



# Cefas



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

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## WORK PROGRAMME FOR THE EURL FOR BACTERIOLOGICAL AND VIRAL CONTAMINATION OF BIVALVE MOLLUSCS, 2014

### 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 2014 work programme year 28 Member States, are considered eligible for EURL assistance and invited to participate in EURL organised training programmes, comparative testing etc. Acceding 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, specific training and assistance.

### WORK PROGRAMME, 2014

#### 1. Scientific advice and support – (up to 130 days)

#### Expected outputs

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 2014 the following activities have been identified:

1.1.1. Provide expert scientific advice with regard to the EU and US trade equivalency negotiations for live bivalve molluscs (LBM) to include provision of position papers, attendance at meetings with stakeholders (US FDA, DG Sanco etc)<sup>a</sup>.

<sup>a</sup>Progress towards bivalve shellfish sanitation system equivalence agreement between EU and US and resumption of trade

1.1.2. Deliver follow-up actions resulting from 2<sup>nd</sup> International Workshop on Molluscan Shellfish Area Classification co-organised by the EURL and US FDA in collaboration with FAO<sup>b</sup>.

<sup>b</sup>Progress towards globally harmonised tool box approach to LBM sanitation systems

1.1.3. Provide scientific assistance, specifically through the Commission expert working group on live bivalve molluscs, to include but not restricted to advice on potential virus controls and actions following LBM associated outbreaks, harmonisation between EU microbiological criteria and Codex with respect to LBM, prohibition zones around discharges, interpretation of monitoring data, stability assessments<sup>c</sup>.

<sup>c</sup>Scientific support and progress within the expert working group towards improved legislation

1.1.4. Develop a scientifically robust framework for an EU surveillance programme for the determination of norovirus (and hepatitis A virus) in LBM to generate baseline data on prevalence, distribution and levels across the community<sup>d</sup> (up to 30 days).

<sup>d</sup>Development of a robust surveillance study protocol to generate data to inform decisions through the restricted working group on potential impacts of the introduction of virus standards in EU legislation

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,



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ISO/CEN, WHO/FAO, ICMSS etc). In 2014 the EURL will:

- 1.2.1 Support 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<sup>e</sup>.  
<sup>e</sup>Publication of reference method for viruses in LBM
- 1.2.2 Assist as a member of the international steering committee towards the publication of the proceedings of 9<sup>th</sup> International Conference on Molluscan Shellfish Safety<sup>f</sup>.  
<sup>f</sup>Publication of conference proceedings
- 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*. Up to 2 missions associated with this activity are anticipated in 2014<sup>g</sup>.  
<sup>g</sup>Progress toward fully quantitative method for determination of total and toxigenic *V. parahaemolyticus* in LBM
- 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<sup>h</sup>.  
<sup>h</sup>Publication of reference method as a full ISO standard
- 1.2.4 Project leader for the revision of the ISO 6887 series part 3 initial preparation and dilutions for aspects of microbiology to harmonise ISO standard with Commission Regulation (EC) No 2073/2005. One mission in 2014, to include review of technical and editorial comments at ISO SC9 level<sup>i</sup>.  
<sup>i</sup>Publication of harmonised ISO standard
- 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<sup>j</sup>.  
<sup>j</sup>Progress towards revision of vibrio ISO to include provision for detection of toxigenic *V. parahemolyticus*
- 1.2.6 To continue to contribute to relevant EFSA expert working groups as required<sup>k</sup>.  
<sup>k</sup>provide feedback on progress at EFSA
- 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<sup>l</sup>.  
<sup>l</sup>provide feedback as necessary
- 1.2.8 Represent the EURL at the annual plenary meeting of the ISO SC9 and CEN WG6 Microbiology working group meeting. One mission (Washington) in 2014<sup>m</sup>.  
<sup>m</sup>provide through collaborative report summary of plenary meeting

## 2 Co-ordination of activities of NRL network – (up to 120 days)



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- 2.1 Participate in annual EURL Director's co-ordination meeting and other EURL co-ordination meetings/workshops as appropriate<sup>n</sup>. <sup>n</sup> EURL representation
- 2.2 Organise, host, and participate in the thirteenth annual EURL workshop, produce resolutions and other workshop outputs (May 13<sup>th</sup> -15<sup>th</sup> 2014, UK, Italy). To include administrative assistance<sup>o</sup>. <sup>o</sup>successful workshop provide feedback as required through report and briefing
- 2.3 Further to the above, undertake EURL activities and commitments agreed in resolutions at annual workshop above (as posted on [www.eurlcefass.org](http://www.eurlcefass.org)).
- 2.4 Publish an updated EURL website ([www.eurlcefass.org](http://www.eurlcefass.org)) to improve relevance and accessibility of contents and development strategies to increase usage of the website services by NRLs and other stakeholders, to include in 2014 online registration for participation in comparative testing<sup>p</sup>. <sup>p</sup>increased accessibility of website, revised content and increase usage

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

- 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<sup>q</sup>. <sup>q</sup>improvements in performance and increased harmonisation across laboratories
- 3.1 Further to 3.1, host a training visit from a member of staff at NRL Italy (Ancona) between September 2013 and March 2014 to provide targeted training in application of EU official controls<sup>r</sup>. <sup>r</sup>as 3.1
- 3.2 Enhancing scientific expertise and capacity across the network in the area of application of methods to detect human pathogenic *Vibrio* spp. In early 2014 a *Vibrio* methods workshop is proposed focusing on methodologies for the detection and characterisation of vibrios of human health relevance in shellfish, climate change impacts and risks associated with trade. (It is anticipated that several international experts from the USA and Europe are would be invited to contribute to key sessions in these areas.)<sup>s</sup> <sup>s</sup>as 3.1 + progress towards EU/US equivalency agreements
- 3.3 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<sup>t</sup>. <sup>t</sup>as 3.1
- 3.4 To include assistance on implementation of methods, accreditation to IEC ISO17025 and quality control requirements (see above)<sup>u</sup>. <sup>u</sup>as 3.1
- 3.5 To provide guidance and review of procedures/data to laboratories wishing to undertake studies to validate of alternative methods according to ISO 16140. To include formal assessment of validation data as required to support official approval (at SCOFCAH) for alternative methods<sup>v</sup>. <sup>v</sup>use of approved of methods across the community



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- 3.6 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<sup>w</sup>.

<sup>w</sup>harmonisation of approaches

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

- 4.1 Organise comparative testing for NRLs for statutory determinands (*E. coli* and *Salmonella* spp.) in bivalve molluscs. Analyse results, produce report, advice and recommendations (4 distributions in 2014)<sup>x</sup>.
- 4.2 Organise two distributions of norovirus and hepatitis A virus comparative testing for quantitative and qualitative analyses. Analyse results, produce report and recommendations. Increased frequency of comparative testing annually in line with the recommendations of the EURL good practice guide and to support implementation of quality assurance standards for virus testing<sup>y</sup>.
- 4.3 Distribution of norovirus and hepatitis A virus reference materials and control materials, and *Vibrio* spp. EURL reference strains on request of NRLs<sup>z</sup>.

<sup>x</sup>comparative testing report published on the EURL website, presented at workshop

<sup>y</sup>comparative testing report published on the EURL website, presented at workshop

<sup>z</sup>improvements in performance and increased harmonisation across laboratories

#### 5 Confirmatory testing and quality assurance – (up to 100 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<sup>aa</sup>.
- 5.1 Maintenance of EURL laboratory competence and expertise in analytical methods for monitoring bacteriological contaminants of bivalve molluscs (*E. coli*, *Salmonella* spp., marine vibrios) using reference methods. To include maintenance of ISO IEC 17025 accreditation of enumeration of *E. coli*, and the detection of *Salmonella* spp. and *Vibrio parahaemolyticus*<sup>bb</sup>.
- 5.2 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. cholerae*)<sup>cc</sup>.
- 5.3 Performance of above tests on outbreak material or on occasion of disputed test results (on request).

<sup>aa</sup>retention of ISO 17025 accreditation where relevant at annual external audit – science quality

<sup>bb</sup>retention of ISO 17025 accreditation at annual external audit

<sup>cc</sup>retention of demonstrable capacity at EURL



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## 6 Development of analytical methods – (up to 100 days)

- 6.1 Verification of revised standard reference methods to detect (and enumerate) pathogenic vibrios in foodstuff; including bivalve shellfish (see section 1.2.2)<sup>dd</sup>.
- 6.1 Development of, homogeneity, stability and shelf-life testing of reference materials and controls to support the implementation and standardisation across user laboratories of the virus standard - 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<sup>ee</sup>.

<sup>dd</sup> Reference method for *Vibrio* spp. in LBM with capacity for semi-quantitative determination

<sup>ee</sup> improvements in performance and increased harmonisation across laboratories

### **Additional item under sections 1, 3 and 6- Scientific advice and support with respect to viruses in non-animal matrices (soft fruits, salad vegetables, bottled water, food surfaces)** – (up to 25 days)

Note. The reference method for viruses in LBM (ISO TS 15216-1 and-2) was published in 2013. The EURL led the working group which elaborated the reference method. This method is applicable to matrices other than LBM, the EURL has to date been providing *ad hoc* technical advice to the EU, MS and laboratories requiring norovirus and hepatitis A virus testing in imported Chinese frozen strawberries in support of Commission Regulation (EU) No. 1235/2012. In 2013 proposes to:

- 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).
- 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.
- Maintain 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, to include extension of ISO IEC accreditation.

<sup>1</sup>provision of high quality advice to DG SANCO and others delivered within agreed timescales

<sup>2</sup>improvements in quality of test results and increased harmonisation across laboratory network

<sup>3</sup> demonstrable capacity at EURL to performance analysis for norovirus and HAV in strawberries

Rachel Hartnell  
EURL Co-ordinator, August 2013