Resolutions of the 7th workshop of Microbiological NRLs for Bivalve Molluscs, Weymouth, UK, 6-8th May, 2008

Supervision of official control laboratories

1. NRLs provided information to update the "Questionnaire to laboratories, 2007". The CRL agreed to update information on bivalve mollusc production, methodology, accreditation and supervision of Official Control Laboratories and post a summary on the CRL website.

Microbiological methods - statutory determinands

2. Further to resolution 25 of the 6th workshop in 2007, and in the absence of additional data from other matrices, it was agreed that the CRL should write to ISO SC9 requesting an extension for ISO TS 16649-3 (*E. coli* reference method) to ensure its continuation as a technical specification. NRLs were encouraged to support the generation of data for matrices other than bivalve molluscs to facilitate its adoption as a full ISO standard method.

3. When deriving *E. coli* MPN values for Official Control testing it was agreed to only accept MPN combinations falling into probability categories 1 (95%) and 2 (4%) as this is an additional quality control check. The CRL provided MPN tables with these probability categories annotated and agreed to work towards updating the 5x3 MPN tables in ISO 7218:2007.

4. The NRLs recognised the comprehensive work undertaken by NRL France on validation of the impedance method (Bactrac 4300) according to ISO 16140. It was noted that following submission of a final report the CRL intended to issue a formal response copied to NRLs and the Commission.

5. NRLs supported the proposal that, if the Bactrac 4300 methodology was found to be equivalent to the *E. coli* reference method (ISO TS 16649-3), a recommendation would be made to DG Sanco to consider formal recognition of the use of the methodology for Official Control testing through a Commission Decision.

6. NRL Netherlands reported on the continued use of ISO16649-2 (TBX method) for Official Control testing in the Netherlands on the instruction of the competent authority. The NRL Netherlands advised that they do not consider the TBX method to be validated according to the requirements in EU Food hygiene legislation and therefore should not be used.

Microbiological monitoring - sanitary surveys and monitoring

7. The workshop noted that there was a lack of systematic activity with respect to the application of sanitary surveys across the EU.This was partially because Member State sanitary survey programmes were based on the previous Commission advice that the sanitary survey provisions of Regulation 854/2004 only applied to newly classified areas. It was identified that this was not clearly stated in the Regulations and the Commission undertook to seek a legal opinion which would be circulated to NRLs when available.

8. The workshop supported the proposal for more formal adoption of the CRL guidance for microbiological monitoring of bivalve mollusc harvesting areas (published on the CRL website). The Commission considered that the format of the 'principles' document would need revision for coherence with other Commission guidance and would advise the CRL on the next steps to progress the document.

9. The CRL informed the workshop that the response rate by NRLs on the questionnaire on monitoring for echinoderms, gastropods and tunicates had been poor. The Commission advised this was important information. The CRL therefore agreed to recirculate the questionnaire among non-responding NRLs who agreed to give this a higher priority. The CRL agreed to produce a dossier of information and lodge it on the website.

Microbiological monitoring - analytical tolerance

10. With reference to the standards for classification of production areas in EU Regulation 854/2004, NRLs reaffirmed their opinion that scientific justification for application of tolerance based upon analytical uncertainty for category B sites applied equally to class A (and C areas).

11. Further to the above, NRLs noted that the lack of information and guidance in the legislation on how to deal with non-compliant class A results caused significant problems for competent authorities in the classification of harvesting areas. The CRL agreed to seek clarification from the Commission and report back to NRLs.

12. The Commission advised NRLs that their working group on implementing measures had considered the 10% tolerance for class B areas (as included in transitional arrangements 1666/2006 - expiry 2009) and currently considered that it should be retained subject to a maximum result upper limit of 46,000 MPN *E. coli*/100g.

Depuration

13. Further to resolutions 17 and 21, of the 5th and 6th workshop in 2006 and 2007, NRLs expressed support for the elaboration of an EU guidance document covering commercial depuration practices with respect to removal of bacteriological contamination.

Proficiency testing for statutory determinands

14. NRLs agreed to maintain commitment to the CRL/HPA EQA as the primary means of proficiency testing for *E.coli* and *Salmonella* spp. amongst the NRL network.

15. The network noted the improvements over recent years, and the current high participation and good performance of NRLs and EU Official Control laboratories in proficiency testing for *E. coli* and *Salmonella* spp (statutory determinands).

16. The CRL agreed to draft a proposal on proficiency testing performance assessment and follow-up for use by NRLs in supervision of Official Control laboratories. The proposal would be circulated for comment and then posted on the CRL website.

17. NRLs recognised the importance of periodic proficiency testing using matrix samples. NRLs requested that the CRL organise a further distribution of whole bivalve shellfish for enumeration of *E. coli* and detection of *Salmonella* spp in the autumn 2008.

18. Further to the above, participation in the whole bivalve shellfish proficiency test would be open to Official Control laboratories nominated by NRLs. However, the CRL would need to recover the costs for Official Control laboratory participation. The CRL would invite expressions of interest from NRLs in due course.

FRNA bacteriophage

19. NRLs recognised that the value of proficiency testing for FRNA bacteriophage was limited due to the low numbers of participants in the scheme. It was agreed that the FRNA bacteriophage PT would be discontinued.

20. However, the CRL would provide, on request, lenticulated reference material for FRNA bacteriophage together with estimated reference values, for laboratories wishing to carry out their own internal quality performance checks.

Viruses

21. NRLs noted the value of the CRL norovirus and hepatitis A proficiency testing scheme and requested that a further distribution should be offered in 2008. The CRL would include information on the reference strains used in the final report. PT samples would be in lenticule format.

22. In addition, NRLs requested that the CRL make available norovirus and hepatitis A reference material in lenticule format with supporting CRL derived reference values and strain characterisation.

23. NRLs supported the work of CEN/TC275/WG6/TAG4 'Viruses in food' on the development of a standard method for detection of norovirus and hepatitis A virus in bivalve molluscs and identified that it was now important to generate data on virus prevalence in bivalve mollusc production areas and end-products to inform risk management options.

24. The workshop noted that action following a suspect bivalve mollusc associated norovirus illness incident, or rapid alert notification, was not formalised within the EU. Action generally performed by the Competent Authority was a local investigation of the circumstance, and a request for norovirus testing of the products causing illness (if available) and the production area. Decisions on closure/opening of production areas were generally on an ad-hoc basis (not formalised) and normally considered risk factors in addition to norovirus test results.

25. With respect to the above the Commission noted that, considering the current absence of specific EU controls on viruses in LBMs, this seemed a reasonable approach under EU Food Hygiene law (Regulation 178/2002).

26. The workshop noted the importance of applying the same sampling and testing approach to own Member State production as was applied to intra-community trade.

Vibrios

27. NRLs recognised the value of the *V. parahaemolyticus* proficiency testing and requested that the CRL organised an additional round of PT for vibrios during 2008-2009. Expressions of interest would be invited amongst the network in due course.

28. NRLs supported the work of CEN/TC275/WG6/TAG3 in the development of enumerative methods for the detection of potentially pathogenic *V. parahaemolyticus.* NRLs identified that it was now important to generate data on prevalence in bivalve molluscs across the EU to inform future decisions on Official Control. It was recommended that any such studies include methods that enable detection of pathogenicity principles.

29. NRLs resolved that there should be a dedicated vibrio session at the next workshop to assist in identifying knowledge gaps, recommend appropriate methodologies and future control strategies. It was recognised that it would be beneficial to invite additional delegates with specific expertise in this area.

Next meeting

30. Provisionally it was agreed that the next workshop of NRLs would be held in Split, Croatia. The provisional date of the next workshop would be between the 12th and 14th of May 2009.