

Resolutions of the 6th workshop of NRLs for bacteriological and viral contamination of bivalve molluscs, Galway 15-17th May 2007.

Communication

1. NRLs recognised their responsibilities to supervise Official Control laboratories in their Member State and to communicate to them relevant technical information and advice issued by the NRLs network and the CRL.
2. NRLs recognised their responsibilities to provide scientific and technical advice and assistance to their Competent Authority (CA) and therefore to communicate to them relevant technical information and advice issued by the NRLs network and the CRL (for example the contents of the Microbiological monitoring of bivalve mollusc harvesting areas- Guide to Good Practice- Technical Application).
3. NRLs welcomed the Istituto Zooprofilattico Sperimentale dell'Umbria e delle Marche Sezione di Ancona to the network and recognised the division of responsibility between the two Italian NRLs into bacteriological monitoring (Ancona) and virological analyses (ISS).

Proficiency testing and accreditation

4. NRLs agreed that the CRL invite expressions of interest in a further FRNA bacteriophage ring trial and resolved to communicate details of the scheme to relevant microbiological laboratories within their country with the intent of increasing the number of participants in the scheme.
5. NRLs agreed that their participation in proficiency testing for the legislative requirements (*E.coli* and *Salmonella*) was mandatory and agreed to continue participation in the CRL/HPA EQA shellfish scheme.
6. NRLs agreed that it was also important to periodically undertake proficiency testing using matrix samples (e.g. whole bivalve shellfish) in order to challenge aspects of the methodologies (e.g. initial sample preparation, preparation of dilutions) that would not be challenged by proficiency testing using laboratory constructed samples (as used in the CRL/HPA EQA shellfish scheme).
7. Further to the above NRLs requested that the CRL organise a whole animal ring trial amongst NRLs. For Member States where there were a small number of Official Control laboratories the CRL would make participation available to in country testing laboratories.
8. NRLs identified some ambiguity regarding their responsibility to become accredited under Regulation (EC) 882 2004, Regulation (EC) 854 2004 and Regulation (EC) 2073/2006 particularly in regard to method specific or general accreditation and to accreditation for *Salmonella*. The CRL resolved to

draft a briefing note to provide clarification and to identify the responsibilities of NRLs.

9. Recognising European legislative requirements NRLs resolved that Official Control laboratories undertaking analyses for the purposes of microbiological monitoring of production areas must be accredited (to ISO 17025), and that this accreditation must be method specific i.e. for analysis of *E. coli* in molluscan shellfish.
10. NRLs resolved that Official Control laboratories undertaking analyses for the purposes of microbiological monitoring of production areas must participate in proficiency testing for *E.coli* determination and that it was the responsibility of the NRL to ensure that this was undertaken.
11. In supervising the above the workshop agreed that NRLs must either arrange the scheme themselves or have full access to details of a scheme provided by a third party. In the latter case the NRL must have full access to the identity of their participating Official Control laboratories and the laboratory results.
12. NRLs noted the content of Commission paper WS6-007 - Protocol for management of underperformance/lack of collaboration of NRLs in comparative testing and lack of collaboration with CRL activities - and that the CRL would follow this protocol with respect to NRL collaboration and performance in proficiency testing for statutory determinants (*E.coli* and if appropriate *Salmonella*).
13. It was resolved that where available NRLs would send information to the CRL on proficiency testing performance assessments, and follow-up of poorly performing laboratories. The CRL agreed to draft a guidance document for NRLs on best practice with respect to performance assessment, follow-up, identification of corrective actions and preventative measures for their supervision of Official Control laboratories – for discussion at the next NRLs workshop.

Microbiological monitoring

14. NRLs agreed that at the next workshop Italy, Portugal, Spain and Ireland would present progress on implementation of sanitary surveys in their Member States.
15. NRLs supported the proposal to publish a European Commission good practice guide on the principles of microbiological monitoring of bivalve mollusc harvesting areas and noted that this would be based on the full technical guidance document available on the CRL website. NRLs agreed to give comments to the CRL on the draft principles guide (WS6-012) by May 31st 2007.

16. The CRL agreed to organise a further training workshop on sanitary surveys, participation would be invited during 2007 attendance should be targeted at those responsible for conducting such surveys.
17. NRLs requested that the CRL formally ask the Commission if the responsibility for monitoring and analysis of echinoderms, marine gastropods and tunicates is under the remit of the NRL network.
18. NRLs resolved to communicate with their CAs regarding EU Regulation (EC) No 1666/2006 and the expiry of this transitional arrangement in 2009 and to establish whether CAs required scientific advice regarding possible consequential arrangements for incorporation of analytical tolerance considerations into EU legislation – and to inform the CRL by the end of September 2007.
19. Further to the above the CRL agreed to communicate this to the EU Commission and, if appropriate, to suggest the establishment of a working group to consider the issue and give scientific advice.
20. The CRL endorsed the opinion of NRL Netherlands that use of a TBX based enumeration approach (ISO 16649-2) was not currently appropriate for Official Control microbiological monitoring of bivalve mollusc production areas in the Netherlands as this method had not been validated against the EU reference method according to ISO 16140.

Treatment and prevention

21. The CRL agreed to communicate to the Commission the NRLs re-endorsement of Resolution 17 2006 with respect to the formation of an EU WG to elaborate a good practice guide covering all aspects of commercial depuration practices to facilitate harmonisation across Europe with respect to removal of bacterial contamination.
22. NRLs agreed the absolute importance of prevention of sewage pollution in protection of public health (particularly considering the poor performance of depuration in removal of viral pathogens from class B bivalve shellfish) and noted, with concern, that the Shellfish Waters Directive (codified version: 2006/113/EC) would be repealed in 2012. The CRL agreed to seek clarification of Commission intentions with regard to this aspect of the new Water Framework Directive and, if necessary, to seek a meeting (to include relevant NRLs) with the responsible Commission DGs to express the scientific concerns.
23. Further to the above NRLs agreed that they should advise CAs that it was not appropriate or sensible to permit the establishment of new aquaculture operations in contaminated areas. The agreed scientific advice from NRLs was that new operations should only be established in areas conforming to the monitoring requirements of class A. This may not be relevant for bivalve shellfish subject to approved heat treatment processes.

Liaison with ISO SC9 and CEN WG6

24. The CRL agreed to review the contents of the FDIS/ISO 7218 with respect to the advice on selection of MPN tube combinations for calculation of *E. coli* MPN and if necessary to seek an amendment to ISO 7218 and/or other appropriate actions.
25. The CRL identified that ISO TS 16649-3 for *E.coli* analysis would expire in Dec 2008 and that further data was required for analysis of *E.coli* particularly in diary products to support its adoption as a full horizontal standard. NRLs agreed to discuss this with colleagues responsible for analysis of diary products and seek supporting data (the CRL can provide guidance for studies).

Viruses

26. NRLs requested that the CRL organise a further ring trial for norovirus and hepatitis A in laboratory constructed samples in LENTICULE format, and that the distribution would include low concentration samples.
27. NRLs recognised the importance of sharing information (and samples) consequential to bivalve shellfish associated outbreaks. It was agreed that the CRL would elaborate a proposal for improving communication with respect to outbreaks across the network and inform the NRLs.
28. NRLs requested that the CRL make available norovirus and hepatitis A reference material in a LENTICULE format. The CRL would inform the network when homogeneity and stability analyses had been carried out and distribute these data along with LENTICULES to NRLs on request.
29. NRLs identified that with the significant advances in standardised quantitative methodology it was now important to generate data on virus prevalence in bivalve mollusc production areas and end-products to inform risk management options and that CAs and other research funders should be encouraged to fund such studies.
30. Further to the above NRLs agreed that the benefit of such studies would be maximised if they included as a minimum: the use of quantitative procedures operating under the principles of quality assurance; include consideration of appropriate sampling strategies; avoiding bias through selection of a representative range of surveillance sites according to a risk based assessment.
31. NRLs agreed that studies on the public health significance of PCR results for viruses were important in relation to possible implementation of virus monitoring controls in the EU, and that they would be interested to collaborate on research studies addressing this issue if funding became available.

Vibrios

32. NRLs requested that the CRL organise a further ring trial distribution for *V parahaemolyticus* with the intent of providing samples that enabled enumeration and determination of potential pathogenicity principles.
33. NRLs supported the work of the NRL network and CEN TAG3 on the development and standardisation of molecular methods enabling enumeration and differentiation of pathogenic *Vibrio* spp.
34. Further to the above NRLs identified that it is important that EU legislation was based upon methods capable of identifying public health risk to avoid unnecessary detrimental impact on trade.

Next meeting

35. NRLs agreed that the next meeting would be held on 6-8 May 2008 at CEFAS, Weymouth, UK.