



European Community Reference Laboratory for monitoring
bacteriological and viral contamination of bivalve molluscs



CEFAS Laboratory, Weymouth, Dorset, DT4 8UB, UK

WORK PROGRAMME FOR THE CRL FOR BACTERIOLOGICAL AND VIRAL CONTAMINATION OF BIVALVE MOLLUSCS, 2008

LEGAL FUNCTIONS AND DUTIES

The functions and duties of the CRL are specified in Article 32 of Regulation (EC) No 882/2004 (Official Journal of the European Communities No L 165 of 30.4.2004).

In the 2008 work programme year 27 Member States and 3 candidate countries (Croatia, Turkey and Former Yugoslav Republic of Macedonia) are considered eligible for CRL assistance and invited to participate in CRL organised training programmes, ring trials/external quality assessments schemes etc. The full integration into the European Union of recent accession Member States continues to be a priority area, and is facilitated via the provision of additional advice, training and assistance.

WORK PROGRAMME, 2008

1. Scientific advice and support

- 1.1. Assist DG Sanco in functioning and implementation of Community food hygiene legislation, e.g. drafting guidance documents, consideration of analytical tolerances, etc.
- 1.2. Participate in relevant EU and International scientific committees (ISO/CEN, WHO/FAO, ICMSS etc). In 2008 the CRL will:
 - Chair and co-ordinate the activities of the CEN/TC 275/WG6/TAG4 developing a CEN standard for detection of norovirus and hepatitis A in foodstuffs, including bivalve molluscs.
 - Lead and co-ordinate the activities of CEN/TC 275/WG6/TAG3 in the elaboration of molecular based enumeration methods for pathogenic marine vibrios in bivalve shellfish (see resolution 33, 6th workshop of NRLs).
 - Participate in ISO/TC34/SC9/WG3 working group on validation of methods (revision of EN ISO 16140) to include the elaboration of ISO technical report on recommendations for establishing/revising reference methods.
- 1.3. Assist DG Sanco with specialist assistance in relation to food and veterinary inspections of Member States, Accession Countries and Third Countries and with other trade issues (e.g. equivalency negotiations, industry initiatives such as SUMO) as they arise.



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- 1.4. Co-operate with, and assist DG TALEX in the provision of training and advice to Accession Countries.
 - 1.5. Undertake CRL missions in support of the above activities.
 - During 2008 missions are foreseen in relation to the annual meetings of ISO and CEN (up to 2 missions); the CEN/TAG4 working group on viruses in food (2 missions); CEN/TAG3 working group on vibrios (2 missions); ISO/WG3 working group on validation of methods (2 missions) and up to 3 missions in support of NRLs and DG Sanco activities.
 - 1.6. Participation in relevant international scientific conferences
 - 1.7. Participate as a member of the steering committee in the ICMSS' international forum on harmonisation of approaches to bivalve shellfish sanitation, including standardisation of methodologies for indicator organisms, and human pathogenic viruses and bacteria.
 - 1.8. Participation in the joint FAO/WHO/Codex Task Force undertaking risk profiling and formulating Food Risk Management Guidance on noroviruses in food, including bivalve shellfish.
- 2. Co-ordination of activities of NRL network and provision of technical assistance and training**
- 2.1. Participate in annual CRL Directors co-ordination meeting and other CRL co-ordination meetings/workshops as appropriate
 - 2.2. Organise, host, and participate in the seventh annual NRL workshop, produce resolutions and other workshop outputs (May 2008, CRL Weymouth). To include CRL administrative assistance.
 - 2.3. Undertake CRL activities and commitments agreed in resolutions at annual workshops (as posted on www.crlcefas.org).
 - 2.4. Organise specialist, targeted, practical training for NRLs, MS competent authorities and the FVO on sanitary surveys - in accordance with the requirements of 854/2004 on official controls.
 - 2.5. In collaboration with the US FDA organise and host a joint workshop on implementation and approaches to sanitary surveys in the EU and US.
 - 2.6. Supply specialist information and advice on bacteriological and



viral methods to NRLs (particularly new MS NRLs and accession countries), Official Control testing laboratories, and third country laboratories. To include assistance on implementation of methods, accreditation to IEC ISO17025, validation of alternative methods according to ISO16140, provision of CRL SOPs and transfer of other technical information.

- 2.7 Provide specialist training and/or training courses to NRLs, accession country NRLs and others in relation to analyses of *E.coli*, *Salmonella* spp., *Vibrio* spp., FRNA bacteriophage, Norovirus, hepatitis A virus and other aspects of bivalve shellfish hygiene as required.
- 2.8 Continue to update and improve the CRL website (www.crlcefas.org) as a primary means of dissemination of information to NRLs and others.

3 Ring trials, comparative testing and quality assurance

- 3.1 Organise comparative (proficiency) testing for NRLs for *E.coli* and *Salmonella* spp. in bivalve molluscs via the CRL/HPA shellfish EQA scheme (see resolution 5 of 6th workshop of NRLs). Analyse results, produce report, advice and recommendations (by May 08).
- 3.2 Organise Norovirus and hepatitis A ring trials (see resolution 26 of 6th workshop). Analyse results, produce report and recommendations (by May 08).
- 3.3 Undertake *Vibrio parahaemolyticus* ring trials appropriate for methods enabling enumeration of pathogenicity principles (thermostable direct and thermostable direct related haemolysins) (see resolution 32 of 6th workshop). Analyse results, produce report and recommendations (by May 08).
- 3.4 Undertake FRNA bacteriophage proficiency testing. Extend provision of EQA material, methods of analysis etc to national testing laboratories if required by NRLs (see resolution 4 of 6th workshop).
- 3.5 To challenge aspects of the *E. coli* and *Salmonella* spp. methods not covered by the standard shellfish EQA scheme organise a whole animal ring trial (see resolution 7 of 6th workshop) for NRLs, the scheme will be extended to selected Official Control Laboratories. Analyse results, produce report, advice and recommendations (by May 08).



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- 3.6 Prepare stable reference material using biological LENTICULE carriers for norovirus and Hepatitis A (see resolution 28 of 6th workshop). Perform homogeneity and stability analyses. Distribute data and LENTICULES to NRLs for use as control material on request.

4 Confirmatory testing

- 4.1 Maintenance of CRL laboratory competence and expertise on analytical methods for monitoring virological contaminants of bivalve molluscs (Norovirus and hepatitis A virus). To include maintenance of IEC ISO 17025 accreditation for detection of norovirus in bivalve shellfish and adoption of CEN method for viruses.
- 4.2 Maintenance of CRL laboratory competence and expertise on analytical methods for monitoring bacteriological contaminants of bivalve molluscs (*E.coli*, *Salmonella* spp., FRNA bacteriophage, marine vibrios). To include maintenance of IEC ISO 17025 accreditation of enumeration of *E. coli* and FRNA bacteriophage and the detection of *Salmonella* spp. and *Vibrio parahaemolyticus*.
- 4.3 Contribution to costs of the maintenance of CRL capability to perform analysis for marine vibrios in bivalve molluscs other than *V. parahaemolyticus*.
- 4.4 Performance of above tests on outbreak material or on occasion of disputed test results (on request of DG Sanco).

5 Development of analytical methods (undertaken at CRL)

- 5.1 Contribution as the project leader towards the validation of the TAG4 reference method for the detection of viruses in food (CEN/TC 275/WG6/TAG4).

Note. Validation of the TAG4 reference method for viruses in foods, including bivalve shellfish is a priority area. In the event of CEN mandate M/381 "Methods of Analysis of foodstuffs concerning food hygiene" (Mandate for standardisation M/381 addressed to CEN) not being fully funded, resources will be diverted from other areas within the work programme to enable validation of the virus method for bivalve shellfish.

- 5.2 Contribution as the project leader towards the elaboration and validation of the TAG3 molecular based standard for the detection of potentially pathogenic vibrios in foodstuff, including bivalve shellfish using molecular methods - both nucleic acid hybridisation



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and real time PCR approaches.

- 5.3 The existing *E.coli* enumeration reference method ISO TS 16649-3 specified in Commission Regulation (EC) No 2073/2005 is published as a technical specification with an expiry of December 2008. It is proposed that the CRL, in collaboration with the NRL network undertakes work to generate data enabling its adoption as a full horizontal standard. Thus enabling it to remain as an ISO recognised method for *E. coli* enumeration in live bivalve molluscs, tunicates, echinoderms and marine gastropods in Regulation.

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