CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 2b) **CX/FFP 14/33/3**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FISH AND FISHERY PRODUCTS

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MATTERS ARISING FROM THE WORK FAO AND WHO

FAO/WHO histamine sampling tool

1. The Joint FAO/WHO Expert Consultation on the "Public health risks of histamine and other biogenic amines in fish and fishery products" held in July 23-27, 2012 analyzed a range of sampling plans implemented under different scenarios of histamine levels. The report noted that the spread of contamination levels in the batch (i.e. the log-transformed standard deviation of contamination levels) has a strong effect on the tolerable average contamination level and, thus, on the number of samples that must be tested to "accept" the batch. The analysis indicated that appropriate selection of the criterion against which test units comprising the sample will be assessed for compliance (the *m* value), can considerably improve the time- and cost-effectiveness of sampling: requiring the lowest number of samples to be tested to achieve the same level of confidence about the disposition of the lot being assessed. The experts acknowledged the utility of having access to the mathematical tools used in this meeting to develop different sampling plans. The group therefore recommended that FAO/WHO find ways to make these available in an easy to use format. Following this recommendation, FAO/WHO have developed a tool that is available online at: http://www.fstools.org/histamine/. The tool supports two main areas:

(a) Designing a sampling plan

This tool function attempts to find sampling plans which meet user-defined objectives, by searching for combinations of the number of samples (n) and a concentration threshold (m) that meet the objective. The user needs to define a number of parameters as follows:

- the maximum acceptable histamine concentration (H), which is often a health-based and/or regulatory limit (e.g. 200 mg/kg);
- the level of protection, which is the maximum acceptable fraction of samples from a lot allowed to exceed the histamine concentration limit (H) (e.g. 1: 1000);
- the desired confidence limit that lots that do not meet the level of protection specified will be rejected by the sampling plan (e.g. 98%);
- the expected standard deviation of the histamine concentration within a lot on the $\log_{10}$ scale (e.g. 0.5);
- the acceptable number of samples (c) above the set concentration threshold "m" (e.g. 0) before the lot is rejected; and,
- the maximum number of samples to test (n_{max}). This is a limit which the user can define to ensure that the proposed plans do not exceed this specified number of samples.

The tool has some default values which the individual user can retain or change to more accurately reflect the scenario for which the sampling plan is being designed. When the user clicks "compute results", the tool provides a table and chart showing the minimum required number of samples to be tested (n) at different concentration thresholds (little m) to achieve the objectives specified by the user.

(b) Analysing the performance of sampling plan.

The "analyse a plan" section of the tool estimates the probability of accepting lots of product given that they are tested according to a user-defined sampling plan.

The parameters that can be set by the user, which essentially describe the sampling plan to be analyzed and the scenario in which they are used are as follows:

- the number of samples to be tested per lot (n);
- the threshold concentration value (m);
- the acceptable number of samples(c), above the threshold concentration value (m) before the lot is rejected;
- the histamine limit (H); and
- and standard deviation (log_{10}).

On clicking "compute the results", a chart displaying the probability of rejecting a given lot when tested using the sampling plan specified, is provided.

2. A user guide with some examples is also available at http://www.fstools.org/histamine/. The tool is available as a free resource for Codex Members and its availability has been brought to the attention of the Electronic Working Group of CCFFP on Histamine.

3. The tool could be useful for risk managers at national level and at different stages of supply chain, considering that the purpose of testing is to verify that all the necessary control measures have been implemented effectively, identify failures in the system and remove implicated products from the market.

***Vibrio* spp. in bivalve molluscs**

4. The 42nd Session of the Codex Committee on Food Hygiene (CCFH) requested FAO/WHO to continue the work on to assess the risk from *Vibrio* spp. in bivalve molluscs in four steps as follows:

- Step 1: Provide recommendations on a range of test methods for quantifying *V. parahaemolyticus* (total and pathogenic (e.g. *tdh*+, *trh*+) and *V. vulnificus* in seawater and bivalves and facilitate performance evaluation of the proposed methodologies;
- Step 2: Develop data collection strategies (that would facilitate the collection of data) by countries to support the modification/development of models with a broader scope than those which currently exist;
- Step 3: Encourage the collection of data in different regions, in different bivalve species and for geographically diverse strains of pathogenic *V. parahaemolyticus* and *V. vulnificus* according to the data collection strategy and using recommended test methods; and
- Step 4: To modify/develop risk assessment models that could be used to address a range of risk management questions in a number of different regions and products, when adequate data becomes available.

5. Steps 1 and 2 were addressed through an Expert Consultation held in Ottawa, Canada on October 17-19, 2011 and based on the outputs, "Guidance on the selection and application of methods for the detection and enumeration of human-pathogenic *Vibrio* spp. in seafood" (FAO/WHO Microbiological Risk Assessment Series 22) has been prepared and is in press. To address step 3, regional workshops were implemented in Singapore in November, 2012, and in Santiago, Chile in December, 2013 in association with the International Life Science Institute (ILSI), Kyoto University, Japan. The Singapore Workshop was organized in Nanyang Polytechnic and 22 participants from 9 countries (China, Indonesia, Vietnam, Thailand, India, Malaysia, Philippines, Brunei and Singapore) were involved. In Chile, the workshop was hosted by the Institute for Public Health of Chile. Four countries (Peru, Chile, Argentina and Brazil) participated. The participants analysed samples of bivalves simultaneously with both culture based and molecular methods and this provided the opportunity of seeing the performance of these methods. The data requirements from the regions were also discussed.

6. Based on post workshop follow-up with participants by FAO/WHO, there are indications that some of the countries are using their new skills to support data collection with respect of ecological factors affecting *V. parahaemolyticus* levels and behavior of this organism in different bivalve species at postharvest stage.

Intergovernmental Oceanographic Commission (IOC) Panel on Harmful Algal Blooms (HAB) highlights the need for work on ciguatoxins:

7. IOC has brought to the attention of FAO/WHO the recommendations of The Eleventh Session of the IOC Intergovernmental Panel on HAB (IPHAB) that met in Paris on 28-30 April, 2013, noting that ciguatera fish poisoning (CFP) affects 1 in 4 persons in the Oceania region, half that number in the Caribbean and is an emerging problem in non-tropical areas. The IOC IPHAB recommended that the IOC and its Member States make the Codex Committee for Fish and Fishery Products and its member countries aware that IPHAB prioritizes international efforts on Ciguatera. FAO/WHO are bringing this information to the attention of the Committee to raise its awareness on the work IOC is doing in this area.

8. Secondly the IOC IPHAB recommended assessing the establishment of a coordinated IOC-FAO-WHO effort on CFP to combine the capabilities of those agencies and that of ecologists, toxin chemists and medical researchers to (i) Develop a coordinated Ciguatera strategy (ii) Improve organism detection and sampling strategies (iii) Improve toxin detection, and (iv) Improve epidemiological data collection, reporting and assessments. FAO/WHO invite the committee to note this recommendation from the IOC, would like to inform the CCFFP that FAO and WHO are currently exploring how they can best collaborate with the IOC on these issues and would welcome any suggestions from the CCFFP on how FAO/WHO should engage in this issue or indeed involve the Committee.

9. In order to assist risk managers in addressing ciguatera issue, FAO, in association with the South Pacific Commission (SPC) and South Pacific University organised a two day workshop in Suva, Fiji on July 9-10, 2013. The workshop was attended by 20 participants from 8 countries in South Pacific. The participants provided a review of the work being done in their countries on management of ciguatera problem, monitoring efforts for collection of baseline data on the prevalence and levels of potential CFP producing benthic dinoflagellates and identification of hotspots. The workshop included practical session on plankton examination to identify causative dinoflagellates and methodology for extraction of toxin. Since none of the countries in the South Pacific have facilities for toxin detection, it was considered important for the countries to have capability to extract the toxin and dry the extracts. This would greatly improve the chances of shipping the extracts to overseas laboratories for further purification and characterization of the toxins. The Workshop also developed an action plan for follow up work in the participating countries.

Development of guidance on the development of shellfish sanitation systems within the framework of Section 7 of the Codex Code of Practice for Fish and Fishery Products

10. FAO and WHO are currently considering a request from the participants (representing 15 bivalve producing/trading countries) of 2nd International Workshop on Molluscan Shellfish Sanitation: Application of sanitary surveys, 24-28 September, 2012, the European Union Reference Laboratory for Monitoring Bacteriological and Viral Contamination of Bivalve Mollucs to support the establishment of an international expert working group to develop scientific and technical guidance on the development of shellfish sanitation systems within the framework of Section 7 of the Codex Code of Practice for Fish and Fishery Products. Section 7 of the Codex Code of Practice for Fish and Fishery Products provides a framework but does not provide sufficient detail for the establishment of a *de novo* program. Consequently, many developed countries have relatively complex shellfish sanitation programs in order to manage the public health risks from consumption of bivalve shellfish. Currently, there are two, somewhat different, major approaches to such systems: The United States 'National Shellfish Sanitation Program (NSSP)' and the EU Food Hygiene Regulations related to bivalve molluscs. These systems are intended to ensure that that bivalve shellfishes are safe to eat but differ in their means of achieving this aim. In this situation, countries wishing to export to both US and EU markets must satisfy the requirements of both. This has substantial resource implications and could preclude some nations, who would otherwise benefit from trading to both markets, from exporting. Further, it is not clear to the countries that wish to introduce a shellfish sanitation program for the protection of their own consumers what is the best route to follow.

11. The purpose of international expert working group would be to draft a "best practice" guide based upon the existing framework in the Codex Code of Practice for Fish and Fisheries Products – section 7- live and raw bivalve molluscs. FAO/WHO would welcome any views from the Committee on the value of developing such guidance and its utility for member countries.

Publications:

12. Report of the Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products (23-27 July 2012, Rome Italy) has been published and is available at www.fao.org/fileadmin/user_upload/agns/pdf/Histamine/Histamine_AdHocfinal.pdf and http://www.who.int/foodsafety/publications/histamine_risk/en/index.html.