



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, 2016-2017

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 2016-2017 work programme 28 Member States and 2 EFTA Member States (Iceland and Norway) are considered eligible for EURL assistance and invited to participate in EURL organised training programmes, comparative testing etc. Third country and other MS laboratories are also invited to participate as appropriate in comparative testing and training workshops on a cost recovery basis.

WORK PROGRAMME, 2016-2017

1. Scientific advice and support

Expected outputs

1.1. The EURL will provide scientific assistance to DG SANTE in operation of existing, and implementation of new, European Union food hygiene legislation, and in particular in 2016-2017 the following activities have been identified:

1.1.1. Attendance at the meetings of the EU Member States restricted working group on bivalve molluscs.

1.1.2. Provision of expert scientific and technical advice with regard to criteria for noroviruses and hepatitis A virus in live bivalve mollusc (LBM) production areas and/or products placed on the market. In particular sampling plans, analytical methods, and reporting for an EU wide baseline survey (with EFSA)^a.

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

1.1.3. Revision of Community Guidance with regard to pending revision of the criteria for E.coli in end-products and class A harvest areas.

1.1.4. Provision of technical advice and any necessary revision to Community Guidance on microbiological monitoring of bivalve molluscs, mitigation of faecal contamination (e.g. buffer zones), virus (or other microbiological) contamination or outbreaks.

1.1.5. Provision of support to DG SANTE and priority MS, as required with recommencement of trade of LBM between EU and US^b.

^b EU and US trade in LBM

1.1.6. Provision of ad-hoc scientific advice and assistance to DG SANTE with respect to determination of norovirus and hepatitis A virus in matrices other than bivalve shellfish (eg soft fruits) covered in ISO 15216 (the virus reference method)^c.

^c Scientific and technical advice to support EU Regulations on viruses in non-bivalve foods.

1.1.7. Assistance to DG SANTE FVO with audits of MS and third countries as



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requested and as other EURL priorities allow (mission costs funded by FVO). Specialist technical advice and support to FVO in support of their remit as requested.

1.2. The EURL will participate in relevant EU and International scientific committees (EFSA, ISO/CEN, WHO/FAO, ICMSS etc). In 2016-2017 the EURL will:

1.2.1. Act as convener for CEN/TC275/WG6/TAG4 'Viruses in food' to assist in the development of EN methods for the determination of viruses in foodstuffs. In 2016-2017 including, but not restricted, to providing responses to official technical and editorial comments from voting members at ISO SC9 level for the publication of EN/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 (due for publication by end of 2016) and drafting of a new revised DIS 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 detection to harmonise with the DIS of part 1^d.

^d Publication of full ISO standard (currently a Technical Specification) as a reference method for quantification of viruses in LBM and other foods. Publication of an updated TS for detection of viruses in LBM and other foods including fresh produce.

1.2.2. Lead and co-ordinate the activities of CEN/TC275/WG6/TAG15 'Vibrios' in the elaboration of methods for the determination of pathogenic marine vibrios in bivalve shellfish, particularly for *V. parahaemolyticus* and *V. vulnificus*^e.

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

1.2.3. Act as 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^f.

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

1.2.4. 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).

1.2.5. Contribute to the project for revision of ISO 22117 on organisation of proficiency testing.

1.2.6. Contribute to relevant EFSA expert working groups, including the WG on heat treatment of bivalve molluscs, and the WG to provide scientific and technical assistance on the baseline survey on Norovirus in oysters, and additional groups as required.

1.2.7. Represent the EURL at the annual plenary meeting of the CEN WG6 and ISO SC9 microbiology working groups^g.

^g EU representation at CEN and ISO microbiology expert groups

1.2.8. Contribute towards the FAO/WHO initiative developing best practice guidance for the application of bivalve molluscan shellfish sanitation programmes^h.

^h Enhanced EURL scientific reputation and



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

impact

The EURL will:-

- 2.1. Conduct project management of the EURL programme according to the requirements of EN ISO 9001 Quality Management Systems^j.
- 2.2. Participate in the EURL Director's co-ordination meeting and other EURL co-ordination meetings/workshops as appropriate.
- 2.3. Organise, host, and participate in the annual EURL workshop of NRLs for monitoring bacteriological and viral contamination of bivalve molluscs, produce resolutions and other workshop outputs. In 2016, the workshop will be held at the NRL Germany at the Federal Institute for Risk Assessment, Berlin, (25th-27th May 2016). A venue and date for the 2017 workshop will be agreed at the 2016 meeting^k.
- 2.4. Further to the above, undertake EURL activities and commitments agreed in resolutions at the annual workshops above (as posted on <https://eurlcefass.org/public-documents/workshops-of-nrls.aspx>).
- 2.5. 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^l.

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

^k harmonisation of official controls across network of NRLs

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

3. Provision of technical advice and training

The EURL will:-

- 3.1. Develop and maintain technical guidance documents describing the generation and calculation of precision characteristics associated with the virus reference method (ISO TS 15216-1) e.g. limit of detection, limit of quantitation, linearity and measurement uncertainty to support the setting of quantitative limits in LBM^m.
- 3.2. Provide technical advice on request on ISO 15216 (the virus reference method) for matrices other than bivalve molluscs (e.g. soft fruits) to MS, NRLs and Official Control testing laboratories^c.
- 3.3. 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 requiredⁿ.
- 3.4. 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. These will be available in the public domain on the EURL websiteⁿ.

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

ⁿ improvements in performance and increased standardisation across laboratories



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- 3.5. Provide assistance on implementation of methods, accreditation to IEC ISO17025 and quality control requirements (see above)ⁿ.
- 3.6. Generate and distribute norovirus and hepatitis A virus reference materials and control materials, and *Vibrio* spp. EURL reference strains on request of NRLsⁿ.
- 3.7. Provide guidance and review of procedures/data to laboratories wishing to undertake studies to validate alternative methods according to ISO 16140. To include formal assessment of validation data as required to support official approval (at SCFCAH) for alternative methodsⁿ.
- 3.8. Provide specialist *ad hoc* training to NRLs and others in relation to analyses of LBM for microbiological contaminants as requiredⁿ.
- 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 (e.g. soft fruits) to NRLs and Official Control testing laboratories. To include advice on sampling plans, sample transport and result interpretationⁿ.
- 3.10. Provide specialist training in application of the standard method for quantification of viruses (ISO 15216-1), to NRLs and Member State OCLs, designated by MS competent authorities to participate in the laboratory testing element of the EFSA baseline survey on Norovirus in oysters. This training to be provided through dedicated workshops hosted at the EURL^p.
- 3.11. Further to the above, the EURL will provide assistance to DG SANTE, EFSA, MS competent authorities, NRLs and OCLs in support of the EFSA baseline survey, through provision of protocols and reagents^p.
- 3.12. Provide advice to NRLs and competent authorities regarding the implementation of official controls.

^p ensuring the EFSA baseline survey is as robust as possible

4. Confirmatory testing and quality assurance

The EURL will:-

- 4.1. Maintain 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^q.
- 4.2. Maintain 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* and attainment and/or maintenance of ISO IEC 17025 accreditation for detection of *Vibrio vulnificus* and *V. cholerae*^q.

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



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- 4.3. Perform the above-named tests on outbreak material or on occasion of disputed test results (on request)^f. ^r technical advice to support EU

5. Comparative testing and ring trials

The EURL will:-

- 5.1. Organise comparative testing for NRLs for statutory determinands (*E. coli* and *Salmonella* spp.) in bivalve molluscs. To include organisation of one whole-animal distribution per calendar year, and co-ordination of NRL participation in one or more of the three non-matrix External Quality Assessment (EQA) schemes organised in collaboration with Public Health England (PHE) per calendar year. For both EURL- and EURL/PHE-organised schemes, the EURL will analyse results and produce a report, plus additional advice and recommendations. To improve quality assurance in test results for EU controls comparative tests organised by the EURL will be available to laboratories outside of the NRLs network on a cost recovery basis^s.
- 5.2. Support implementation of quality assurance standards for virus testing by organising two distributions of samples containing norovirus and hepatitis A virus in each calendar year for comparative testing for quantitative and qualitative analyses. The EURL will analyse results, and produce a report and recommendations. 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^s.
- 5.3. Further to the above, the EURL will include non-NRL Member State OCLs, designated by MS competent authorities to participate in the laboratory testing element of the EFSA baseline survey for Norovirus in oysters, in one distribution of samples containing norovirus and hepatitis A virus in 2016 for comparative testing for quantitative analyses. Analyse results, produce report and recommendations specifically to support the survey^p.
- 5.4. Organise comparative testing for pathogenic *Vibrio* spp. (one distribution per calendar year) to support methodological improvements. Analyse results, produce report and recommendations^s.

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

6. Development of analytical methods

The EURL will:-

- 6.1. Develop methods for inclusion in ISO TS 21872 (detection of vibrios), particularly to enable enumeration of total / pathogenic *V. parahaemolyticus* in imported / indigenously produced bivalve shellfish^e.
- 6.2. Work with colleagues, including the EU Joint Research Council, Geel, to elaborate control materials to assist in the standardisation of ISO methods for noroviruses and hepatitis A virusⁿ.



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- 6.3. Work with the NRLs network to identify means to improve the harmonisation of quantification between laboratories using ISO 15216-1, the standard method for detection of viruses in foodsⁿ.
- 6.4. Develop methods to improve determination of the potential infectivity of noroviruses detected in bivalve shellfish^t.
- 6.5. Undertake analysis of dye-tracing studies carried out in 2015, and using the expertise developed during those studies, provide support to Member States wishing to apply that approach in support of satisfying additional requirements for production areas from which LBM are harvested for export to the USA^b.

^t improved understanding
of the public health
significance of norovirus
test results

NOTE: to support development of analytical methods under 6.1 and 6.4 it is proposed that a studentship(s) is supported by the EURL up to a maximum value of £10,000 per calendar year.