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

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WORK PROGRAMME FOR THE CRL FOR BACTERIOLOGICAL AND VIRAL CONTAMINATION OF BIVALVE MOLLUSCS, 2010

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 2009 work programme year 27 Member States and 3 candidate countries (Croatia, Turkey and 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, 2010

1. Scientific advice and support

1.1. Assist DG Sanco in the application of the Community food hygiene legislation, e.g. drafting guidance documents, equivalency of CODEX standards for LBM, consideration of tolerances, alternative methods, and implementation of Water Framework Directive etc, and any other activities as required.

1.2. Participate in relevant EU initiatives and International scientific committees (ISO/CEN, WHO/FAO, expert working groups etc). In 2010 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 (see resolution 27, 8th workshop of NRLs). Two expert meetings are planned in 2010.

- Progress plans for formal validation of the above virus standard in preparation for work to deliver M/381 EU mandate to CEN for validation of methods in food microbiology.

- 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.

- Chair and co-ordinate an expert working group to make recommendations on fit-for-purpose methods for human pathogenic vibrio determination and their application in LBM.

- 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.

- Participate in working group CEN/TC 275/WG6/TAG6 on sampling methods

(revision of ISO 6887) specifically ISO 6887 part 3 and make recommendations on sampling bivalve molluscan shellfish.

1.3. Provide DG Sanco with specialist assistance in relation to food and veterinary inspections of Member States, Accession Countries and Third Countries and give advice and support on other technical issues related to trade as required.

1.4. Co-operate with, and assist DG Taiex in the provision of training and advice to Accession Counties.

1.5. Undertake CRL missions in support of the above activities.

- During 2010 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), CEN/TAG6 working group on sampling and up to 6 missions in support of NRLs and DG Sanco activities.
- Mission to the US associated with the second joint EU/US FDA workshop on implementation and approaches to sanitary surveys (item 2.4)
- Up to 2 missions to JRC/IRMM Geel, Belgium (item 3.6)

1.6. Organise an annual review meeting between CRL representatives and designated DG Sanco representative in the area in Brussels or alternative mutually convenient location.

1.7. Complete a revision and publish (on the CRL website) the 4th issue of Microbiological monitoring of bivalve shellfish harvesting areas, Guide to good practice: technical application.

1.8. Participate in relevant international scientific conferences, e.g. Food and Water borne microbiology symposium, Istambul, Turkey, 4th International calicivirus conference, location to be announced.

1.9. Participate as a member of the organising committee in “Vibrios in the Environment”.

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 eighth annual NRL workshop, produce resolutions and other workshop outputs (May 2010 NRL Ancona, Italy). 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 and participate in the second joint EU/US FDA workshop on implementation and approaches to sanitary surveys to be held in US in 2010, as a follow up to the first workshop held in 2008 at the CRL (associated costs for travel for up to 6 staff members).

2.5 Produce a report on the implementation and approach to sanitary surveys of LBM harvesting areas in EU member States.

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 county laboratories. To include assistance on implementation of methods, accreditation to IEC ISO17025, validation of alternative methods according to ISO16140, provision of CRL SOPs, protocols from TAG4 viruses in foods 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 21, 8th workshop of NRLs). Analyse results, produce report, advice and recommendations (by May 10).

3.2 Produce a CRL guidance document on supervision of Official Control laboratories with respect to assessment and follow-up activities in proficiency testing to encourage a harmonised approach across the network for dissemination through the CRL website.

3.3 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 resolutions 22 and 23 , 8th workshop of NRLs) for NRLs, the scheme will be extended to selected Official Control Laboratories. Analyse results, produce report, advice and recommendations (by May 10).

3.4 Organise norovirus and hepatitis A ring trials (see resolution 24, 8th workshop of NRLs). Analyse results, produce report and recommendations (by May 10). Ring trial to be open to non-NRL laboratories on a cost recovery basis.

3.5 Organise norovirus and hepatitis A ring trials using matrix samples (i.e. whole bioaccumulated bivalve shellfish) to test laboratory performance in application of the entire virus method. Ring trial to be open to non-NRL laboratories on a cost recovery basis.

3.6 In collaboration with JRC/IRMM Geel, Belgium undertake pilot studies on the production of virus reference material using matrix samples, to include up to two meetings at Geel.

3.7 Prepare fully characterised stable reference material using biological carriers for norovirus and Hepatitis A (see resolution 26, 8th workshop of NRLs). Perform homogeneity and stability analyses. Distribute to NRLs for use as control material on request.

3.8 Undertake *Vibrio parahaemolyticus* ring trials appropriate for methods enabling enumeration of pathogenicity principles (thermostable direct and thermostable direct related haemolysins) (see resolution 33, 8th workshop of NRLs). Analyse results, produce report and recommendations (by May 10).

3.9 Provision of reference material to support analysis of FRNA bacteriophage in LBM 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).

4.2 Maintenance of CRL laboratory competence and expertise on analytical methods for molecular identification and characterisation of human pathogenic *Vibrio* spp. associated with LBM to include routine implementation of typing using Pulse Field Gel Electrophoresis.

4.3 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*.

4.4 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 Practical 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).

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 and real time PCR approaches.

5.3 Continue to contribute towards research to assist in the clarification of the significance of quantitative PCR results for norovirus in bivalve molluscan shellfish in terms of public health risk is undertaken (see note below).

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