

National Reference Laboratory: Annual report

FS616026/C8333 - Bacterial contamination of bivalve molluscs

Authors: Dr Craig Baker-Austin and Louise Stockley

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Project Manager:	Myriam Algoet
Report compiled by:	Dr Craig Baker-Austin & Louise Stockley
Quality control by and date:	Michelle Price-Hayward, 22/04/2022
Approved by and date:	Dr Myriam Algoet, 01/07/2022
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1. Executive summary

This report outlines the key delivery outputs from the Cefas National Reference Laboratory (NRL) FS616026/C8333 - Bacterial contamination of bivalve molluscs for the period April 2021 to March 2022.

Highlights include:

- Maintenance of expertise in bacteriological analysis of bivalve molluscs, including maintenance of accreditation for all relevant methods
- Successful participation in all relevant proficiency testing schemes
- Re-launch of standalone website for the NRL
- Active participation in committees and working groups addressing standardisation of methods relevant to foodborne viruses
- Provision of advice to official laboratories and competent authorities on methodologies
- Contribution to review of official methodology and capabilities within the UK for *E.coli* testing of shellfish
- Assessment of *E.coli* method suitability for use in periwinkles and sea-urchins.

2. Glossary

BSI	British Standards Institution
CA	Competent Authority
Cefas	Centre for the Environment, Fisheries and Aquaculture Science
CEN	European Committee for Standardisation
<i>E. coli</i>	<i>Escherichia coli</i>
EURL	European Union Reference Laboratory
FSA	Food Standards Agency
FSS	Food Standards Scotland
ISO	International Organisation for Standardisation
KPI(s)	Key Performance Indicator(s)
OL(s)	Official Laboratory (ies)
NRL	National Reference Laboratory
MPN	Most Probable Number
PT	Proficiency Testing
SOP	Standard Operating Procedures
SSWG	Shellfish Stakeholder Working Group
UKAS	United Kingdom Accreditation Service
UKHSA	UK Health Security Agency (previously known as Public Health England (PHE))

3. Introduction

Cefas was redesignated as the National Reference Laboratory (NRL) for Bacterial contamination of bivalve molluscs by the FSA in the Spring of 2021, following on directly from previous designations covering the period February 2018 to March 2021.

The roles and responsibilities of the NRLs have changed significantly in recent years. The services required to be delivered under the scope of the current Cefas/FSA agreement include duties, based on Articles 100-101 of Regulation (EU) 2017/625 (retained from January 1st 2021 in UK law subject to amendments through Statutory Instrument 2019 No. 665; The Official Controls for Feed, Food and Animal Health and Welfare (Amendment etc.) (EU Exit) Regulations 2019):

- (a) cooperate internationally in their area of competence (and where possible, the relevant European Union Reference Laboratory (EURL);
- (b) collaborate with international laboratories (where possible with the relevant EURL) and participate in training courses and inter-laboratory comparative tests organised by these laboratories;
- (c) coordinate the activities of laboratories designated by FSA and FSS (the competent authorities (CA)) as official laboratories (OLs) under Article 37 of Retained Regulation (EU) 2017/625 (OCR) for the *E. coli* monitoring of shellfish from England, Wales and Scotland;
- (d) where appropriate, organise comparative tests between OLs and ensure an appropriate follow-up of such comparative testing;
- (e) ensure the dissemination of any information required by the CA;
- (f) provide scientific and technical assistance to the CA for the implementation of multi annual national control plans (MANCP) in accordance with Article 109 and of co-ordinated control plans adopted in accordance with Article 112 of (retained) Regulation (EU) 2017/625;
- (g) where necessary, conduct training courses for OL staff;
- (h) upon request by the competent authority, actively assist in relevant emergency

situations and in cases of non-compliance of consignments, carry out confirmatory analysis;

- (i) be responsible for carrying out other specific duties as required by the CA, where appropriate and by prior agreement.

This technical report summarises the activities carried out by the NRL during the financial year 2021-22 (April 2021-March 2022). Delivery of the responsibilities of the NRL has been divided into the following key objectives of the Agreement signed between FSA and Cefas:

1. Provision of core functions/secretariat services (Section 4)
2. Advice and representation within the UK and internationally (Section 5)
3. Production of standard operating procedures, codes of practice and guidance documents (Section 6)
4. Compliance assessment via audits and PT (Section 7)
5. Co-ordination within the UK of international initiatives (Section 8)
6. Communication of results and data use (Section 9)
7. Discussion of specialised areas, e.g. research activities (Section 10)
8. Link to NRL website (Section 11)

4. Core function: secretariat services

Item	Activity in period
Disseminating relevant information to the CA and OLs	<p>In addition to the scheduled project review meetings with the FSA/FSS customers on 29th July, 6th October, 9th December and 9th March, the NRL Director and team have been in regular contact with the FSA during the year to provide the CA, OLs and industry with advice on key matters such as:</p> <ol style="list-style-type: none">1) Performance characteristics regarding the MPN method and impacts of class A criterion (CA, Spring and Summer 2021).2) Availability and performance characteristics of alternative <i>E. coli</i> test methods, including impedance and pour plate methods provided to CA and industry (Spring and Summer 2021).3) Provided questionnaire on this issue to OLs Winter 2021 and collated responses to FSA for consideration.4) Implementation of <i>E. coli</i> testing requirements post-Brexit (OLs, Summer 2021).

	<p>5) Availability of various culture media (OLs, various Summer 2021).</p> <p>6) Cefas provided a liaison with OLs and CAs in relation to NRL network meeting (Winter 2021).</p> <p>7) Enquiries regarding the origin of upper limit of 700 <i>E. coli</i> MPN/100g for bivalve shellfish class A areas and supporting publications (CA, June 2021).</p> <p>8) Performance of designated OLs for <i>E.coli</i> in shellfish (CA, Winter 2021).</p> <p>9) National capacity and national monitoring plans (CA, Winter 2021).</p>
<p>Co-ordinating the activities of OLs responsible for analysis of official control samples to ensure verification of compliance with feed and food law</p>	<p>The NRL held formal liaison meetings with the designated OLs from UK Health Security Agency (UKHSA) (previously Public Health England) on 6th May 2021 and again on December 12th 2021. A formal review meeting was held with designated OLs from Public Health Wales on 5th November 2021.</p> <p>Issues covered during these meetings included impacts of Covid on OL testing, changes to UKHSA, staffing considerations and issues, update on classification changes, reporting of results and timely identification of outwith results against agreed key performance indicators (KPIs).</p> <p>The annual network meeting was held in December 2021 (delayed by staffing availability and workloads associated with Covid pandemic).</p>
<p>Providing regular updates to the CA, OLs and other labs</p>	<p>As per the FSA/Cefas agreement, formal updates are in the form of monthly finance updates and (from November 2021) activity logs as well as 6-monthly reports submitted in the Autumn and Spring of each year.</p> <p>Issues reported in period:</p> <ul style="list-style-type: none"> • Updates to OLs regarding the availability of culture media has taken place over the last 12 months; • Requirements for reporting method uncertainty (MU) and impact on accreditation; • Update on the impact of Brexit and the Covid-19 pandemic on OL delivery; • Shortages of consumables.
<p>Creation & maintenance of NRL website</p>	<p>Following the split of the virus and bacteriological NRLs, a dedicated website providing information on the bacteriological contamination of bivalves NRL was launched and edited accordingly (Spring 2021). The website was modified based on feedback from FSA and is subject to continuous informal improvements. Some edits to specific content areas (e.g. removal of reference to EU regulations, retained UK legislation, etc.) have</p>

been carried out during the last 12 months. Specific maintenance of sections such as methods, current activities, PT, laboratory network information, and an information centre page with reports, publications and other relevant documents relating to bivalve shellfish sanitation were also prepared. Further amendments were conducted after review of the website by FSA. Following the NRL meeting (December 2021), presentations and PT report were uploaded to the NRL website in January 2022.

The content of the website was checked for compliance with accessibility rules and corrections made where required.

See section 11 of this report for link to the website

5. Core function: advice and representation within the UK and internationally (including a summary of meetings attended and any international collaboration activities)

Item	Activity in period
Providing impartial advice to the NRL laboratory network on analytical methodology and risk assessment	<p>Discussions with FSS, OLs and other laboratories on echinoderm and gastropod testing for <i>E. coli</i> (various through Summer 2021-Spring 2022).</p> <p>Provided advice to various OLs regarding the method uncertainty associated with the <i>E. coli</i> MPN method (March 2022). Questions and subsequent discussion regarding this were also brought up at the NRL network meeting, December 2021.</p> <p>Provision of ongoing support to FSS/Laboratory in relation to suitability of <i>E. coli</i> methodology used by a commercial laboratory appointed by Scottish Industry (Spring and Summer 2021).</p> <p>The UK NRL contributed to the review of the FSA MANCP for FY22/23 (submitted in January 2022).</p> <p>The UKNRL responded to the FSA review of National Capacity in January 2022.</p>
Representing the UK at relevant international meetings and working groups	<p>No EURL meeting was held in the reporting period.</p> <p>The NRL attended (virtually) the ISO/TC 34/SC 9 plenary meeting in June 2021 and presented at this meeting on method standardisation efforts regarding vibrios.</p> <p>The NRL also attended (virtually) the BSI AW/9 meetings (UK committee on standardisation of Food Microbiology Methods) in May and August 2021.</p> <p>The NRL has also provided representation at various SSWG (Shellfish Stakeholder Working Group including Seafish, Industry & regulators) meetings organised in the last 12 months, including meetings virtually on 27/5/21, 12/10/21 and 7/12/21.</p>
Participating in other international activities	No activity delivered/requested in period.
Advising on best scientific practice	The UK NRL provided miscellaneous advice to FSA and FSS on a number of matters during the Summer and Autumn of 2021, including an NRL perspective on laboratory performance (e.g. commercial testing laboratories and their testing methods for <i>E. coli</i> determination in shellfish), and enquiries regarding the origin of

	<p>upper limit of 700 <i>E. coli</i> MPN/100g for bivalve shellfish class A areas and supporting data. The NRL has also developed various SOPs and a report based on various experiences of gastropod and echinoderm testing (Winter and Spring 2021/2022, respectively).</p> <p>The UK NRL also provided advice to both FSA and industry on alternative <i>E. coli</i> testing methods such as pour plate. The UK NRL attended a FSA-led meeting on this matter in January 2022.</p>
Maintaining expertise	<p>See other sections of this table for attendance at national and international scientific conferences, workshops and for activities relating to standardisation.</p> <p>Laboratory activities have been undertaken towards maintenance of UKAS accreditation of the NRL.</p> <p>Liaison with Marine toxins NRL in relation to testing of marine gastropods and ongoing collaboration with foodborne viruses NRL and other UK NRLs.</p> <p>The UK NRL engaged with UKAS and FSA/FSS prior to & following LAB33 consultation.</p>
Involvement in standardisation activities relevant to work area	<p>The Director of the UK NRL has been actively involved in method standardisation activities linked to general areas of competence. Craig Baker-Austin participated in ISO WG standardisation efforts (vibrios) throughout 2021 and 2022. These included reviewing the final drafts of International Standards (ISO) documents and providing comments to the secretariat, clarifying issues related to the ISO 21872-1 (<i>vibrio</i>) test methods. Dr Baker-Austin also collated edits from the ISO WG (WG27) regarding amendments to the <i>Vibrio</i> ISO (21872-1), (Winter 2021).</p>
Supporting FSA/FSS with emergency situations	<p>No activity delivered/requested in period.</p>

6. Core function: production of standard operating procedures, codes of practice and guidance documents

Item	Activity in period
Contributing to the development of standardised protocols	<p>Through 2021 and early 2022, the UK NRL has liaised with both FSA and FSS and contributed to discussions and initiation of laboratory work for echinoderm and gastropod testing with the aim to develop a</p>

and advisory documents	NRL SOP for <i>E. coli</i> testing in these species. Laboratory work has recently been completed (March 2022) and will be summarised in a report as well as a short SOP.
Validating reagents	Discussions held with OLs regarding alternative suppliers of media

7. Core function: compliance assessment via audits and ring trials

Item	Activity in period
Ensuring consistency and quality of testing approaches	<p>The UK NRL conducts a 12-monthly review of the accreditation status of UK designated official laboratories for statutory testing and found all laboratories in the network with the current and necessary accreditation status for classification testing of live bivalve shellfish. The NRL provides appropriate support for OLs in relation to problems experienced in the examination of foods within scope or the bacteriological examination of bivalve molluscs. During this 12-monthly period no issues were observed in this context. No other laboratories carrying out live bivalve shellfish testing for official testing purposes have put forward to join the network in the last year (April 2021-March 2022).</p>
Organising PT for GB OLs & ensuring appropriate follow up	<p>PT 85 (whole animal <i>E. coli</i> and Salmonella) was circulated to all UK OLs in April 2021. Eleven OLs received the samples within 24 hours of dispatch as recommended by the NRL, and all eleven laboratories analysed the samples on the day of arrival. All results for <i>E. coli</i> and Salmonella were satisfactory based on the results provided.</p> <p>In the absence of a designated NI UKNRL for bacterial contamination when PT87 was launched (Winter 2021), Cefas extended the scope of this PT to Northern Ireland OLs.</p> <p>PT 87 (whole animal <i>E. coli</i> and Salmonella) was circulated to all UK OLs in December 2021. Eleven OLs analysed the samples on the day of arrival. Information provided by laboratories on the arrival temperature of the samples showed the maximum temperature recorded by participants did not exceed the recommended transport temperature of <10°C set out in the NRL generic protocol. In general, most of the results for <i>E. coli</i> and Salmonella were satisfactory based on the results provided, with a small number of exceptions: Two laboratories out of eleven reported both replicate results between ± 3 and ± 5 SD of the participants' median and scored 9 and 6 respectively (sample 2). One laboratory out of nine incorrectly reported the absence of <i>Salmonella</i> spp. and received a score of 0</p>

	(again sample 2). For sample 3, one laboratory out of eleven involved in this PT reported both replicate results ± 3 and ± 5 SD of the participants' median and scored 6. One laboratory reported 1 replicate result outside ± 5 SD of the participants' median and scored 7.
Co-ordinating the participation of GB OLs and other relevant laboratories in international method validation studies and other initiatives	No activity delivered/requested in period
Participating in PT and method validation studies organised by international organisations	<p>During the reporting period, the UK NRL has participated in 4 relevant proficiency testing (PT) schemes:</p> <ul style="list-style-type: none"> • EURL Salmonella PT - Round 2 was organised in August 2021 (was expected in March) comprising 6 spiked samples. The NRL correctly reported the presence or absence of <i>Salmonella</i> spp. in each sample. • EQA Shellfish scheme: <ul style="list-style-type: none"> ○ Results received for SF067 in April 2021. Only 1 replicate <i>E. coli</i> result was reported for both samples. Full marks were recorded for the enumeration of <i>E. coli</i> and the detection of <i>Salmonella</i> spp. ○ Participated in SF068 (July 2021). Full marks were recorded for the enumeration of <i>E. coli</i> and the detection of <i>Salmonella</i> spp. • EQA Vibrio scheme - Participated in V060 (July 2021). <i>Vibrio parahaemolyticus</i> was reported correctly for both samples.
Co-ordinating training exercises to promote best laboratory practice in respect of analysis	<p>No activity delivered/requested in period.</p> <p>Training and/or demonstration activities are delivered in conjunction with the annual NRL network meeting.</p>
Providing OLs advance notice of PT	Notice to OLs that PT 87 (Enumeration of <i>E. coli</i> and the detection of <i>Salmonella</i> spp. in shellfish matrix) was emailed to participating laboratories on 13 th September 2021. PT scheme sent December 2021 to OLs.

8. Core function: co-ordination within the UK of international initiatives

Item	Activity in period
Co-ordinating the implementation in the UK of international initiatives	No relevant CEN/ISO recommendations were received by the NRL during this reporting period.

9. Core function: communication of results and data use

Item	Activity in period
Providing regular updates to the CA	<p>The NRL has provided regular reporting to the FSA, through the means of email, telephone (where appropriate), and via monthly and 6-monthly reports.</p> <p>Because of the current Covid-19 pandemic no face-to-face meetings were conducted in the last year.</p> <p>Quarterly review meetings were held on 29/07/2021 (Q1), 06/10/2021 (Q2), 09/12/2021 (Q3) and 09/03/22 (Q4).</p> <p>In addition, Cefas provided FSA with monthly summaries of costs showing staff effort and non-pay costs throughout the year, and with monthly technical delivery summaries from November 2021 onwards.</p>
Notification of deviations or unusual occurrences	<p>No deviations identified in this reporting period.</p> <p>Issues linked to EU Exit/Covid-19 (consumables and media shortages for example) were reported to FSA as and when they occurred in the period.</p>
Completing annual reports	The annual report for the previous contract was submitted to the FSA on the 9 th July 2021. It has since been approved and posted on the NRL website.
Managing data and information	Data and documents associated with the NRL function has been stored in accordance with Cefas' data management systems.
Providing meeting reports	Notes from contractual update meetings were provided to FSA within the agreed timeframe.

Notes from other meetings attended on behalf of the NRL were also provided to FSA in the period, with the exception of SSWG and UKAS meetings which were also attended by FSA. See list of reports in Section 12.
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10. Discussion of specialised areas e.g. research activities

Note: the NRL workplan for FY21/22 was drafted for review by FSA at the Q1 review meeting but only formally agreed at the Q2 review meeting held on 06/10/2021. The table below lists the activities delivered against each of the agreed priorities for FY2122.

Agreed priority for FY2122	Activity in period
Validation of current <i>E. coli</i> MPN method for gastropods/echinoderms	The NRL has contacted various OLs as well as international laboratories that conduct echinoderm and gastropod testing and gathered SOPs regarding the sample processing of these shellfish species. We have studied various SOPs with the aim of merging these approaches into our current workflow. We have also obtained advice and clarification regarding our accreditation status regarding this testing. In addition, we have sought commercially available shellfish species and carried out various laboratory testing of gastropods in the Spring of 2022. We have collated a detailed report on this work which will be circulated to FSA shortly.
Effects of different storage temperatures on media	We have designed a preliminary experimental approach to study the impact of media temperatures (e.g. MMGB) on <i>E. coli</i> testing results. Due to staff shortages, this work was postponed to Q1 of FY22/23.

11. Link to NRL website

[UK National Reference Laboratory \(NRL\) for bacteriological contamination of bivalve molluscs - Cefas \(Centre for Environment, Fisheries and Aquaculture Science\)](#)

12. Annex – Summary of documents produced from NRL activities

Date produced	Title of document
17.05.21	PT 85 – Whole animal enumeration of <i>E. coli</i> and the detection of <i>Salmonella</i> spp. in bivalve molluscan shellfish (PT 85)
04.06.21	PT 84 – PHE EQA shellfish scheme final report submitted to FSA (PT exercise conducted under previous NRL contract)
26.07.21	Draft workplan for FY21/22 submitted to FSA
03.08.21	Summary report of annual plenary meeting of CEN/TC463 and ISO/TC34/SC9 (June 2021) submitted to FSA
05.08.21	Summary report of BSI AW/9 May 2021 meeting (UK committee on standardisation of food microbiology methods) submitted to FSA
24.08.21	Summary report of BSI AW/9 August 2021 meeting (UK committee on standardisation of food microbiology methods) submitted to FSA
Monthly	Summary of cost breakdown submitted to FSA
05.08.21	Draft minutes of NRL Q1 meeting submitted to FSA within the agreed turnaround time. Minutes amended following submission of comments by FSA
30.09.21	Draft agenda and documentation for Q2 review meeting submitted to FSA
04.10.21	Research priority breakdown for FY2122 submitted to FSA
19.10.21	Draft minutes of NRL Q2 meeting submitted to FSA within the agreed turnaround time. Minutes amended following submission of comments by FSA
28.10.21	Draft National Reference Laboratory for Bacteriological contamination of bivalve molluscs Interim report submitted to FSA

30.11.21	Final National Reference Laboratory for Bacteriological contamination of bivalve molluscs Interim report submitted to FSA
Monthly (from November onwards)	Technical update reports submitted to FSA
03.12.21	Draft agenda and documentation for Q3 review meeting submitted to FSA
04.01.22	Draft minutes of NRL Q3 meeting submitted to FSA within the agreed turnaround time. Minutes amended following submission of comments by FSA
12.01.22	PT 87 – Whole animal PT final report submitted to FSA and OLs
25.01.22	Draft minutes of BSI AW9 meeting (UK committee on standardisation of food microbiology methods) submitted to FSA
16.02.22	UK NRL submitted contribution to MANCP
Feb 22	UK NRL submitted response to Defra online survey on EURL engagement
08.03.22	Draft agenda and documentation for Q4 review meeting submitted to FSA
08.03.22	Interim summary of OLs responses to NRL questionnaire on <i>E. coli</i> alternative methodologies provided to FSA
11.03.22	Draft minutes of NRL Q4 meeting submitted to FSA within the agreed turnaround time. Minutes amended following submission of comments by FSA
21.03.22	Final report on 2021 OL performance submitted to FSA
21.03.22	Final summary of OLs responses to NRL questionnaire on <i>E. coli</i> alternative methodologies provided to FSA
29.04.22	Draft National Reference Laboratory for Bacteriological contamination of bivalve molluscs Annual report submitted to FSA



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Pakefield Road, Lowestoft, Suffolk, NR33 0HT

The Nothe, Barrack Road, Weymouth DT4 8UB

www.cefasc.co.uk | +44 (0) 1502 562244

