



Food and Agriculture Organization
of the United Nations



World Health
Organization

Elaboration of best practice 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*.

CALL FOR DATA

Background: When it comes to the safety of bivalve molluscs, the Codex Alimentarius Commission has developed several relevant standards. These include a *Standard for Live and Raw Bivalve Molluscs* (Codex Stan 292-2008 (http://www.codexalimentarius.org/download/standards/11109/CXS_292e.pdf)) and the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) (http://www.codexalimentarius.org/download/standards/10273/CXP_052e.pdf), which has a section (Section 7) on the *Processing of Live and Raw Bivalve Molluscs*. Like other Codex documents, the Code of Practice is intended to provide guidance to the national competent authorities on the steps needed to be taken to produce a product that will meet the Codex Standard. In the case of live and raw bivalve molluscs, with respect of food safety, the final product has to meet hygiene criteria and biotoxin criteria specified in the standard. The Code of Practice provides information on the prerequisite programs, the classification of shellfish growing areas and the sanitary surveys and biotoxin monitoring programmes that are required to produce bivalves meeting the Codex Standard.

In the case of classification of growing areas and the related monitoring, the guidance given in the Code of practice is very broad and does not specify the precise manner in which the classification is to be established and monitored; for example it does not indicate whether the sanitary surveys should be based on samples of shellfish tissue or growing waters, the indicator bacteria to be chosen for the sanitary survey and monitoring, the frequency of sampling or limits for the chosen indicator bacteria. As a consequence, many countries have developed different approaches to shellfish sanitation programs in order to manage the public health risks from consumption of bivalve shellfish. Globally, two different approaches have dominated, one based on the United States 'National Shellfish Sanitation Program (NSSP) and the other based on the European Union (EU) Food Hygiene Regulations

Both systems are intended to ensure that bivalve shellfish are safe to eat but differ in their means of achieving this aim. As a consequence of these two distinct systems, countries wishing to access both US and EU markets must satisfy the requirements of both. This has had substantial resource implications, resulted in complex shellfish sanitation programs and has prevented some nations, who would otherwise benefit from trading to both markets, from exporting. The lack of one approach to shellfish sanitation also means that it is often not clear to countries wishing to establish a shellfish sanitation program for the protection of their own consumers the best

route to follow.

FAO and WHO are embarking on a programme of work to develop practical scientific and technical guidance on the development of shellfish sanitation systems in accordance with Section 7 of the Codex *Code of Practice for Fish and Fishery Products*.

The need for international level guidance was specifically identified by the participants (representing 15 bivalve producing/trading countries) of the 2nd International Workshop on Molluscan Shellfish Sanitation: Application of sanitary surveys, 24-28 September, 2012, and supported by the 33rd session of the Codex Committee on Fish and Fishery Products (CCFFP) in February 2014. The development of such guidance for countries is also in line with FAOs new Strategic Framework in terms of ensuring countries have the tools and capacity to implement systems based on international standards that would facilitate access to markets

In developing this “Best Practice Guideline”, FAO/WHO would like to build upon the experiences and data of member countries and ensure that any guidance developed is grounded in sound technical and scientific information. To this end the first step in the collection and analysis of data and other relevant information from countries about their shellfish sanitation systems, the basis for these systems, the data generated and the successes, challenges and limitations of these systems. There may be countries adopting dual practices to access different markets and data from such countries would be particularly useful in getting an understanding of the differences if any, in the outcomes due to these practices.

Call for data

In this context, FAO/WHO is requesting member country organisations responsible for shellfish sanitation programmes to provide data and information on these systems. To facilitate data collection a short questionnaire has been developed as outlined below in order to provide countries with a standard format for providing this information. :

1. Do you have different programme requirements for export and domestic trade of bivalves? If so, please identify the main differences or provide separate responses for each set of requirements for the following questions.

2. Does your programme follow the?
 - a. the US system
 - b. the EU system
 - c. both EU and US system
 - d. Another system (in this case please provide a short description of the basis of the system)

3. Do you have protocols or other documents relating to the basis and application of all or part of your shellfish hygiene (sanitation) programme? If so, we would welcome any that you could provide along with your response(s). If any aspects of your programme(s) has (have) been published in the scientific literature or on the

internet, please provide copies or references/web-links, as appropriate.

4. Do you undertake sanitary surveys of the bivalve harvesting areas as part of your shellfish hygiene programme? If so, what is the primary aim/output of the sanitary survey?
5. With respect to microbiological monitoring in harvesting areas, do you monitor:
 - a. shellfish flesh
 - b. water
 - c. Both of the above?
6. How do you determine the sampling plan for each area?
7. What is the normal frequency of sampling?
8. What faecal indicator organism(s) do you use?
9. What are the criteria used for classification of harvesting areas?
10. What actions are taken when results exceed the limits for the classification status of the area?
11. Are management actions undertaken in other circumstances (e.g. sewage spills, rainfall events)?
12. What criteria are used to remove those additional management criteria (e.g. to re-open areas after closures)
13. Are there any criteria for waiving high results in certain circumstances?
14. What are the microbiological requirements for product marketed for human consumption?
15. If possible, please provide a map, sampling plan, microbiological results and classification status for one or more harvesting areas. If using more than one approach (e.g. sampling both shellfish and water) please provide data for each).
16. Have you had import refusals/compliance failures detected by bivalve importing countries? If yes, please provide details?
17. Do you have epidemiological data on any illnesses associated with bivalves commercially produced under your shellfish hygiene programme? If so, please provide data (e.g. for the last 5 years).

Confidential and/or unpublished data

FAO and WHO recognize that some of the information and relevant data which is now required may be unpublished or of a confidential nature. With regard to

unpublished information and data, this remains the property of the author for subsequent publication by the owner as original material. Unpublished confidential studies that are submitted will be safeguarded in so far as it is possible to do so without compromising the work of FAO and WHO. Specific issues relating to confidentiality should be discussed directly between the information and data owners and FAO/WHO. For these and other issues please contact FAO and WHO at the contacts provided.

Deadline

Please submit any relevant information (electronic and/or hard copies - electronic submissions are preferred, either via e-mail (if not too large) or on CD ROM), in any official United Nations language (English, French, Spanish, Arabic, Chinese, Russian), if possible, to the addresses below, by **30 November 2014**.

Data submissions in response to the call for data should be sent to:

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Policy and Economics Division
Fisheries and Aquaculture Department
FAO

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With copy to

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