European Union Reference laboratory for monitoring bacteriological and contamination of bivalve molluscs

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WORK PROGRAMME FOR THE EURL FOR BACTERIOLOGICAL AND VIRAL CONTAMINATION OF BIVALVE MOLLUSCS, 2012

LEGAL FUNCTIONS AND DUTIES

The functions and duties of the EURL 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 2012 work programme year 27 Member States and 3 candidate countries (Croatia, Turkey and Republic of Macedonia) are considered eligible for EURL assistance and invited to participate in EURL organised training programmes, comparative testing 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, 2012

1. **Scientific advice and support –** (up to 100 days)

1.1. The EURL will provide scientific assistance to DG SANCO in operation and implementation of European Union food hygiene legislation, and in particular in 2012 the following activities have been identified:

1.1.1. Provide scientific and statistical assistance with the ongoing equivalency negotiations between EU and US for live bivalve molluscs (LBM).

1.1.2. Provide final recommendations on harmonisation of standards for class A shellfish and end products in EU hygiene legislation with CODEX standards for LBM with respect to *E. coli* and potential implications for *Salmonella.*

1.1.3. Publish harmonised protocols for alternative methods validated according to ISO 16140 or equivalent for official control use.

1.1.4. Provision of updated dossier of information on application of sanitary surveys across MS with LBM production areas.

NOTE. The EURL will provide any other additional advice within its area of expertise as required, and undertake supporting expert missions on request of the European Union.

1.2 Participate in relevant EU and International scientific committees (EFSA, ISO/CEN, WHO/FAO, ICMSS etc). In 2012 the EURL will:

1.2.1 Co-ordinate the activities of the CEN/TC 275/WG6/TAG4 for the elaboration of the standard methods for detection of norovirus and hepatitis A in foodstuffs, including bivalve molluscs. In 2012 this activity will be restricted to responding through electronic working groups to technical comments arising from the publication process for the technical specifications for quantitative and qualitative standards.

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1.2.2 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, particularly for *V. parahaemolyticus*. Two missions associated with this activity are anticipated in 2012.

1.2.3 Lead the revision of the EU reference method for enumeration of *E. coli* in LBM for official control (ISO TS 16649-3) to establish the method as a full standard. To be conducted through electronic working group.

1.2.4 Project leader for the revision of the ISO 6887 series part 3 initial preparation and dilutions for aspects of microbiology associated with LBM (incl. in fish and fisheries products). Two missions are envisaged in 2012.

1.2.5 Lead the revision of ISO TS 21872-1 and 2 detection of *Vibrio* spp. in seafood. One mission is envisaged in 2012.

1.2.6 To continue to contribute to relevant EFSA expert working groups as required, to identify potential control options for viruses in LBM, e.g. risk based, quantitative virus standards, water quality improvements, environmental legislation and depuration. Up to two missions envisaged in 2012.

1.2.7 Assist DG SANCO with specialist advice in relation to food and veterinary inspections of Member States, Accession Countries and Third Countries as they arise.

1.2.8 Represent the EURL at the annual plenary meeting of the ISO SC9 and CEN WG6 Microbiology working group meeting. One meeting in Brussels in anticipated in 2012.

2 **Co-ordination of activities of NRL network –** (up to 180 days)

2.2 Participate in annual EURL Director's co-ordination meeting and other EURL co-ordination meetings/workshops as appropriate.

2.3 Organise, host, and participate in the eleventh annual EURL workshop, produce resolutions and other workshop outputs (April 24th to 26th 2012, Ljubljana, Slovenia). To include administrative assistance.

2.4 Undertake EURL activities and commitments agreed in resolutions at annual workshop above (as posted on www.crlcefas.org).

2.5 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.

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2.6 Conduct a review in consultation with NRLs and other stakeholders of the EURL website (www.crlcefas.org) to improve contents and ease of accessing information.

3 Provision of technical advice and training - (up to 70 days)

3.1 Organise an expert technical meeting to further develop and harmonise scientific expertise across the EU with respect to control methods for human pathogenic *Vibrio* spp. associated with LBM (particularly raw oysters). It envisaged that a small working group will be convened with up to 2 international invited experts; the physical working group will be hosted at the EURL, to enable practical activities and demonstrations to be undertaken.

3.2 Supply technical advice on bacteriological and viral methods to NRLs, Official Control testing laboratories, and third county laboratories. In the form of EURL harmonised protocols, standard operating procedures etc, to include approved alternative methods for official control analysis.

3.3 To include assistance on implementation of methods, accreditation to IEC ISO17025 and quality control requirements (see above).

3.4 To provide guidance and review of procedures/data to laboratories wishing to undertake studies to validate of alternative methods according to ISO 16140.

3.5 Provide specialist training and/or training courses to NRLs, accession country NRLs and others in relation to analyses of LBM for microbiological contaminants as required.

4 **Comparative testing and ring trials -** (up to 270 days)

4.2 Organise comparative testing for NRLs for *E. coli* and *Salmonella* spp. in bivalve molluscs via the EURL/HPA shellfish EQA scheme. Analyse results, produce report, advice and recommendations (by May 2012).

4.3 Organise norovirus and hepatitis A virus comparative testing distribution for quantitative and qualitative analyses. Analyse results, produce report and recommendations (by May 2012).

4.4 Undertake collaborative trials to test aspects of developmental *Vibrio* spp. methods in matrix and laboratory constructed samples. Analyse results, produce report (By December 2012).

4.5 Organise comparative testing amongst NRLs for *E. coli* and *Salmonella* spp. in live bivalve molluscs samples to test aspects of official methods no examined in standard EQA, i.e. initial dilutions, homogenisation. This item is specifically at the request of the NRL network to assist in the requirements of accreditation bodies. Analyse results, produce report, advice and recommendations (by May 2012).

4.6 Distribution of reference materials for all relevant microbiological determinants on request of NRLs.

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5 **Confirmatory testing and quality assurance –** (up to 80 days)

5.1 Maintenance of EURL laboratory competence and expertise in analytical methods for monitoring virological contaminants of bivalve molluscs (norovirus and hepatitis A virus). To include maintenance of requirements for ISO/IEC 17025 accreditation for quantitative determination of norovirus in LBM.

5.2 Maintenance of EURL laboratory competence and expertise in analytical methods for monitoring bacteriological contaminants of bivalve molluscs (*E. coli*, *Salmonella* spp., marine vibrios). To include maintenance of ISO/IEC 17025 accreditation of enumeration of *E. coli*, and the detection of *Salmonella* spp. and *Vibrio parahaemolyticus.*

5.3 Contribution to costs of the maintenance of EURL capability to perform analysis for human pathogenic strains of marine vibrios associated with LBM (e.g. serotyping *V. parahaemolyticus*, molecular characterisation of pathogenic strains of *V. parahaemolyticus, V. vulnificus* and) non01/0139*V. cholera*e).

5.4 Performance of above tests on outbreak material or on occasion of disputed test results (on request of DG SANCO).

6 Development of analytical methods – (up to 110 days)

6.1 In collaboration with JRC/IRMM Geel production of norovirus and hepatitis A virus reference material using freeze-dried oyster samples.

6.2 Characterisation studies of virus reference materials (homogeneity, stability, shelf life etc).

6.3 Limited interlaboratory studies amongst NRLs to establish reproducibility and precision of reference materials.

6.4 Practical developmental to support elaboration of standard molecular methods to detect pathogenic vibrios in foodstuff; including bivalve shellfish (see section 1.2.2).

NOTE. In 2012 it is recommended that a studentship is partially supported by the EURL up to a maximum value of £5,000 to enable the establishment of a fully characterised EU/global Vibrio strain bank. This will provide an extremely valuable resource to European laboratories (NRLs and others) and will assist in standardisation and harmonisation of Vibrio methods.

Rachel Hartnell
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August 2011

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WORK PROGRAMME FOR THE EUROPEAN UNION REFERENCE LABORATORY FOR BACTERIOLOGICAL AND VIRAL CONTAMINANTS OF MOLLUSCS, 2012

Annex 1

Resources necessary to fulfil the listed activities

I. LEGAL FUNCTIONS AND DUTIES

The functions and duties are specified in Articles 3 and 4 of Council Decision 1999/313/EC (Official Journal of the European Communities No L 120 of 8.5.1999).

PROGRAMME FOR THE PERIOD JANUARY – DECEMBER 2012

Item	Baseline Activity	Resources required (£)	7% Overheads (£)	TOTAL budget requested (£)
1	Scientific advice and support	38,910.04	2,723.70	41,633.74
2	Co-ordination of activities of NRL network	41,589.81	2,911.29	44,501.10
3	Provision of technical advice and training	22,693.16	1,588.52	24,281.68
4	Comparative testing and ring trials	79,754.27	5,582.80	85,337.07
5	Confirmatory testing and quality assurance	14,323.49	1,002.64	15,326.13
6	Development of analytical methods	37,314.24	2,262.00	39,576.24
	Total Baseline Costs	**234,585.01**	**16,070.94**	**250,655.76**
	Workshop	**38,336.00**		**38,336.00**