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, 2013

## 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 2013 work programme year 27 Member States, and 1 acceding country (Croatia) are considered eligible for EURL assistance and invited to participate in EURL organised training programmes, comparative testing etc. Candidate countries are also invited to participate in comparative testing and training workshops. The full integration into the European Union of Member States continues to be a priority area, and is facilitated via the provision of additional advice, training and assistance where required.

## WORK PROGRAMME, 2013

1. **Scientific advice and support** –

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 2013 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), especially following on from the 2nd International Workshop on Molluscan Shellfish Area Classification co-organised by the EURL and US FDA.

1.1.2. Provide scientific assistance, specifically through the Commission expert working group on live bivalve molluscs.

1.1.3. Provide scientific advice and assistance on request with respect to determination of norovirus and hepatitis A virus in matrices other than bivalve shellfish (eg soft fruits) covered in the ISO TS 15216 parts 1 and 2 (the virus reference method).

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 2013 the EURL will:

1.2.1 Participate as a member of the international steering committee towards the organisation of the 9th International Conference on Molluscan Shellfish Safety, Sydney, Australia 17-21st March 2013 http://www.icmss2013.com/

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1.2.2 Further to the above EURL staff (maximum 2) to present keynote speeches, chair sessions, deliver oral scientific presentations and poster presentations on application of sanitary surveys, control options and surveillance of norovirus in live bivalve shellfish at the 9th International Conference on Molluscan Shellfish Safety, Sydney, Australia 17-21st March 2013.

1.2.3 Oversee the publication of ISO TS 15216-1, Microbiology of food and animal feed — Horizontal method for detection of hepatitis A virus and norovirus in food using real-time RT-PCR — Part 1: Method for quantitative determination and ISO TS 15216-2, Microbiology of food and animal feed — Horizontal method for detection of hepatitis A virus and norovirus in food using real-time RT-PCR — Part 2: Method for qualitative determination). To include responding to official technical and editorial comments from voting members at ISO SC9 level.

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 2013.

1.2.3 Complete 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. Including responding to official technical and editorial comments from voting members at ISO SC9 level.

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). One mission is envisaged in 2013, to include completion of the document and responding to official technical and editorial comments from voting members at ISO SC9 level.

1.2.5 Lead the revision of ISO TS 21872-1 and 2 detection of *Vibrio* spp. in seafood. To inform the Commission of progress under the CEN mandate M/381.

1.2.6 To continue to contribute to relevant EFSA expert working groups as required.

1.2.7 To contribute towards the FAO/WHO initiatives in the development of a broader application of the current international risk assessments for *V. parahaemoloyticus* and *V. vulnificus*, in terms of both geographical relevance and bivalve species.

1.2.8 Assist DG SANCO with specialist advice in relation to food and veterinary inspections of Member States, Accession Countries and Third

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Countries as they arise.

1.2.9 Represent the EURL at the annual plenary meeting of the ISO SC9 and CEN WG6 Microbiology working group meeting. One mission in 2013.

2 **Co-ordination of activities of NRL network –**

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 twelfth annual EURL workshop, produce resolutions and other workshop outputs (May 7th -9th 2013, Rome, Italy). To include administrative assistance.

2.4 Further to the above, undertake EURL activities and commitments agreed in resolutions at annual workshop above (as posted on www.eurlcefas.org).

2.5 Continue to improve the EURL website (www.eurlcefas.org) to improve relevance and accessibility of contents and development strategies to increase usage of the website services by NRLs and other stakeholders.

3 **Provision of technical advice and training –**

3.1 Provide specialist training and/or training courses to NRLs, accession country NRLs and others in relation to official control analyses (*E. coli*, *Salmonella* spp.,) and non-statutory analyses (*Vibrio* spp., FRNA bacteriophage, Norovirus, hepatitis A virus) and other aspects of bivalve shellfish hygiene as required.

3.2 Further to 3.1, organise a limited training course at the EURL to provide specialist training in quantitative analysis of noroviruses in bivalve shellfish for NRLs.

3.3 Further to 3.1, host a training visit from a member of staff at NRL Italy (Ancona) to provide targeted training in application of EU official controls related to bivalve molluscs (sanitary surveys, laboratory analyses and quality assurance, depuration and traceability).

3.4 Continue to build scientific expertise and capacity across the network in the area of application of methods to detect human pathogenic *Vibrio* spp. associated with LBM (particularly raw oysters) developing on the outputs of the EURL expert *Vibrio* expert working group of 2012.

3.5 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.

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

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

3.8 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.

3.9 Supply technical advice on request on ISO TS 15216 parts 1 and 2 (the virus reference method) for matrices other than bivalve molluscs (eg soft fruits) to NRLs and Official Control testing laboratories.

4 **Comparative testing and ring trials –**

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 2013).

4.3 Organise norovirus and hepatitis A virus comparative testing distribution for quantitative and qualitative analyses. Analyse results, produce report and recommendations (by May 2013).

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 2013).

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 2013).

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

5 **Confirmatory testing and quality assurance –**

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.

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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 Progress towards accreditation to ISO/IEC 17025 of approved, validated alternative methods for enumeration of *E. coli* in LBM, to include.

5.4 Enumeration of *E. coli* in live bivalve molluscs by the direct impedance technique using BacTrac 4200 analyser

5.5 Enumeration of *E. coli* in live bivalve molluscs by the colony count technique (based on ISO 16649-2).

5.6 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).

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

## 6 Development of analytical methods –

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

6.2 Undertake practical laboratory based studies to support the accreditation to ISO/IEC 17025 of approved, validated alternative methods for enumeration of *E. coli* in LBM, to include in house verification/secondary validation of:

- Enumeration of *E. coli* in live bivalve molluscs by the direct impedance technique using BacTrac 4200 analyser (see Annex I for detail of experimental work).

- Enumeration of *E. coli* in live bivalve molluscs by the colony count technique (based on ISO 16649-2).

6.3 Undertake preliminary work to investigate methods to examine the efficacy of technical adaptations to ISO TS 15216-1, Microbiology of food and animal feed — Horizontal method for detection of hepatitis A virus and norovirus in food using real-time RT-PCR — Part 1: Method for quantitative determination, to enable determination of viable viruses.

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6.4 Undertake preliminary work to investigate the efficacy of depuration to remove norovirus in oysters.

6.5 Develop further competence and expertise in practical analytical methods for determination of norovirus and hepatitis A virus in matrices other than bivalve shellfish to include development of appropriate sampling strategies. During 2013 work will be conducted on soft fruit including strawberries.