



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, 2015

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 2015 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 and additional laboratories are also invited to participate in comparative testing and training workshops (on a cost recovery basis). 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, 2015

1. Scientific advice and support

Expected outputs

1.1. The EURL will provide scientific assistance to DG SANCO in operation of existing, and implementation of new, European Union food hygiene legislation, and in particular in 2015 the following activities have been identified:

1.1.1. The provision of expert scientific and technical advice with regard to criteria for noroviruses in live bivalve mollusc (LBM) production areas and/or products placed on the market^a.

1.1.2. Further to the above, the development of technical guidance (based upon analysis of existing data) describing the precision characteristics associated with the virus reference method (ISO TS 15216-1) e.g. level of detection, limit of quantitation, linearity and measurement uncertainty to support the setting of quantitative limits in LBM^b.

1.1.3. The provision of expert scientific and technical advice with regard to a potential criterion for hepatitis A virus in LBM.

1.1.4. The provision of supplementary advice with regard to implementation of 3 class plan (applied over time in harvesting area assessments) for testing *E. coli* in LBM to harmonise EU legislative requirements with Codex STAN 292-2008^c.

1.1.5. Provide technical advice to the Commission on issues associated with microbiological monitoring of bivalve molluscs, including but not restricted to decisions after monitoring, implementation of prohibition 'buffer' zones around sources of faecal contamination, virus (or other microbiological) outbreaks^d.

^a Regulation covering *inter alia* standards for norovirus in LBM – improvement in public health

^b Evidence to support the setting of robust standards for EU legislation.

^c Successful implementation of amendments to EU legislation.

^d EU and US trade in LBM



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- 1.1.6. To provide support to DG SANCO and priority MS, as required with recommencement of trade between EU and US LBM^d.
- 1.1.7. Provide scientific advice and assistance to DG SANCO 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)^e.
- 1.1.8. Supply technical advice on request on ISO TS 15216 parts 1 and 2 (the virus reference method) for matrices other than bivalve molluscs (e.g. soft fruits) to MS, NRLs and Official Control testing laboratories^e.

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.

^e Scientific and technical advice to support EU Reg 1235/2012.

1.2 Participate in relevant EU and International scientific committees (EFSA, ISO/CEN, WHO/FAO, ICMSS etc). In 2015 the EURL will:

- 1.2.1 Act as convener for CEN/TC275/ WG6/TAG4 ‘Viruses’ to assist in the development of CEN methods for the determination of viruses in foodstuffs. In 2015 including, but not restricted, to providing responses to official technical and editorial comments from voting members at ISO SC9 level for the publication of ISO 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 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)^f.

- 1.2.2 Assist as a member of the international steering committee towards the organisation of 11th International Conference on Molluscan Shellfish Safety providing guidance and comment upon the developing programme as it relates to microbiological safety of bivalve molluscs^g.

^f Publication of full ISO standard (currently a Technical Specification) as a reference method for viruses in LBM

- 1.2.3 Further to the above up to two members of EURL staff to attend the 11th International Conference on Molluscan Shellfish Safety. To chair sessions, deliver keynote presentations in the area of viruses in shellfish, future direction of legislative controls and to contribute to EU / US technical and advisory initiatives on the development of best practice in microbiological monitoring to LBM to enhance public safety and trade^g.

- 1.2.4 Lead and co-ordinate the activities of CEN/TC275/WG6/TAG15 in the elaboration methods for the determination of pathogenic marine vibrios in bivalve shellfish, particularly for *V. parahaemolyticus* and *V. vulnificus*. Up to 2 missions associated with this activity are anticipated in 2015^h.

^g Enhanced EURL scientific reputation and impact, provision of best quality, state of art advice to EU



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1.2.5 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. No physical meetings in 2015 activity restricted to review of technical and editorial comments at ISO SC9 levelⁱ.

^h Reference method for determination of total and toxigenic *V. parahaemolyticus* and *V. vulnificus* in LBM of particular importance in US traded product

1.2.6 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. No physical meetings in 2015, activity restricted to review of technical and editorial comments at ISO SC9 levelⁱ.

ⁱ Publication of the EU *E. coli* reference method as a full ISO standard

1.2.7 Act as sub project leader for the revision of the ISO 7218 General rules for microbiology, covering revision of sections on MPN tables (with relevance to the EU reference method for *E. coli*) and molecular detection methods (viruses and vibrios). Two missions in 2015.

^j Standard harmonised with EU Reg. 2073/2005 with respect to minimum number of animals comprising a sample

1.2.8 To contribute to relevant EFSA expert working groups as required^g.

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

1.2.10 Represent the EURL at the annual plenary meeting of the ISO SC9 and CEN WG6 Microbiology working group meeting. One mission (Berlin) in 2015^k.

1.2.11 Contribute towards the FAO/WHO initiative developing best practice guidance for the application of bivalve molluscan shellfish sanitation programmes: global technical application activity restricted to 10 days to support production and review of documentation^l.

^k EU representation at CEN and ISO microbiology expert groups

^l Enhanced EURL scientific reputation and impact

2 **Project management and co-ordination of activities of NRL network**

2.1 Project management of EURL programme according to the requirements of EN ISO 9001 Quality Management Systems^m.

^m retention of EN ISO 9001 demonstration of project management quality

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

2.3 In 2015 the EURL will participate in the EURLs in the food and feed and animal health sectors expert working groups onⁿ;

2.3.1 Development and evaluation of NRL workshops and training programmes,

ⁿ EURL impact, harmonisation across network of EURLs

2.3.2 Development of best practices amongst the EURL network.



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- 2.4 Organise, host, and participate in the fourteenth annual EURL workshop of NRLs for monitoring bacteriological and viral contamination of bivalve molluscs, produce resolutions and other workshop outputs. In 2015, the workshop will be held at the NRL France at IFREMER, Nantes (May 19th -21st 2015)^o.
- 2.5 Further to the above, undertake EURL activities and commitments agreed in resolutions at annual workshop above (as posted on <https://eurlcefass.org/public-documents/workshops-of-nrls.aspx>)
- 2.6 Maintain and continue to improve the EURL website 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 2015 the launch of online registration for comparative testing services^p.

^o harmonisation of official controls across network of NRLs

^p increased accessibility of website, revised content and increase usage

3 Provision of technical advice and training

- 3.1 Provide specialist training to NRLs, and others in relation to official control analyses (*E. coli*, *Salmonella* spp.) and non-statutory analyses (*Vibrio* spp., norovirus, hepatitis A virus FRNA bacteriophage,) and other aspects of bivalve shellfish hygiene as required^q.
- 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^q.
- 3.3 To include assistance on implementation of methods, accreditation to IEC ISO17025 and quality control requirements (see above)^q.
- 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. To include formal assessment of validation data as required to support official approval (at SCFCAH) for alternative methods^q.
- 3.5 Provide specialist *ad hoc* training to NRLs and others in relation to analyses of LBM for microbiological contaminants as required^q.
- 3.6 Supply technical advice on request on ISO TS 15216 parts 1 and 2 (the virus reference method) for matrices other than bivalve molluscs (e.g. soft fruits) to NRLs and Official Control testing laboratories. To include advice on sampling plans, sample transport and result interpretation^q.

^q improvements in performance and increased standardisation across laboratories

4 Confirmatory testing and quality assurance

- 4.1 Maintenance of EURL laboratory competence and expertise in analytical methods for monitoring virological contaminants of bivalve



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molluscs (norovirus and hepatitis A virus). To include maintenance of requirements for ISO IEC 17025 accreditation for quantitative determination of norovirus in LBM^r.

- 4.2 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*^r.
- 4.3 Carry out activities associated with extension of scope of ISO IEC 17025 accreditation to include *V. vulnificus* and *V. cholerae*^r.
- 4.4 Contribution to costs of the maintenance of EURL capability to perform enumeration analyses in LBM for the sanitary indicator organism FRNA bacteriophage^r.
- 4.5 Contribution to costs of the maintenance of EURL capability to perform further characterisation of human pathogenic strains of marine vibrios associated with LBM (e.g. serotyping and molecular characterisation of pathogenic strains of *V. parahaemolyticus*, *V. vulnificus* and) non01/0139 *V. cholerae*,^r.
- 4.6 Maintain competence and expertise in practical analytical methods for determination of norovirus and hepatitis A virus in matrices other than bivalve shellfish (specifically soft fruit including strawberries), to include development of appropriate sampling strategies. In support of Commission Regulation (EU) No. 1235/2012^r.
- 4.7 Performance of above tests on outbreak material or on occasion of disputed test results (on request)^s.

^r retention of ISO IEC 17025 accreditation where relevant at annual external audit – demonstration of science quality

^s technical advice to support EU

5 Comparative testing and ring trials

- 5.1 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 2015, March, July, October and November). To improve quality assurance in test results for EU controls comparative tests will be available to laboratories outside of the NRLs network on a cost recovery basis^t.
- 5.2 To support implementation of quality assurance standards for virus testing organise two distributions of norovirus and hepatitis A virus for comparative testing for quantitative and qualitative analyses (provisionally June and December 2015). Analyse results, produce report and recommendations^q.
- 5.3 Distribution of norovirus and hepatitis A virus reference materials and control materials, and *Vibrio* spp. EURL reference strains on request of NRLs^u.

^t comparative testing reports published on the EURL website, presented at workshop, identification of satisfactory performance of NRLs and follow-up of unsatisfactory performance

^u improvements in



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- 5.4 Organise comparative testing for pathogenic *Vibrio* spp. (specifically in 2015, it is proposed that this comprises analyses for toxigenic strains of *V. parahaemolyticus* and *V. vulnificus* in LBM^f.

performance and increased harmonisation across laboratories

6 Development of analytical methods

- 6.1 Development of methods for inclusion in ISO TS 21872 (Standard method for detection of vibrios) of an enumeration annex to enable enumeration of total / pathogenic *V. parahaemolyticus* in imported / indigenously produced bivalve shellfish^{h,s}.
- 6.2 Examination and statistical assessment of norovirus datasets to determine precision characteristics of ISO TS 15216-1 (virus reference method) including measurement uncertainty / confidence intervals etc to support setting of norovirus limits in LBM^{a,b}.
- 6.3 Further to Recommendation 364 taken at CEN/WG6/TAG4 work with colleagues, including the EU Joint Research Council, Geel, to elaborate control materials to assist in the standardisation of ISO technical specifications for noroviruses and hepatitis A virus^o.
- 6.4 Undertake activities associated with dye-tracing studies to assess size of prohibition 'buffer' zones to assist in development of guidance to support Annex II of the Community Guide to the Principles of Good Practice for the Microbiological Classification and Monitoring of Bivalve Mollusc Production and Relaying Areas with regard to Regulation 854/2004 covering additional requirements for production areas from which LBM are harvested for export to the USA^s.

NOTE. In 2015 it is proposed that a studentship is partially supported by the EURL up to a maximum value of £6,208 to assist with development of analytical methods under 6.1 and 6.2.