributes control plan:

- Criterion of acceptability or "threshold of decomposition" of 100 ppm (in case of exceeding, measures of correction of the good practices of hygiene must be applied).

m- 200 ppm safety criterion, in line with the recommendations of the FAO / WHO expert work conducted in 2012. Failure to comply with this safety criterion, validated at the October 2015 CCFPP34, results in the withdrawal from the market of fishery products concerned.

Both thresholds had been approved by the Codex Alimentarius Commission pending further data. This validation within the framework of the Codex thus reinforced the 3-class attributes plan.

Therefore under 7.1.1 explicit reference should be made to the recommendation of a three class attribute plan.

However, the document under discussion seems to suggest an orientation towards a 2-class plan with a M value of 100 mg / kg. This appears in particular in the table provided under point 7.1.2 comparing the level of consumer protection according to the sampling plan chosen. This approach is moving away from risk analysis as defended in the EU by failing to incorporate the notions of acceptability and security. It thus induces the possible rejection of products that do not present a health risk. In the absence of any evidence of the added value of adopting a 2-class plan with a single threshold of 100 ppm, the EUMS consider that the 3-class scheme, and the two thresholds it includes, remains the most

relevant regulatory approach. Therefore it is proposed to delete the table under point 7.1.2. In case the table is maintained, it should be completed by information on three-class attribute plans.

The EUMS consider that the number of samples to be taken (59) for the assessment of GMP / HACCP performance is too high.

It is not clear whether it is applicable to each link in the chain. If this were the case, it could not be applied by all operators (due to cost, time, availability of products). Appropriate modalities should therefore be defined. In any case, this can only apply to large lots, the size of which should, moreover, be defined.

Therefore, it is proposed to delete under 7.1.1 any reference to the confidence interval and to delete the sentence in the first bullet under 7.1.1 starting with "At minimum, ..."

In line with these comments, in the second bullet of 7.1.2., reference to the 95 % confidence and also the specific figure (5%) of maximum percentage given as example should be deleted. Furthermore, it is appropriate to replace the example of 15 mg/kg histamine by "up to 200 mg/kg"

3. Referring to the comments made under point 2, it is appropriate to describe for the new Annex [B] additional examples using pooling for less sample units.

4- The ML of 400 mg / kg, applicable for fish sauce, should be added to this table with reference to the internationally recognized ISO 19343 method published in July 2017 as applicable method meeting the criteria for the control of the ML of 200 mg/kg

The ISO 19343 method should also be added as applicable method meeting the criteria for the control of the ML of 200 mg/kg.

In addition:

- The abbreviations and terms used in the table should be made explicit, including "ML", "RSDR" and "Recovery";

- For the ML of 100 mg / kg, it is stated "on average", whereas for the ML of 200 mg / kg it is specified "per unit". This distinction should be explained or otherwise the entry should be deleted.