



Cefas



European Union Reference laboratory for
monitoring bacteriological and viral
contamination of bivalve molluscs

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Resolutions of the 11th workshop of Microbiological NRLs for Bivalve Molluscs, 24-26th April 2012

Official controls – microbiological monitoring and classification

1. The final recommendations to the Commission concerning harmonisation of Codex Standards (292-2008) and EU hygiene regulations for *E. coli* criteria were presented to NRLs. Recommendations include adoption of the Codex 3 class plan as an end product microbiological criteria and introduction of the Codex criteria applied 'over time' as criteria for classification of A grade production areas. These recommendations were now with Member States (MS) for consideration and the EURL would report progress to NRLs in due course.
2. Issue 3 (incorporating MS comments) of the proposed Community Guide to the Principles of Good Practice for the Microbiological Classification and Monitoring of Bivalve Mollusc Harvesting Areas was presented to NRLs. The guide was now with MS for comment prior to submission to SCFCAH. It was noted that adoption as an official Community guide would confer legal status. The EURL would report progress to NRLs in due course.
3. The EURL thanked NRLs for the updated information on sanitary surveys conducted in their MS. Outstanding information would be supplied within 3 weeks of the workshop. The finalised document would be circulated to NRLs prior to distribution to the Commission and publication on the EURL website (public domain).
4. The EURL presented recommendations for revision of the stability assessment included in the Microbiological Monitoring Good Practice Guide (a reduced frequency of monitoring is acceptable for 'stable' areas). The EURL proposed additional work to develop new criteria and, following definition of requirements, will request monitoring datasets to assist evaluation. In the interim a revised revision of the Guide (issue 5) will be distributed to NRLs and published on the EURL website (public domain).
5. The EURL announced the 2nd international workshop on molluscan shellfish area classification on 24th – 28th September 2012 at Newport, Rhode Island, USA jointly organised by the EURL and the US FDA. It was noted that this workshop would focus on comparison of EU and US systems and was regarded as important for informing the ongoing US/EU equivalency negotiations. NRLs and Competent Authorities from MS interested in exporting to the US were encouraged to attend via notification of either the Commission or the EURL.

Official control – Comparative testing

6. The EURL thanked NRLs for the updated information on official control laboratories (OCL) and proficiency testing in their MS. Following supply of outstanding information (within 3 weeks of the workshop) a summary document would be circulated to NRLs prior to distribution to the Commission and publication on the EURL website (public domain).
7. Supervision of the quality of OCL testing through proficiency testing and other measures is a legislative responsibility of NRLs under EC Reg 882/2004. NRLs require access to OCL proficiency test results to discharge this responsibility. Competent Authorities have an obligation to work with NRLs to ensure access to this information.



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8. Four annual proficiency testing distributions for *E. coli* and *Salmonella* are available (3 HPA/EURL non-matrix and 1 EURL matrix based distribution). It was agreed that the minimum requirement for satisfactorily (>70% score) performing NRLs was participation in the EURL matrix distribution and at least one other non matrix distribution. This was in accordance with the minimum participation frequency specified in the Good Practice Guide. NRLs with <70% scores should participate in all available distributions.

Marine vibrios

9. NRLs noted that, with the exception of O1/O139 *V. cholerae*, illness related to *Vibrio* spp. were not generally notifiable in the EU. Considering the potential impact of climate change on *Vibrio* spp. occurrence, better quality epidemiological information was vital to inform risk assessment. The EURL would contact the European Communicable Disease Centre (ECDC) regarding this issue.
10. The EURL announced a *Vibrio* methods workshop in July 4-5th 2012, NRLs were encouraged to consider attending the workshop. Expressions of interest should be sent to the EURL.

Viruses

11. NRLs considered control limits for hepatitis A virus (HAV) in bivalve molluscs. Given the severity of the infection and the rare occurrence in mollusc production areas in the EU, the workshop recommended a bivalve mollusc microbiological criterion of HAV absence (non detectable) when tested by the ISO CEN standard method.
12. It was agreed that to improve the quality of viral analysis, and hence risk management support available to producers, NRLs should write to commercial laboratories undertaking testing of live bivalve shellfish for norovirus and HAV and recommend the use of virus reference materials (available from the UK HPA) and participation in available, appropriate proficiency testing.
13. Several cross border EU outbreaks related to norovirus in oysters were reported by NRLs. It was noted that traceability of batches related to outbreaks was often problematical. This was particular relevant to trans-shipment of product between MS for further processing prior to final packaging and issue of health marks. The workshop recommended that this issue be brought to the attention of the Commission.
14. Following the recent EFSA reports, and data available from outbreaks and EU production area surveillance, NRLs considered possible control limits for norovirus in bivalve molluscs. NRLs agreed that an absence standard, whilst conservative for public health, would have a high impact on producers that would not seem justified by available epidemiological evidence.
15. The workshop agreed that for norovirus differential quantitative standards for products intended to be eaten raw, and cooked in the home or restaurant may be appropriate. Data gaps were the protection afforded by home and restaurant cooking, commercial depuration and on norovirus levels in species other than oysters.



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16. NRLs were informed that the ISO CEN standard method - ISO TS 15216-1 Microbiology of food and animal feed: Detection of norviruses and hepatitis A virus, part 1: Quantitative determination would be published in 2012/13. An EURL harmonised protocol for molluscs based upon the standard was distributed and will be available on the EURL website (public domain).
17. The workshop noted encouraging performance in virus proficiency testing, particularly with respect to an increasing number of laboratories applying quantitative methods. NRLs noted that performance of laboratories using methods closely derived from the CEN standard method (ISO TS 15216-1) tended to perform better in proficiency testing than those using alternative methods.
18. Further to the above NRLs noted that further work was still required to improve comparability of quantitative results for norovirus prior to the introduction of quantitative legislative criteria. The EURL agreed to continue to develop quantitative reagents (standards) to help underpin accurate quantitation and to organise further proficiency testing distributions using matrix samples and dsDNA standards.
19. NRLs requested that the EURL provide technical training on quantitative determination of norovirus in bivalve shellfish. A formal training workshop would be proposed for early 2013.
20. NRLs agreed with the EFSA recommendation on pollution reduction strategies (e.g. prohibition zones) and agreed to have a dedicated session on this aspect at the next workshop.
21. NRLs agreed with the EFSA opinion that the current class B criterion of 10% of samples up to 46,000 *E. coli* MPN/100g was too high and may allow highly contaminated product to be placed on the market. It was agreed that the upper tolerance should be based upon practical performance of the method.

Date and time of next meeting

22. The next workshop would provisionally (subject to confirmation of costs) be held at ISS in Rome, Italy 7-9th May 2013.