



# Cefas



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

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## **RESOLUTIONS OF THE 15<sup>th</sup> WORKSHOP OF MICROBIOLOGICAL NRLs, 25-27<sup>th</sup> MAY 2016, BERLIN, GERMANY**

### Official controls

1. The commission reported to the workshop the emerging situation with tetrodotoxin contamination of LBMs. The possible connection with *Vibrio* sp. was noted and the workshop supported the need for further collaborative research with algal toxin scientists.
2. The commission informed the workshop that consequential on trade discussions with the US FDA, an audit of additional Member States would not be required prior to approval of that Member State for export. The EURL reminded the workshop of the need for Member States seeking approval to comply with the Good Practice Guide including Annex 4 on export to the USA.
3. The EURL presented draft version 6 of the Good Practice Guide and draft issue 3 of the Community Guide. The EURL further agreed to address comments on holding areas and alert levels for class A areas, and to recirculate the updated drafts amongst NRLs by June 17<sup>th</sup> 2016. NRLs agreed to provide any additional comments by July 15<sup>th</sup> 2016.
4. Further to the above, the EURL informed the workshop of the complications with respect to seasonal classification and proposed to further consider this within the expert Working Group and report back at the next workshop.

### *E.coli* and *Salmonella*

5. The EURL reiterated the requirement to test 10 animals for *E.coli* analysis and acknowledged the current discrepancy within ISO 6887-3:2003 (cross-referenced in regulation 2015/2285) and informed the workshop that this will be resolved with the forthcoming publication of the revised ISO 6887-3 (currently at FDIS stage).
6. The EURL agreed to progress the development of a bivalve-specific MPN calculator (including reporting values of <18, >18,000 and >180,000 *E.coli* MPN/100g) and to endeavour to incorporate reference to this calculator within the forthcoming revision of ISO 7218.
7. The EURL agreed to review ISO 6579-1 and undertake an evaluation of any available validation data for proprietary *Salmonella* detection systems to determine whether such methods can be used within the scope of the ISO as a screen.
8. The EURL informed the workshop that for the February 2017 EURL/Public Health England *E.coli* and *Salmonella* External Quality Assessment distribution, and for future annual distributions, the EURL would meet the costs of NRLs, and that participation would therefore be mandatory.

9. The EURL agreed to include both *E.coli* and *Salmonella* analysis in future whole animal proficiency testing distributions to assist NRLs in their accreditation requirements.
10. Following analysis of responses to an EURL questionnaire, the workshop noted that all EU Official Control Laboratories performing analysis for *E.coli* and *Salmonella* in Member States with production areas participated in proficiency testing for those determinands, under the supervision of their NRL, with the exception of Official Control Laboratories in Bulgaria and Norway.
11. The workshop noted the guidance on determination of measurement uncertainty for MPN methods provided by the EURL. The importance of sub-sampling prior to the homogenisation stage, for tests where replicate sample test measurements are required, was reinforced.

### Vibrios

12. The workshop noted the need for a clearer definition of “fresh” or “frozen” seafood within ISO 21872 in relation to the selection of the initial incubation temperatures. NRLs were encouraged to submit comments through their National Standardisation Bodies to facilitate this.
13. The TAG 15 group leader informed the workshop that the primary objective of TAG 15 was to establish robust quantitative methods for pathogenic *Vibrio parahaemolyticus*. The workshop agreed that the primary focus of this methodological development should be an MPN format with sufficient precision to enable robust quantification, confirmed using molecular methods.
14. The TAG 15 group leader encouraged NRLs with expertise in vibrios to join TAG 15 through nomination by their National Standardisation Bodies. In addition NRLs were encouraged to propose other relevant experts in their Member States to seek nomination.
15. The workshop agreed that EURL ring trials for vibrios organised during 2016-17 would focus on assisting method development and standardisation in collaboration with TAG 15 rather than assessment of laboratory competence.
16. In relation to EU/US trade, the workshop noted the increasing risk of shellfish-related vibriosis in the USA however data indicates that recently-introduced cold-chain measures may mitigate this risk.
17. The workshop agreed the need to share information regarding vibriosis associated with bivalve mollusc consumption, including any associated with US imports, in order to inform future review of risk.

### Viruses

18. The workshop commended the excellent work conducted by the European Food Safety Authority regarding alternative heat treatments for bivalve molluscs and noted the further steps necessary to revise the criteria if appropriate.
19. Regarding the EU-wide baseline survey for norovirus in oysters, the workshop noted an inconsistency within the European Food Safety Authority protocol between the body text (section 2.3.3) and the method specification (Appendix B) regarding use of

archived materials for EU-wide and national studies and sought clarification from the European Food Safety Authority on this issue. The workshop recommended that Member State Competent Authorities should be free to decide the most appropriate use of archived samples collected in their Member State without the need for consultation of the Standing Committee on Plants, Animals, Food and Feed.

20. Further to the above, the workshop agreed the importance of analysis of the baseline survey samples for HAV as a priority, considering the severity of this pathogen and the lack of data on the prevalence of HAV in oysters in the EU.
21. The workshop noted the growing awareness and importance of Hepatitis E virus as a foodborne pathogen and acknowledged the lack of data regarding the potential role of bivalve molluscs as a transmission vehicle for this virus within the EU. The workshop agreed the possibility to address this data gap through analysis of the archive from the baseline survey.
22. Following discussion, the EURL agreed to circulate the proposal for competence scoring for use in the virus proficiency testing prior to the baseline survey by the end of June 2016 for comment by NRLs by end of July 2016.
23. Following discussion on the non-mandatory EURL guidance on determination of a Limit of Detection (LOD) and Limit of Quantification (LOQ) for the norovirus method, the EURL agreed to incorporate comments on the rationale for the assigned maximum standard deviation value, and to incorporate a provision for user laboratories to use appropriate methods for interpolation of LOQ between tested levels. A revised draft would be circulated by end of June 2016 for comment by NRLs by end of July 2016.
24. Based on information supplied by NRLs, the workshop noted that in most Member States samples for the baseline survey were planned to be collected by official samplers for both production areas and dispatch centres.
25. The next workshop will be held 3<sup>rd</sup>-5<sup>th</sup> May 2017, in Split, Croatia (subject to confirmation by the EURL).