



RESOLUTIONS OF THE 16TH WORKSHOP OF NRLS FOR MONITORING BACTERIOLOGICAL AND VIRAL CONTAMINATION OF BIVALVE MOLLUSCS, 3 – 5TH MAY 2017, SPLIT, CROATIA

Future of the network

1. The workshop thanked Mr Paolo Caricato (DG SANTE) for setting out the immediate future for the EURL and the network of NRLs in this field, following the UK's vote to exit the EU, and welcomed the extension to the existing EURL designation for one calendar year to December 2018. The workshop further welcomed the formation of an EURL for viruses in foods.
2. The workshop noted the excellent progress that the network had made with respect to microbiological controls for bivalve molluscs since its establishment in 1999. It was agreed that this was due largely to the integrated approach that the application of diverse scientific disciplines and expertise has allowed.
3. Further, it was noted that live bivalve molluscs are a high risk food stuff that present a unique set of public health challenges due to their mode of production and consumption, and that they therefore require highly specific monitoring systems at the primary production stage for controlling the public health risks that they present.
4. The workshop further acknowledged that a particular strength of the network is its role as a forum to advance and disseminate applied scientific knowledge within this field, as evidenced by the ongoing development of the Guidance for Best Practice for Microbiological Monitoring of Production Areas and Community Guidance, in addition to the network's support for the EFSA baseline survey for norovirus in oysters.
5. The workshop expressed significant concerns with respect to future plans described by DG SANTE to split the methodological and monitoring aspects of the network, particularly with regards to the specific technical demands of the bivalve mollusc matrix, and to integration of analysis and management.
6. It was noted that EURL networks exist for *E. coli* (although currently limited in scope to human pathogenic *E. coli*), *Salmonella* and now viruses, therefore, it was emphasised that bivalve mollusc matrix-based proficiency testing should be continued. It was however noted there was no network for vibrios within the EU.
7. The workshop identified substantial concerns with respect to maintaining sufficient scope and depth of expertise in the EU in the absence of a defined EURL covering monitoring of bacteriological and viral contamination of bivalve molluscs. The absence of a specialist EURL for this topic in EU Regulations would result in the disbanding of the NRL network, and discontinuation of NRL designations within Member States as there would be no legal requirement for continuation.
8. Further to the above, NRLs were encouraged to discuss these concerns with their Competent Authorities and to encourage them to communicate to the Commission.

Official Controls

9. NRLs reported on the use of seasonal classifications and the methodology implemented in their Member State for determining seasonally classified areas. On the basis of the information provided, the expert Working Group responsible for the Good Practice Guide on Microbiological Monitoring would consider the issue with a view to the inclusion of a harmonised approach in the next issue of the Guidance.
10. The workshop noted the publication on April 7th 2017 of Regulation (EU) 2017/625 on Official Controls. Regulation 882/2004, Articles 32 and 33 covering the role of European Union (formerly Community) and National Reference Laboratories were replaced by Articles 95 and 101 of the new regulation respectively. NRLs were advised to familiarise themselves with these Articles which defined an expanded scope for Reference Laboratories and which would come into force on 29th April 2018.
11. The EURL informed the workshop that the US Food and Drug Administration had accepted additional statistical analysis that demonstrated the continued equivalency of US approved and EU class A areas consequential to the entry into force of Commission Regulation (EU) 2015/2285 amending the EU class A criterion.
12. Further to the above the workshop noted the current exclusion of US states with implemented control plans for *Vibrio vulnificus* from the bilateral US-EU trade agreement. The workshop were informed that the formation of a technical working group was anticipated to evaluate the potential risks of *V. parahaemolyticus* in product exported from the EU to US.

Marine vibrios

13. The workshop thanked the invited expert Professor James D. Oliver (University of North Carolina at Charlotte) who provided an overview of vibriosis in the USA, vibrio control plans and post-harvest treatments for reduction of vibrios in live bivalve molluscs.
14. The workshop thanked the invited expert Dr Jan Semenza (ECDC) for his presentation on the ECDC food and waterborne surveillance systems (FWD-NET). The workshop noted the emerging risks of non-cholera vibrio infections in the EU as determined by sea surface temperature and to a lesser extent salinity. It was further noted that more structured epidemiological reporting in the EU would improve understanding of the health burden from vibrios associated with shellfish consumption.
15. Further to the above the workshop noted that in order to extend the ECDC FWD-NET surveillance system to *V. parahaemolyticus* and *V. vulnificus*, requests to ECDC via the national focal points, and agreement at the Member State level would be required. The EURL would consider the options with the Commission and report progress at the next workshop.

E. coli and Salmonella

16. The workshop noted the publication of ISO 6887-3 on Preparation of test samples, initial suspension and decimal dilutions for microbiological examination – Part 3: Specific rules for the preparation of fish and fishery products, which harmonises the minimum number of individual animals comprising a sample for Official Control testing for *E. coli* in live bivalve molluscs of 10 animals with Commission Regulation (EC) No. 2073/2005.
17. The continued good performance of NRLs in EURL proficiency testing for *E. coli* and *Salmonella* was noted. Laboratories were reminded that with respect to derivation of MPN/100g values of *E. coli*, guidance in ISO 7218:2007/Amd 1:2013, clause 10, Enumeration should be used; this amendment replaces all previous ISO guidance on bacterial enumeration in this standard.

Outbreaks

18. The workshop discussed outbreaks of bacteriological and viral illness linked to consumption of live bivalve molluscs in the previous twelve months within the EU. A relatively small number of confirmed or unconfirmed outbreaks were reported, however it was considered that under-reporting of illnesses and, in some Member States, inefficiencies within surveillance systems may have contributed to the number of outbreaks reported.

Viruses

19. The workshop noted the publication of ISO 15216-1:2017, a validated standard for quantification of viruses in food matrices including bivalve molluscs and the forthcoming publication of ISO 21872:2017, the method for detection of potentially pathogenic vibrios in seafood. The contribution to the development and validation of these standards by the NRLs network and the EURL was acknowledged, demonstrating the value of the network with respect to important method development and standardisation activities within the field of food safety.
20. The workshop noted the experience of a small number of NRLs with respect to the quality of test results for norovirus in bivalve molluscs provided by some commercial laboratories. The EURL agreed to produce guidance aimed at industry stakeholders giving recommended requirements on selection of commercial testing services.
21. The workshop thanked the invited expert Dr Nele Meeus (JRC) for her presentation on the functions of JRC with particular respect to Reference Materials and noted the collaboration between the EURL and JRC. The ongoing development by JRC of matrix-based Reference Materials for norovirus in bivalve molluscs was welcomed. The need for other matrix-based Reference Materials for detection and quantification of other determinands in bivalve shellfish, and for viruses in other foods, was expressed.
22. With respect to the EU-EFSA European baseline survey of norovirus in oysters the EURL agreed to provide free participation in matrix-based virus proficiency testing distributions throughout the duration of the survey to all laboratories designated to undertake quantitative testing for the surveillance. The EURL would inform EFSA of any performance issues to ensure the highest possible standard of data is used in the final assessment.
23. The workshop noted the good progress reported in the first 6 months of the baseline survey as presented by EFSA. The workshop further noted some evidence of a lack of accuracy in some reported data fields, and agreed the need for good communication between the laboratories and Competent Authorities. The EURL undertook to reinforce this point with Competent Authorities at the next Restricted Working Group on bivalve molluscs in June 2017.
24. NRL Italy presented data regarding a 2015 outbreak of hepatitis A linked to contamination in a shellfish production area in Southern Italy. The network noted the significant prevalence of shellfish with hepatitis A identified during surveillance of LBM in the surrounding areas of the outbreak, and the use of the reference method coupled to modelling to track the reduction in prevalence of hepatitis A over time. It was agreed that this study provided an excellent example of integration between laboratory analysis and management of production areas.
25. The workshop noted preliminary molecular data on *Toxoplasma gondii* detected in mussels and oysters from France, and agreed that more information in this and related areas to elucidate the public health risks from parasites associated with consumption of bivalve molluscs would be valuable. The EURL undertook to communicate with the EURL for parasites on this topic.
26. The workshop noted an interesting presentation by NRL France regarding recent progress in the development of a cultivation method for norovirus. The utility of approaches for the propagation of norovirus using enteroids was outlined and the successful replication of norovirus was noted. The potential future applications of this technology to a wide range of issues surrounding the viral risk posed by bivalve molluscs was highlighted.

27. NRL Sweden presented data on the application of digital PCR for quantification of viruses in bivalve molluscs. It was agreed that in the future this technology may become more widely used within the field. The workshop also noted the potential of mismatches between PCR primers and probes and target virus sequences to confound accurate quantification.

28. The next workshop will be held 16th – 18th May 2018, in the United Kingdom (confirmation of venue to follow).