UK Health Security Agency

Audit of Official Laboratories capabilities and accreditation status in the UK

2019 and 2022 results

Contents

Executive summary

The UK Health Security Agency (UKHSA, formerly Public Health England) has provided the UK's National Reference Laboratory (NRL) for food microbiology for the Food Standards Agency (FSA), as part of the UK's obligation to adhere to the Regulation (EU) 2017/625 for official controls. This report details the 2019 results from a survey sent to the Official Laboratories (OLs) from the NRL, to ensure appropriate support is given to the OLs.

Most of the same questions were used in this survey as in the 2016 version of the survey in order to draw comparisons over time. The online survey tool, Select Survey, was used to send the questions to 14 OLs. Details of food examiner (FE) status, schedule of tests performed, participation in proficiency test (PT) schemes and reporting mechanisms for unacceptable results were requested. All 14 OLs responded, although some data was missing from one OL. To ascertain the impact of COVID-19 and EU Exit on the OLs, a further set of questions were sent to the OLs in 2022, where 12 OLs submitted responses.

This audit revealed that the number of laboratories has remained stable since the last audit in 2016, and numbers of food examiners have increased from 40 to 45 between 2016 and 2019, which will help to improve the capacity for microbiological testing of food for official control purposes. The distribution of FEs in the OL network vary considerably, and this is reflected in the number of official control samples received, as these are also unevenly dispersed between the OLs. However, there appears to be a continued effort to increase staff resource, expertise and knowledge, as there were 10 trainee FEs in 2019, supported by 8 OLs, and all UK OLs are accredited to the new version of ISO 17025 (2017), covering general requirements for the competence of testing and calibration laboratories.

Overall, there has been improvement in the testing capabilities of the UK OL network, according to the EU microbiological criteria (as stipulated in EC 2073/2005). Notably, detection of Shiga toxin producing E.coli (STEC) in sprouts (criterion 1.29) and enumeration of Campylobacter in broiler carcases (2.1.9) have seen good implementation in the OLs, due to them being recent additions to the microbiological criteria, for which the NRL has run training workshops to support the OLs. In contrast, a few tests were only accredited in a small number of laboratories including detecting the presence of staphylococcal enterotoxins in cheeses, milk powder and whey powder (1 of 14 laboratories), Cronobacter in dried products intended for less than 6 months (1 of 14) and histamine in fish (3 of 14). Reasons for the low uptake of these tests may include that they are highly specialised tests, and/or rarely requested in the UK, making maintaining accreditation and competence in OLs difficult to attain and justify. However, the NRL can notify OLs where this testing can be performed when it is required, to retain the UK's capability to adhere to the Official Control Regulations.

There is also an increase in participation in PTs by the UK OLs, and there is no evidence of ongoing poor performance by any of the laboratories when assessing the OLs using the European Food Microbiology Legislation Scheme. PT participation assures competence and

quality when generating laboratory results, which is particularly important for official controls and formal samples. Ten OLs rely on their customers to report unacceptable results to FSA, although several commented that they also report some results directly to contacts in the FSA. A clear mechanism to report unacceptable results is recommended to improve reporting levels, increase consistency and accelerate possible mitigation actions.

In order to continually improve and match the needs of the OLs, the survey included questions regarding NRL activities. Most OLs are aware of the National methods on the NRL web page and would like more training from the NRL, including ‘Interpretation of EC 2073/2005’, which will be covered in a training workshop in 2023.

Additional questions were asked in March 2022, after leaving the EU and the COVID-19 pandemic. These events caused suspension of OL work and reduced staffing levels (both due to COVID-19) and problems procuring laboratory consumables (due to a combination of both events). However, the OLs have shown resilience and continued to offer microbiological testing in food for the UK. A repeat survey to ascertain the ongoing situation will provide a clearer picture of how leaving the EU and the COVID-19 pandemic has affected the UK OLs on a longer term basis.

Abbreviation list

Abbreviation	Meaning
AMR	Antimicrobial resistance
CEFAS	Centre for Environment, Fisheries and Aquaculture Science
COVID-19	Coronavirus Disease 2019
CPS	Coagulase-positive Staphylococci
EFL	European Food Microbiology Legislation (scheme)
EQA	External Quality Assurance
FBO	Food Business Operator
FE	Food Examiner
FEPTU	Food and Environmental Proficiency Testing Unit
FSA	Food Standards Agency
FSS	Food Standards Scotland
FWEMS	Food, Water and Environment Microbiology Service
ISO	International Standards Organisation
NRL	National Reference Laboratory
OL	Official Laboratory (previously OCL, Official Control Laboratory)
OCR	Official Control Regulations
PCR	Polymerase Chain Reaction
PHE	Public Health England
PT	Proficiency Test
PHC	Process Hygiene Criteria
RTE	Ready to eat
STEC	Shiga-toxin producing *E. coli*
UKAS	UK Accreditation Service
UKHSA	UK Health Security Agency

Introduction

Since 2011, Public Health England (PHE) has provided the UK's National Reference Laboratory (NRL) service for food microbiology for the UK's Competent Authority, the Food Standards Agency (FSA). The NRL's main function is to provide advice, training and other support to the other UK Official Laboratories (OLs), as defined in Regulation (EU) 2017/625 (adopted by UK Statutory Instrument 2019 No. 665), for the following work areas: AMR, *Campylobacter* coagulase-positive staphylococci, *Escherichia coli* (including STEC), *Listeria monocytogenes and Salmonella.*

In 2013 and 2016, the NRL undertook audits of the OLs to ascertain accreditation status, numbers of food examiners employed, tests available and membership of proficiency test (PT) schemes. Gaps in testing or training areas were identified from those audits, which led the NRL to perform certain activities, such as organising practical training workshops in STEC detection and *Campylobacter* enumeration, where accreditation of these methods amongst OLs were low. Consequently, in 2016 there were 3 OLs accredited for *Campylobacter* enumeration compared to no OLs being accredited in 2013, thus increasing the UK's capability.

In 2019, a third audit was organised to evaluate whether the UK has adequate capability and capacity for microbiological testing from food, especially in light of EU Exit and updates in UK and EU legislation. Due to the COVID-19 pandemic, publishing of this report was delayed. Therefore, an additional series of questions was sent to the OLs in 2022 to ascertain whether the COVID-19 pandemic and/or EU Exit has impacted on their capability and running as an OL. The UK NRL will use this information to support and advise the UK OLs.

Method

The questions from the 2016 audit were reviewed and an updated survey was drafted, which requested information on capabilities and capacity, including food examiner status, accreditation under ISO 17025:2017, participation to PT schemes and reporting routes for official control results. To ascertain which test methods the OLs perform on which matrices and their accreditation status, the approach used for the 2016 audit was repeated, and Annex 1 of the 2073/2005 microbiological criteria (including amendments) was modified. This facilitated data gathering and entry for the OLs and results could be directly compared with 2016 data. The final part of the survey captured information regarding services from the National Reference Laboratory, such as training and support activities.

Select Survey was used to maximise response rate and minimise data entry. After testing the survey internally, the URL link and amended Annex 1 table were sent to all the OL contacts identified from NRL records and the FSA website (n=14 laboratories), in October 2019. The closing date for responses was 31 December 2019. Responses were then downloaded from

Select Survey and analysed on a question-by-question basis using Excel. For those questions that were identical from previous audits, direct comparisons were then made.

A further set of questions were sent in March 2022 to the OLs, to capture any changes found during and after the COVID-19 pandemic and EU Exit. These were added to the Excel sheet and analysed on a question-by-question basis.

Results

All 14 OLs submitted results, generating a response rate of 100%. However, one laboratory did not upload the amended Annex 1 table, therefore data from 2016 was used for this OL.

Results of the audit is presented in sequential order. Questions 1 and 2 relate to contact details, therefore results are not included in this report to retain anonymity. Results for question 16 which relates to the examinations performed in accordance to the microbiological criteria of EU 2073/2005 (as amended) are presented by the microorganism in specific food groups. The tables show the 2019 results and the charts compare these to the 2016 audit results.

The additional questions from 2022 are shown separately and were responded to by 12 of the 14 OLs.

Comments are found in the Discussion and Conclusion section.

Audit questions sent October 2019

Q3. Do you currently perform microbiology tests in food and feed?

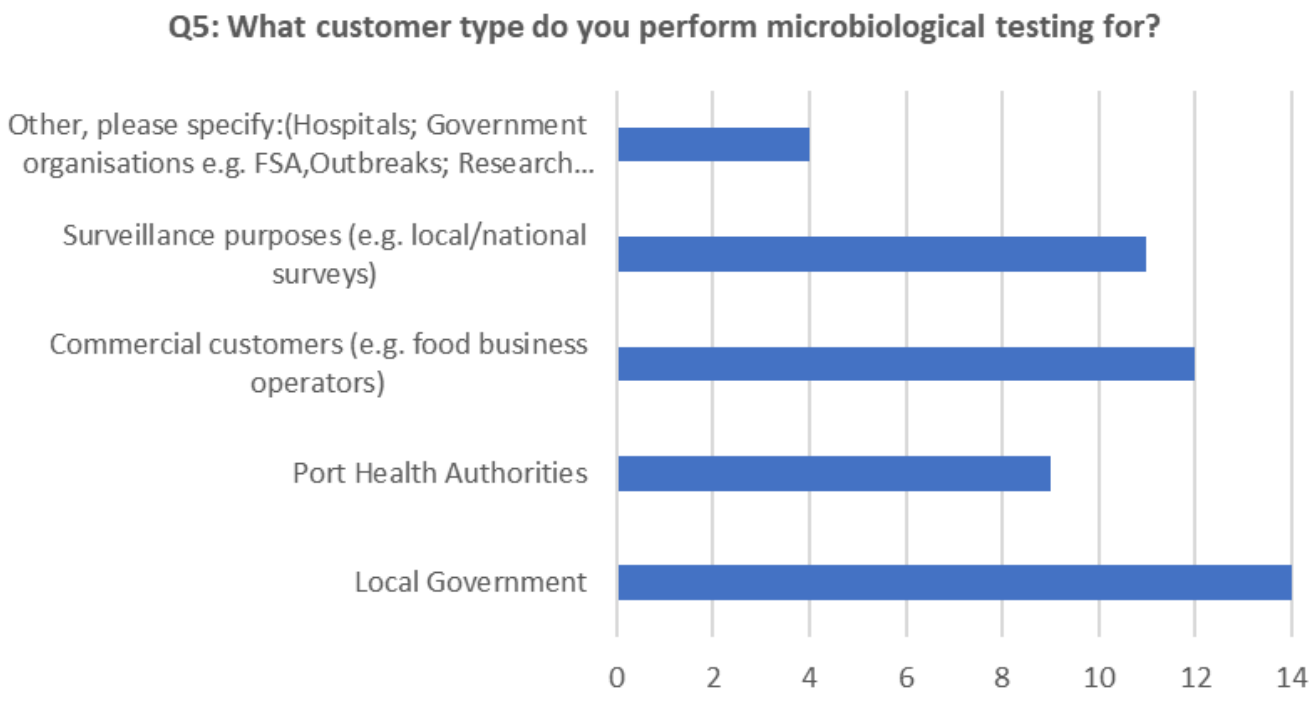
Yes:	14	(100%)
No:	0	(0%)

Q4. Do you currently perform microbiology tests for Official Control purposes in food and feed, including for any other government bodies?

Yes:	14	(100%)
No:	0	(0%)

Q5. Do you perform microbiological testing for the following:

Customer Type	Number of OLs
Local Government	14
Port Health Authorities	9
Commercial customers (for example food business operators)	12
Surveillance purposes (for example local or national surveys)	11
Other, please specify: (Hospitals, Government organisations for example FSA,Outbreaks, Research Projects such as Food Standards Scotland, and Private customers)	4



Q6. On Average, how many Official Control samples are submitted for testing every year?

7 OLs responded

Number of samples: 1; 200; 220; 550; 6,700; 10,000; 10,000

Q7. Do you send samples to another laboratory for microbiological testing that your own laboratory is unable to do?

1 OL did not respond

Yes, to another UK laboratory	5	(38%)
Yes, to another EU laboratory	0	(0%)
No, able to perform all testing	8	(62%)

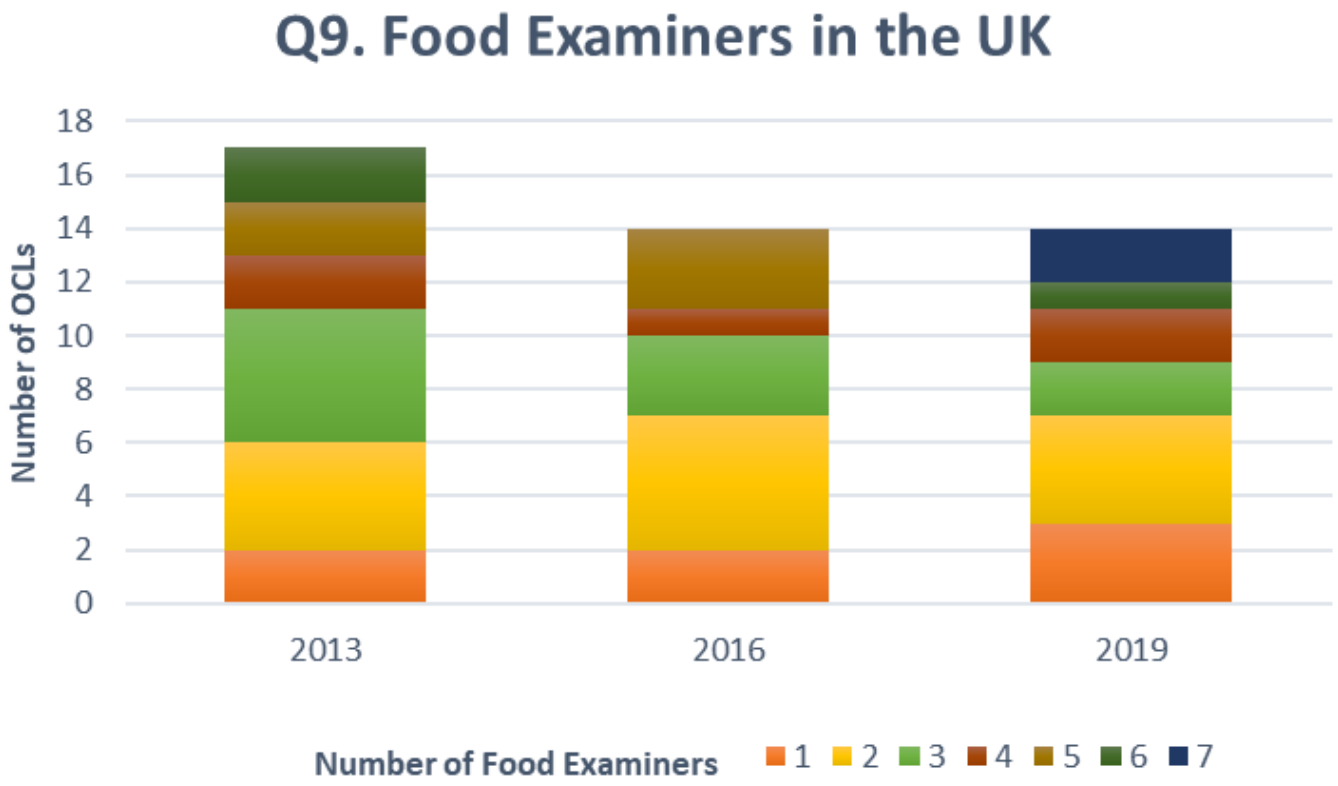
Q8. If yes, is the laboratory an OL in their own country?

5 OLs did not reply

Yes	7
No	1
Don’t know	1

Q9. How many staff are designated as food examiners?

Number of food examiners	Number of OLs
1	3
2	4
3	2
4	2
6	1
7	2



Year	Total Number of food examiners	Total Number of laboratories
2013	55	17
2016	40	14
2019	45	14

Q10. How many staff are designated as public analysts and supervise microbiological testing for official control purposes?

Number of public analysts	Number of laboratories
0	12
1	1
2	1

Q11 and 12. Are there any trainee food examiners? If yes, how many?

Yes: 8 OLs, No: 6 OLs

Number of trainee food examiners	Number of laboratories
1	4
2	2
3	2

Q13. If no trainee food examiners at the OL, when can you achieve this?

One lab responded of the 6 OLs, stated in 2023.

Q14. Has the laboratory implemented the new ISO 17025:2017 under UKAS accreditation?

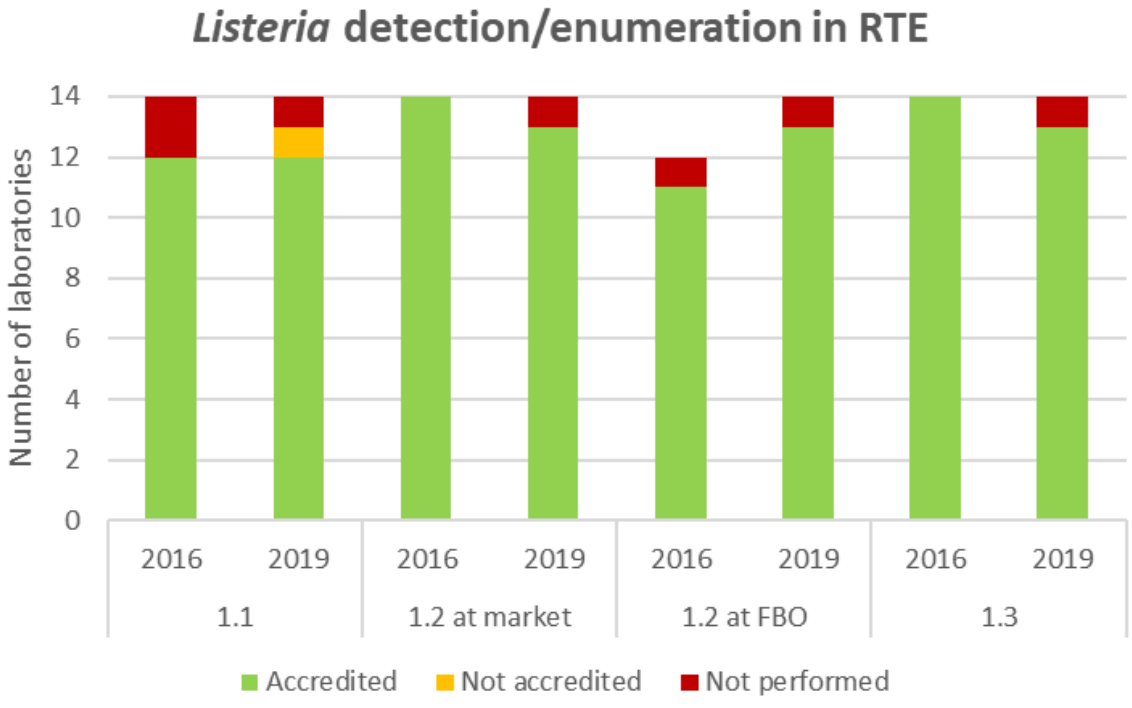
Yes	12
No	2

Q15. Do you perform challenge or shelf-life testing for FBOs or other customers?

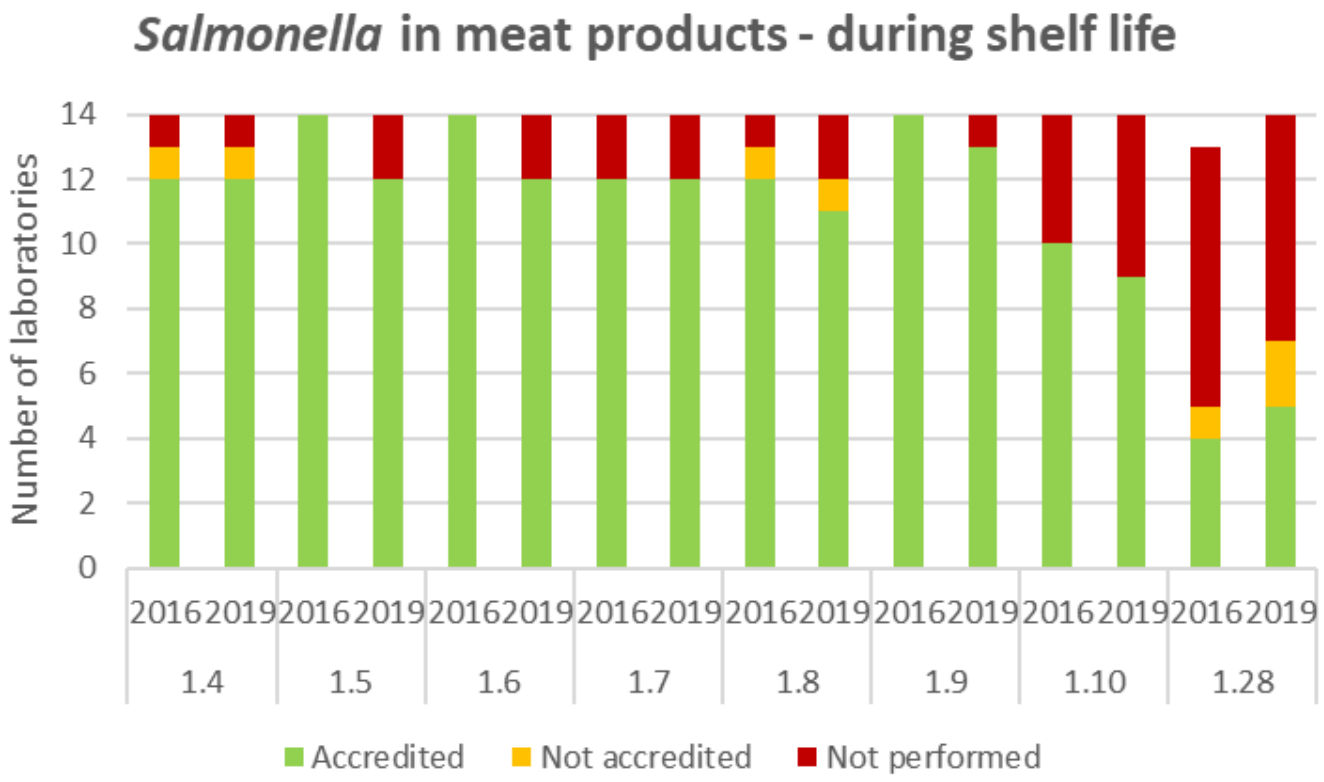
Yes	7
No	7

Q16. What testing does your laboratory perform, according to the Microbiological Criteria EC 2073/2005?

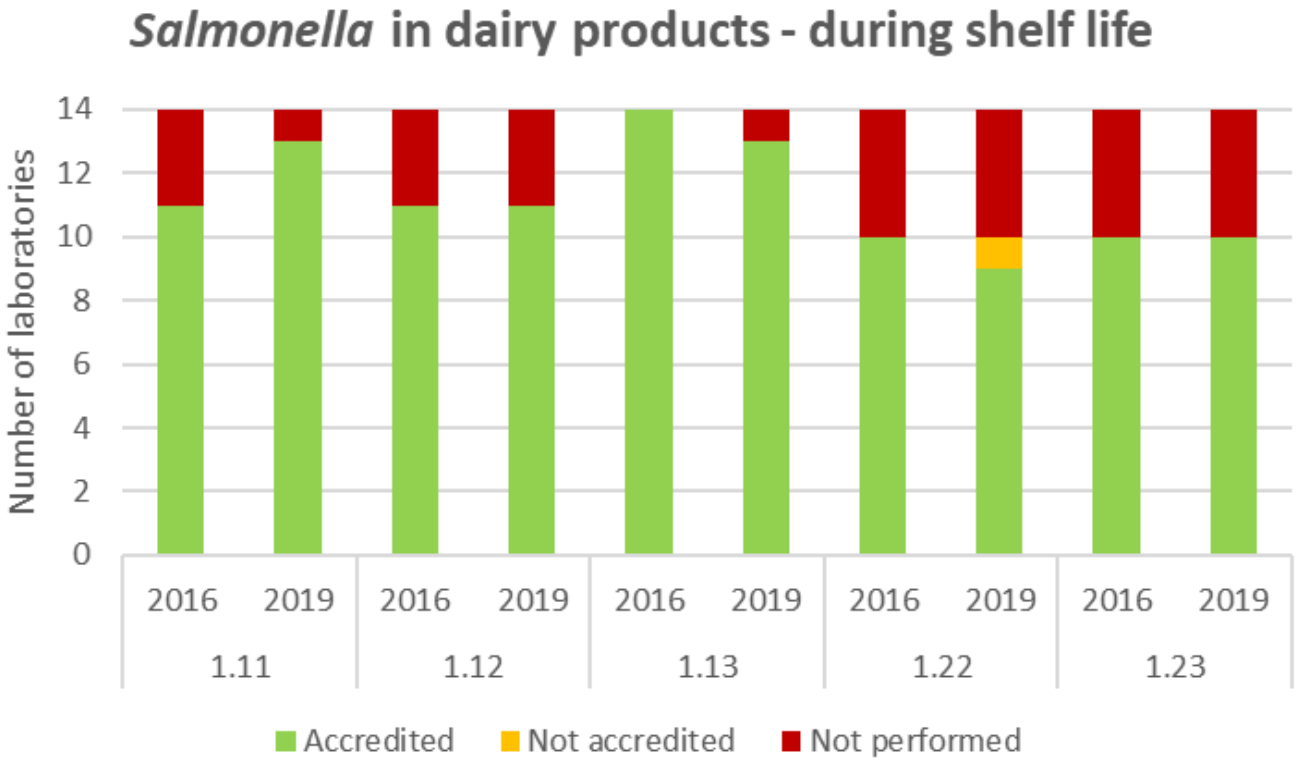
***Listeria* in ready-to-eat (RTE) products**	**Accredited**	**Not accredited**	**Not performed**
1.1 RTE for infants and for special medical purposes	12	1	1
1.2 RTE supports growth at market	13		1
1.2 RTE supports growth at FBO	13		1
1.3 RTE unable to support growth	13		1



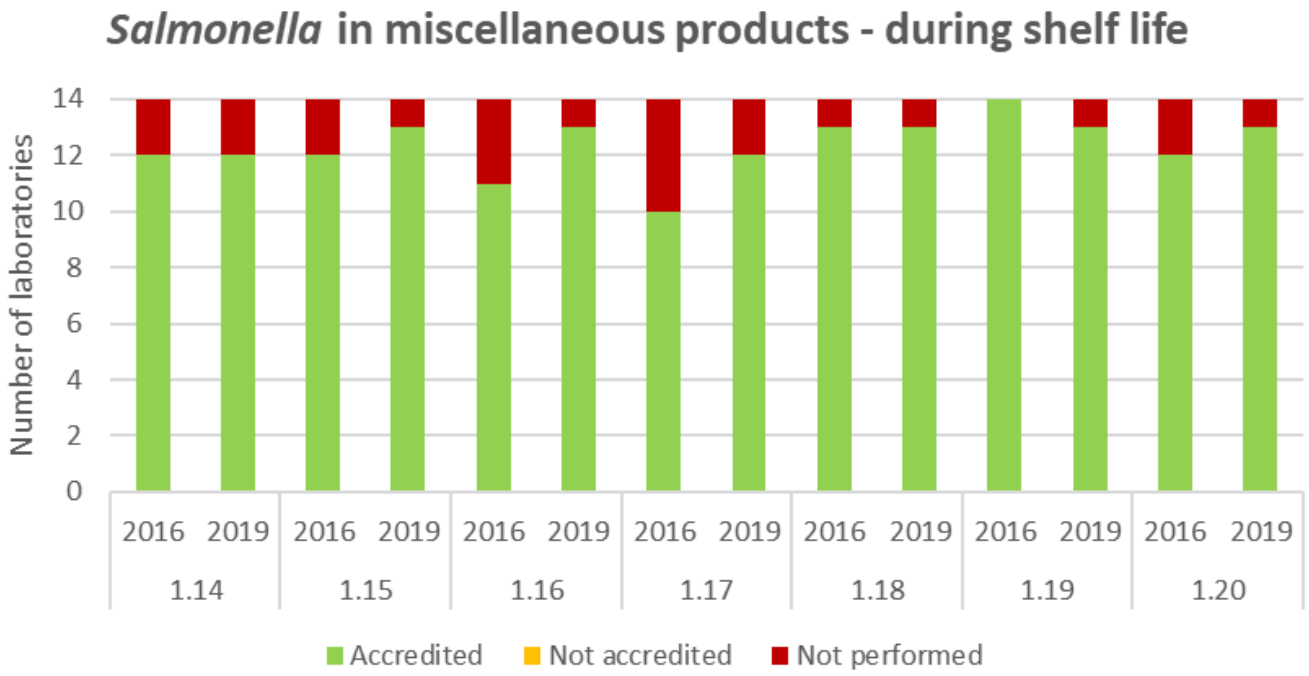
***Salmonella* in meat products**	**Accredited**	**Not accredited**	**Not performed**
1.4 minced meat and other meats eaten raw	12	1	1
1.5 poultry preparations eaten cooked	12		2
1.6 meat preparations other than poultry and eaten cooked	12		2
1.7 MSM	12		2
1.8 meats intended to be eaten raw	11	1	2
1.9 poultry meat products intended to be cooked	13		1
1.10 gelatine and collagen	9		5
1.28 fresh poultry meat	5	2	7



***Salmonella* in dairy products**	**Accredited**	**Not accredited**	**Not performed**
1.11 cheese, butter, cream lower heat than pasteur	13		1
1.12 milk and whey powder	11		3
1.13 ice cream	13		1
1.22 dried infant formula and dietary foods less than 6 months	9	1	4
1.23 dried follow-on formula	10		4

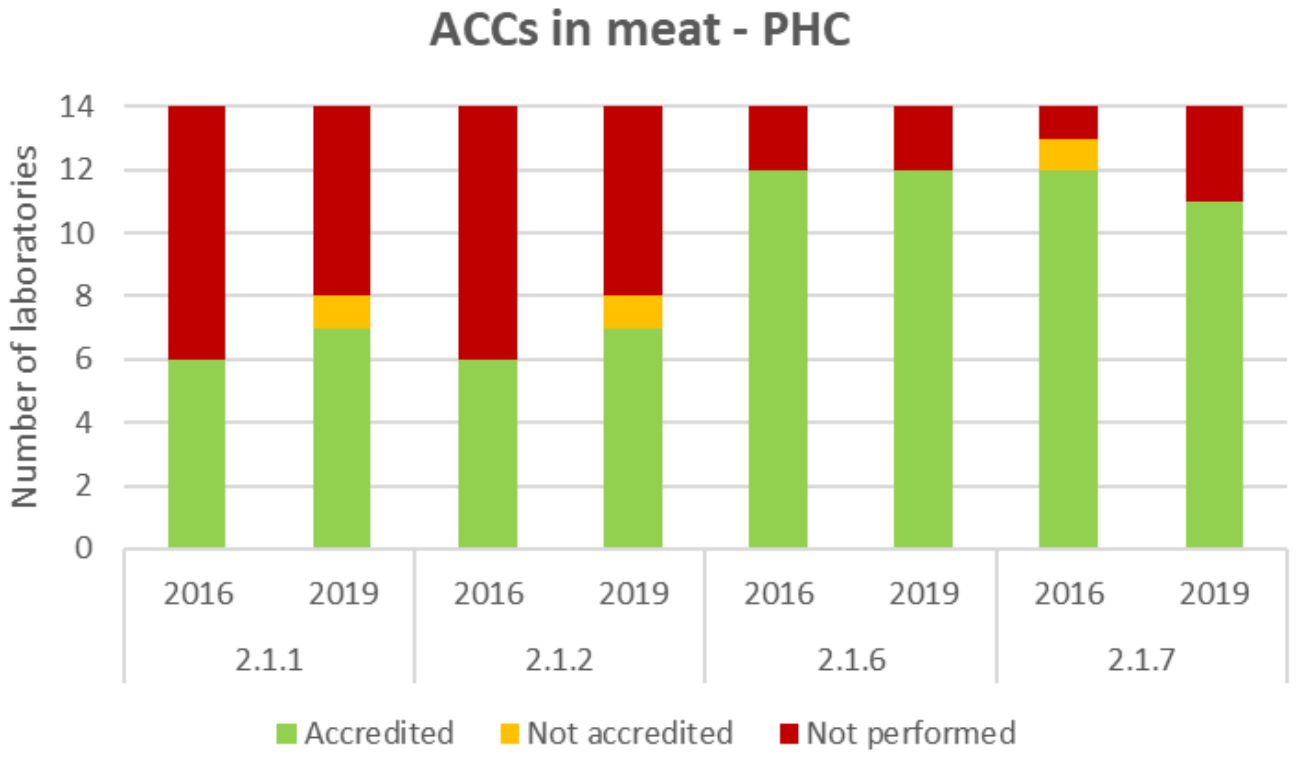


***Salmonella* in miscellaneous products**	**Accredited**	**Not accredited**	**Not performed**
1.14 egg products	12		2
1.15 RTE foods containing raw eggs	13		1
1.16 cooked crustaceans and molluscs	13		1
1.17 live shellfish	12		2
1.18 sprouted seeds	13		1
1.19 precut fruit and vegetables	13		1
1.20 unpasteurised fruit and vegetables juices	13		1

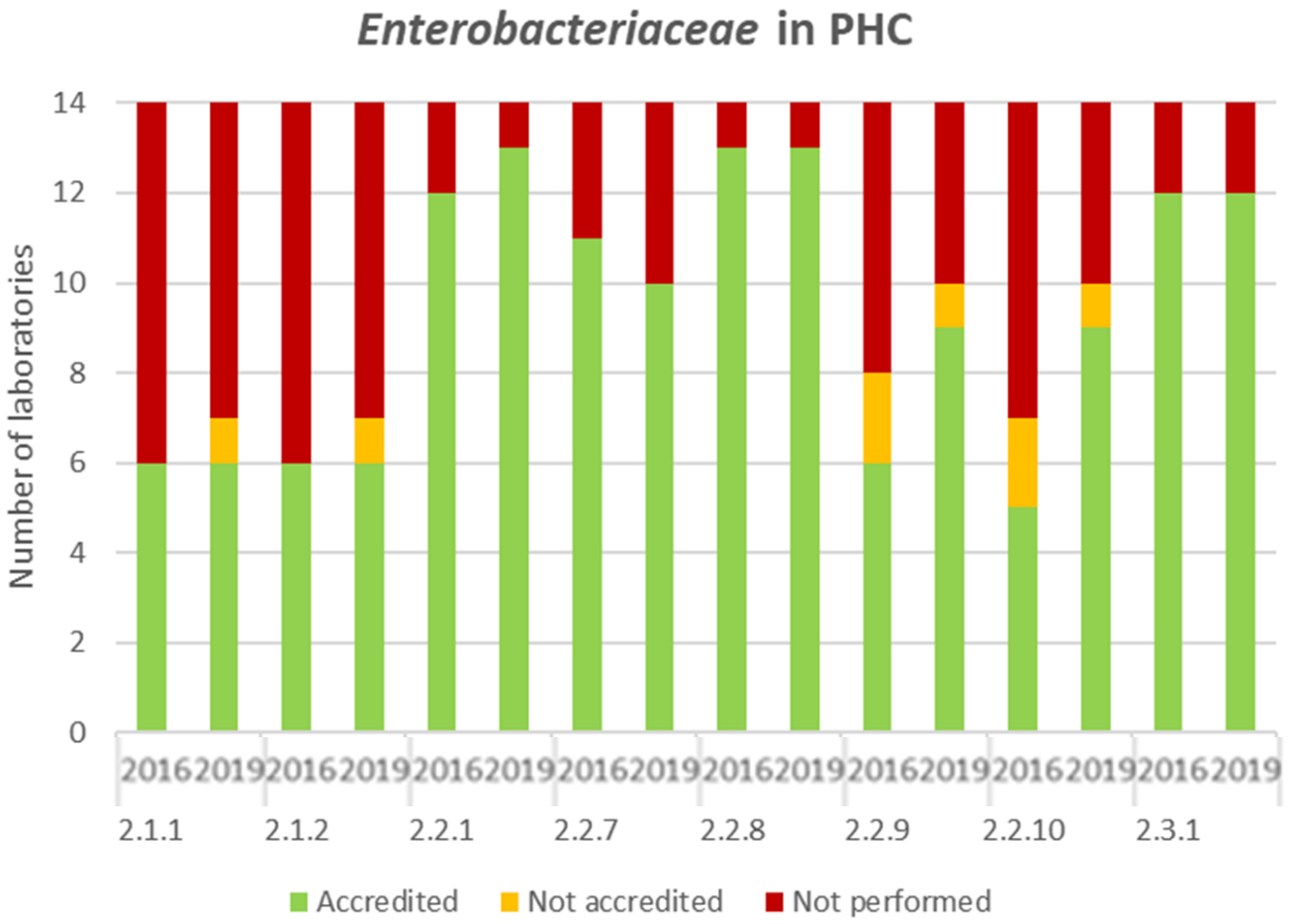


Miscellaneous in food safety criteria	Accredited	Not accredited	Not performed	Method if not ISO
1.21 Staph tox in cheese and milk or whey powder	1		13	3M Tecra Staph Enterotoxin VIA ELISA
1.24 Cronobacter in dried products intended for less than 6 months	1	1	12	Pathatrix Auto system followed by Real-Time PCR using Taqman detection kit
1.25 E.coli in live shellfish	10		4	2 OLs stated method based on CEFAS method
1.26 Histamine in fish associated with high histidine	3	1	10	2 OLs use ELISAs; one states R-Biopharm Ridascreen Histamine ELISA kit
1.27 Histamine in brined fish associated with high histidine	2	2	10	1 OL states R-Biopharm Ridascreen Histamine ELISA kit
1.29 STEC in sprouts	5	1	8	1 OL states only accredited for O157

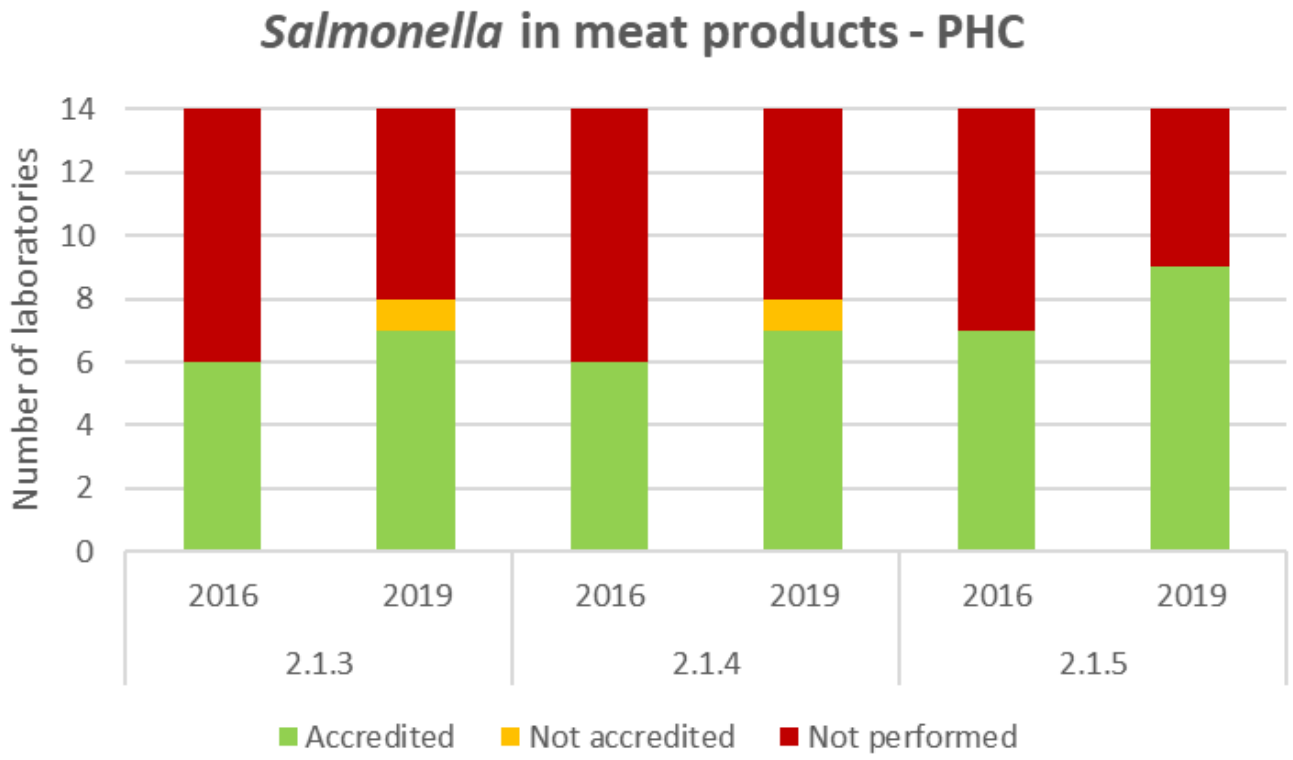
ACCs in meat – Process Hygiene Criteria (PHC)	Accredited	Not accredited	Not performed
2.1.1 cattle, sheep, goat and horse carcases	7	1	6
2.1.2 pig carcases	7	1	6
2.1.6 minced meat	12		2
2.1.7 mechanically separated meat	11		3



Enterobacteriaceae in PHC	Accredited	Not accredited	Not performed
2.1.1 cattle, sheep, goat and horse carcases	6	1	7
2.1.2 pig carcases	6	1	7
2.2.1 pasteurised milk and other liquid dairy	13		1
2.2.7 milk powder and whey powder	10		4
2.2.8 ice cream and frozen dairy products	13		1
2.2.9 dried infant formula and dietary foods less than 6 months	9	1	4
2.2.10 dried follow-on formula	9	1	4
2.3.1 egg products	12		2

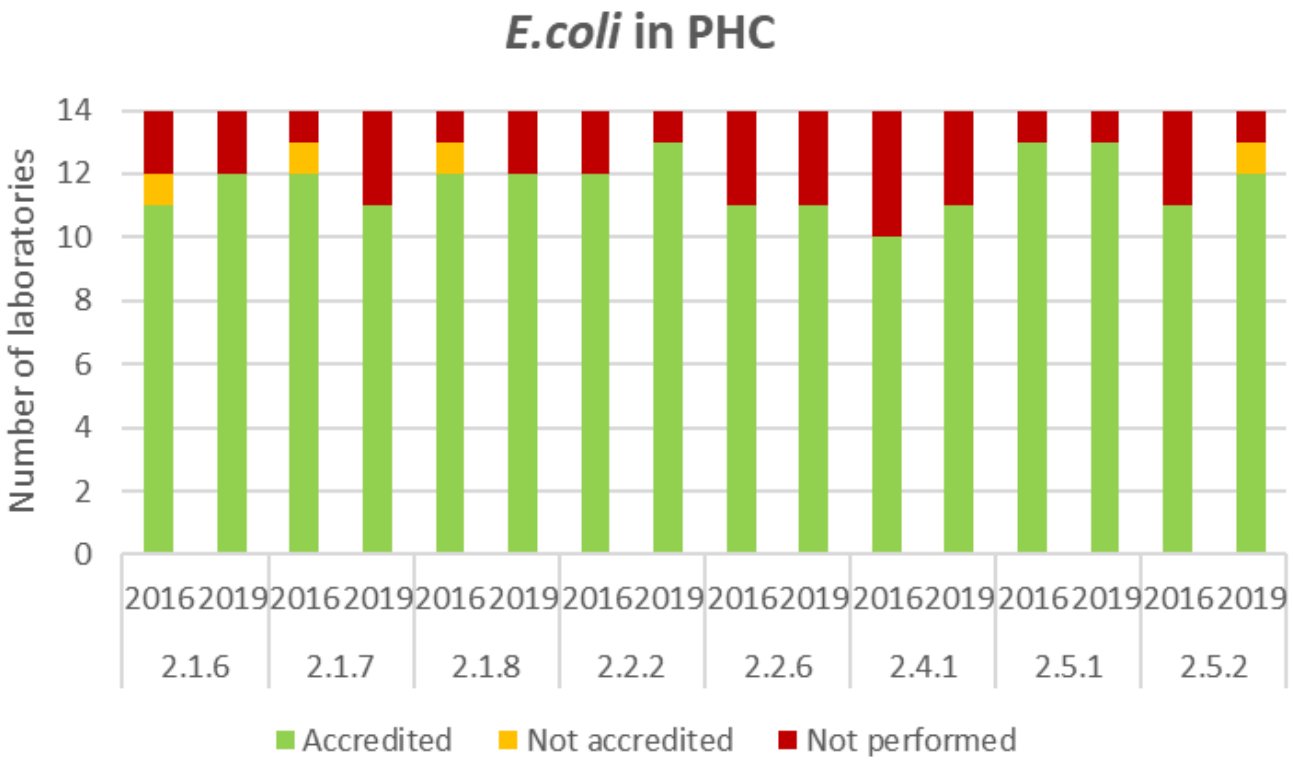


***Salmonella* in meat products (PHC)**	**Accredited**	**Not accredited**	**Not performed**
2.1.3 cattle, sheep, goat and horse carcases	7	1	6
2.1.4 pig carcases	7	1	6
2.1.5 broiler and turkey carcases	9		5

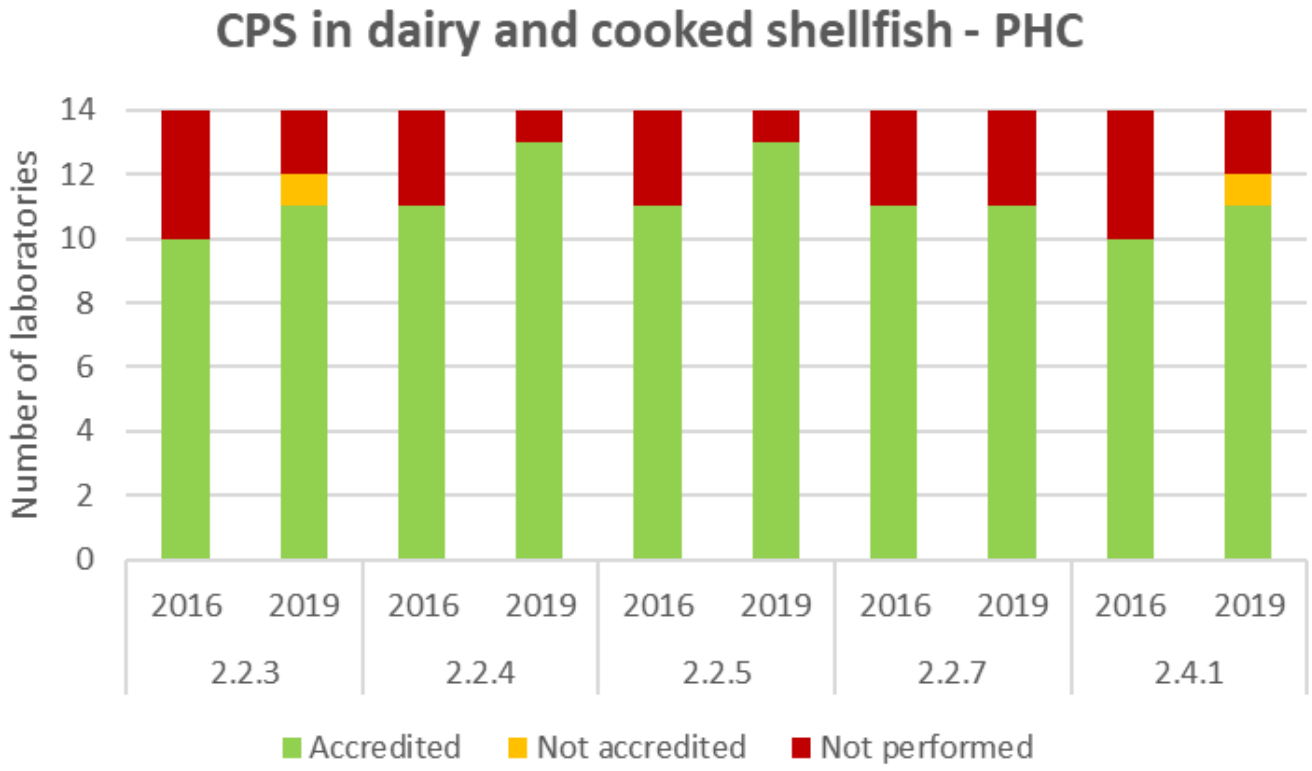


***Campylobacter in broiler carcases* (PHC)**	**Accredited**	**Not accredited**	**Not performed**
2.1.9 broiler carcasses, 2019	5	2	6
before criteria in place, 2016	3	2	9

E.coli in PHC	Accredited	Not accredited	Not performed
2.1.6 minced meat	12		2
2.1.7 mechanically separated meat	11		3
2.1.8 meat preparations	12		2
2.2.2 cheese from heat treated milk or whey	13		1
2.2.6 butter, cream and milk lower heat than pasteur	11		3
2.4.1 shelled/shucked cooked shellfish	11		3
2.5.1 precut fruit and vegetables (RTE)	13		1
2.5.2 unpasteurised fruit and vegetables juices	12	1	1



CPS in dairy and cooked shellfish (PHC)	Accredited	Not accredited	Not performed
2.2.3 cheese from raw milk	10		4
2.2.4 cheese from less than pasteur and ripened cheese less than pasteur	11		3
2.2.5 unripened cheese from pasteurised milk or whey	11		3
2.2.7 milk and whey powder	11		3
2.4.1 shelled/shucked cooked shellfish	10		4



Bacillus cereus in infant formula	Accredited	Not accredited	Not performed
2.2.11 (2019)	9		5
2.2.11 (2016)	10		4

Q17. Are there any food matrices that your laboratory has difficulty in classifying, processing and/or interpreting results for any target organism?

Yes:	2	(14%)
No:	10	(72%)
No reply	2	(14%)

Q18. If yes, which matrices cause problems?

- novel vegan foods
- STEC – interpretation of results, although this may be due insufficient experience of using the method and dealing with different situations

Q19. Do you have any further comments or problems regarding microbiological testing of food?

No:	2	
Yes:	1	
Not answered:	11	

The bacterial contributions of raw veg and spice ingredients cannot be assessed with much confidence and are often not made clear in food descriptions submitted.

Q20. Do you participate in any PTs or EQAs other than the European Food Law scheme for food microbiology? If so, please list (multiple answers)

PT/EQA Scheme	2016	2019
FEPTU Standard	7	7
FEPTU Environmental Swab	2	4
FEPTU Non-Pathogen	3	4
FEPTU Pathogenic Vibrio	1	2
FEPTU STEC	2	3
FEPTU/CEFAS Shellfish scheme	5	5
FEPTU Campylobacter scheme	Not available	2
LGC Standard	3	3
LGC Dairy Chemistry (pH and phosphatase)	1	1
LGC Food Chemistry (Aw)	1	1
LGC Vet	1	

PT/EQA Scheme	2016	2019
FAPAS Standard	1	1
Don Whitley (spiral plater)	1	1
Eurofins Bacterial Endotoxin Testing/LAL		1
Did not answer	1	

Q21. How do you report unacceptable results to FSA?

Directly using UKFSS:	4
Directly using email/phone:	2
Rely on customer to send details:	10
Other:	4
Please specify:	Via Director of FWandE Service (2); Scottish Food Sampling Database; Reporting to Local authority who report to FSS, but some situations may require to liaise with FSS directly.
Did not answer:	*2*

Q22. If you contact the FSA using email or phone, please give the email address or phone number

[Withholding 1 phone number]

Q23. The NRL have deposited some National Methods on the .gov.uk website. Have you found them useful?

Yes:	9	(64%)
No:	3	(22%)
Unaware of them	2	(14%)

Q24. If you have attended an OL User Day, would you like to see smaller discussion groups?

Yes:	3	(22%)
No:	9	(64%)
Not answered:	2	(14%)

Q25. If yes, what topics would you like to discuss?

- problems encountered with particular methods
- food outbreak information and intelligence
- which labs do what tests so can source suitable labs for tests that labs do not do
- a Scottish group would be welcome

Q26. What topics would you like the NRL to cover in future trainings as either practical or Skype sessions? Please choose any that apply

Campylobacter enumeration:	4
PCR techniques (focus on STEC):	6
Uncertainty of Measurement:	5
Validation/verification of ISOs	10
Impact assessment of ISOs	7
Interpretation of EC 2073/2005	8
ISO 17025:2017 accreditation	4
Implications of new OCRs, EU 2017/625	11
Other	2

Q27. If there are other topics of interest, please state:

- Rapid Confirmation Methods, for example PCR, MALDI-TOF and any new emerging technologies

Q28. Have you any other comments or suggestions for the NRL's service?

- requesting Skype [Teams] meetings due to travel ban
- can the NRL ask FSA what the clear mechanism to report failures is
- the NRL should review and distribute email notifications of relevant new legislation, guidelines and maintain a master list that can be used by all labs and is acceptable to UKAS

Additional audit questions sent in March 2022

2022: Q3. Between March 2020 and now, did you have to suspend any testing due to COVID-19?

Yes:	6	(50%)
No:	6	(50%)

2022: Q3a. If yes, what services did you have to suspend and for how long?

- all work (3): several weeks from March, 6 weeks
- private work suspended and LA reduced (2): from lockdown (16 March 2020) to 1 May 2020
- private work suspended and only public health work performed (1)

2022: Q4. Between March 2020 and now, has your laboratory been operating with reduced staff levels, and by approximately how much?

Yes:	9	(75%)
No:	3	(25%)

2022: Q4a. Staffing levels reduced by approximately:

- 2 staff down (1)
- COVID-19 5% to 10% and 10% to 15% vacancies (1)
- between 20% and 30% reduced (2)
- 50% reduced due to social distancing (2)
- 50% to 80% reduced (3)

2022: Q5. Did you request any help from PHE (now UKHSA) or the NRL?

Yes:	1	(8%)
No:	9	(75%)
N/A	2	(17%)

2022: Q5a. If yes, what was the request?

[Answer withheld as could reveal identity of OL]

2022: Q6. Has EU Exit hampered in acquiring provisions, such as consumables, media, testing kits, equipment?

Yes:	9	(75%)
No:	3	(25%)

2022: Q6a. If yes, what was the problem and how did you overcome it?

Problem	Number of Respondents	Resolved by:
Delays in consumables and media	7	Brexit stockpiling: over-ordering in advance
Having to use alternatives	5	Campy latex kits, gloves, plastic consumables, control strains
Moving samples across Europe for testing in sister laboratories	1	Having to sub-contract to UK labs, leading to higher costs

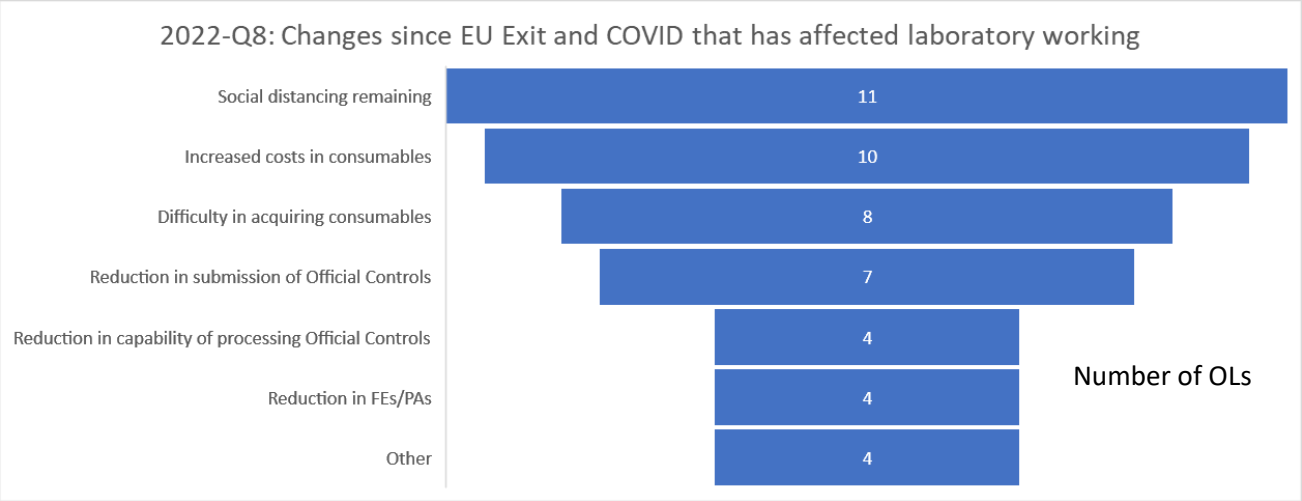
2022: Q7. Currently, is your laboratory fully functioning as it was before EU Exit and COVID-19 or are there services that you have been unable to reinstate?

Yes:	9	(75%)
Partial:	2	(17%)
No:	1	(8%)

2022: Q7a. If partial, what services have not been reinstated?

- pool-side testing in schools and Legionella sampling in nursing homes
- non-microbiological tests
- not accepting new clients and advising longer turnaround times

2022: Q8. Have there been any other changes since EU Exit and COVID-19 that have affected your laboratory?



2022: Q8a. If Other, please state

- delayed recruitment
- recruitment and sickness absence
- border control problems caused FE to leave, in turn causing low morale
- received large number of non-micro work; working with LAs to coordinate batched submissions to streamline work

2022: Q9. Have there been any outcomes since EU Exit and/or COVID-19 that has made a positive impact on the running of your laboratory?

Yes:	4	(33%)
Partial	7	(59%)
No:	1	(8%)

2022: Q9a. If yes, please state

- senior staff able to WfH and focus on quality, safety, etc. (2)
- [Microsoft] Teams use increases comms with other labs
- hybrid/flexible working
- stronger team working

2022: Q10. Please let us know of any other information that may be relevant

- experienced drastic reductions in food samples
- suggest for consumable provision: could a framework be introduced so all labs could use?
- social distancing still in place and can be challenging
- logistics still to be worked out with EU NRLs and have concerns if an outbreak were declared
- continue to have a strong relationship with UK NRLs, but need clarity on what our future relationship should be

Discussion and Conclusions

Microbiology testing and capacity: Q3 to Q15

All 14 OLs currently perform microbiological testing on samples collected by public bodies for official controls (OC). These include local government, port health authorities, commercial customers and also for surveillance or outbreaks via local and national surveys and UKHSA and FSA, respectively. The number of laboratories has increased since 2016 and has not changed significantly since the 2013 audit. Since requesting the additional information in 2022, the number of laboratories has not changed after EU Exit and the COVID-19 lockdowns.

Seven OLs submitted the total number of OC samples received annually, but these varied significantly, from 1 sample to 10,000. Interpretation when answering this question may have differed from OL to OL, however this appears to indicate that workload is not spread evenly across the OL network. The majority of OLs are able to perform all testing in their own laboratory (N=8). The laboratories used for referrals are all based in the UK, which ensures capability of microbiology testing within the UK.

From the 2019 audit, there were 45 food examiners (FE) working in UK OLs, an increase from 2016 (N=40), but less than in 2013 (n=55). There has been an increase in the number of OLs having only one FE (N=3), however, 2 OLs have 6 or 7 FEs to perform and oversee official control testing. There were 3 public analysts (PAs) supervising microbiological testing in 2019, compared to just 2 in 2016 and 18 PAs in 2013. The number of qualified staff such as FEs and PAs in UK OLs seems to be unstable and may be due to the highly specialised work performed and the resources required to train competent staff as FEs. However, it is reassuring that 8 of 13 OLs had between 1 and 3 trainee FEs (total 10 trainee FEs) in 2019.

In 2017, the ISO standard for the competence of testing and calibration laboratories was revised and re-issued as ISO 17025:2017. When asked, 12 OLs had implemented the requirements of

the new revision and achieved UKAS accreditation against this standard. At the time of writing, the remaining 2 OLs have also achieved ISO 17025:2017 accreditation.

Shelf-life and challenge testing of food requires expertise, knowledge of the food matrix, the behaviour of pathogenic and spoilage micro-organisms, interpretation of legislation, and the resources to perform testing. The OLs receive queries and potential work from local authorities and Food Business Operators (FBOs), however, only half the OLs perform challenge or shelf-life testing (7 out of 14), which has not changed from the 2016 audit. As this was a potential knowledge gap for OLs, the NRL organised a one-day workshop for OLs in October 2017 to equip them with the background and knowledge necessary to address queries in this area. Although this may have helped labs to provide advice to FBOs and local authorities on this topic, the number of OLs with capability for performing challenge testing has not increased. This area of work requires different procedures to the majority of testing work carried out by OLs, involving introducing known pathogens or surrogate organisms into food. This intentional introduction of pathogens does not fit well with routine examination of food samples, and creates a potential risk for cross-contamination within the laboratory. Therefore, there is a need for separate work areas and different expertise for the technicians involved, making it difficult for OLs to support this complex area of food microbiology. There may be provision for this type of work within commercial laboratories, but availability is likely to be relatively limited.

Testing according to EC 2073/2005 microbiological criteria: Q16

In the 2016 audit, data was gathered from the OLs according to the annexes in the microbiological criteria, EC 2073/2005, and data was gathered in the same way for this audit in 2019. Thus a direct comparison can be made regarding testing provision as illustrated in the charts in the results section. This also enables the evaluation of compliance with the microbiological criteria and whether alternative methods to the reference ISO methods (as stipulated in EC 2073/2005) were used. The microbiological criteria annexes are split into 2 chapters; Chapter 1. Food Safety Criteria and Chapter 2. Process Hygiene Criteria (PHC). The Food Safety Criteria are discussed first.

At least 11 of the 14 OLs are accredited for testing *Listeria monocytogenes* in the different ready-to-eat (RTE) food categories (1.1 to 1.3), which is broadly similar to both previous audits. Capacity of *Salmonella* detection is dependent on the matrix and microbiological criteria, with 11 OLs or more accredited for matrices comprising meat and meat products, cheese and milk, eggs, and fruit and vegetables (1.4 to 1.9; 1.11 to 1.16; and 1.18 to 1.20, inclusive). This has improved slightly since the 2016 audit. There have been slight changes in the remaining criteria related to *Salmonella* detection since the 2016 audit (gelatine and collagen (1.10), dried infant and follow-on formula (1.22 and 1.23), and live shellfish (1.17)), where there is either an

additional OL capable of testing or the converse. Accreditation for *Salmonella typhimurium* and *Salmonella enteritidis* testing in fresh poultry meat (1.28) is still low and performed in only 5 of 14 laboratories, which is a slight increase from the 2016 audit of 4 of 14 laboratories. This microbiological criterion requires serotyping *Salmonella* using the White-Kauffmann-Le Minor scheme or whole genome sequencing (WGS) (as a validated alternative method), which OLs may not have the capacity to undertake. However, the Gastrointestinal Bacteria Reference Unit at UKHSA Colindale and the Scottish Salmonella Reference Laboratory can identify *Salmonella* species and the OLs are invited to submit their presumptive isolates for confirmation.

The provision for testing against the remaining Food Safety Criteria in chapter 1 varies in both matrices and analytes, where demand for testing is low in the UK. Consequently, the capability varies between OLs and compared to the 2016 audit, capacity of most of these remaining criteria have either remained the same or declined in the UK. Capacity has not changed for *E.coli* testing in live shellfish (1.25), where 10 OLs perform this. One OL is accredited for the detection of presence of staphylococcal enterotoxins in cheeses, milk powder and whey powder (1.21), but uses an alternative method to the reference specified in the EC regulation. This particular test is highly specialised and is only a requirement after ≥ 10^5 cfu/g of coagulase positive staphylococci are detected in the food. In addition, the UK has experienced very low referrals for this testing, and as such, the NRL has an agreement with a designated official laboratory in the EU that perform this test, where the UK last sent an official sample to them for testing in 2017.

Capacity of *Cronobacter* testing (1.24) has declined by one OL since 2016, where only one OL performs this as an accredited test and another is not accredited. This criterion is dependent on the outcome of *Enterobacteriaceae* testing, according to a separate process hygiene criterion. The *Enterobacteriaceae* procedure is a simpler test and is seen as a precursor to *Cronobacter* detection, with subsequent *Cronobacter* testing rarely required in practice. This could explain why so few OLs test for *Cronobacter* spp.

Histamine testing (1.26 and 1.27) is available from fewer OLs than in 2016 (3 of 14 and 2 of 14 OLs, respectively, compared to 6 of 14 OLs for either in 2016). Detection and quantification of histamine does not employ conventional microbiological methods and consequently this test is more commonly performed in public analyst (PA) laboratories. Whilst this survey was not sent out to all PA laboratories, this decline of histamine testing is suggestive of a reduction of capacity in the UK.

One microbiological criterion that has seen a consistent increase in UK capability is detection of Shiga toxin producing *E.coli* (STEC) in sprouts (1.29). In the 2019 audit, 5 OLs were accredited for this test compared to 3 OLs in 2016 and 2 OLs in 2013. This has been partly due to the practical training workshops that the NRL organised in 2013 and 2019, which focused on detection of STEC using PCR and according to the reference method TS/ISO 13136:2012. However, there are practical and infrastructure hurdles to this method and organism that can challenge laboratories, as handling STEC requires a Schedule 5 licence (according to the Anti-terrorism, Crime and Security Act 2001) and the provision of containment level 3 facilities for

isolation of the organism. Further support can be offered by the NRL for OLs wishing to implement STEC testing in their accreditation schedule.

Within the process hygiene chapter, there are many criteria for testing animal carcases, which could also be tested by OLs for veterinary microbiology (2.1.1 to 2.1.5). Nonetheless, 6 to 9 food microbiology OLs are accredited to test carcases for aerobic colony counts, *Enterobacteriaceae* and/or *Salmonella*. A new process hygeine criterion came into force on 1 January 2018 for enumeration of *Campylobacter* in broiler carcases (2.1.9) using EN ISO 10272-2. The UK NRL supported the UK OLs before this was in place, by delivering practical training for *Campylobacter* testing in 2013 and 2017 and responding to specific queries. Due to NRL's support and the introduction of the criterion, there has been a steady increase in UK capability. In 2013, no OLs were accredited for *Campylobacter* enumeration but 4 OLs could perform the test. This increased in 2016, with 3 OLs accredited and 2 performing the test without accreditation. This audit in 2019 reveals a further increase, with 5 OLs accredited to perform *Camplyobacter* enumeration and 2 unaccredited. The NRL will offer further support to OLs where necessary to expand *Campylobacter* enumeration capacity in the UK.

Meat and meat products which are at the end of the manufacturing process are more likely to be tested by the food microbiology OLs, and this has been generally stable in capability between the 2016 and 2019 audits, with 11 or 12 OLs testing these matrices for the relevant microorganisms (2.1.6 to 2.1.8). Overall, there has been a slight improvement in capability between the 2016 and 2019 audits for testing dairy products according to the process hygiene criteria including the quantification of *Enterobacteriaceae*, *E.coli* and coagulase-positive staphylococci in cheeses made from raw milk, ice cream and frozen dairy desserts (2.2.1 to 2.2.8); between 10 and 13 OLs are accredited. Capability for testing *Enterobacteriaceae* in dried infant and follow-on formula (PHCs 2.2.9 and 2.2.10) has also improved, where 9 OLs are accredited for this investigation,compared to only 6 and 5 OLs, respectively, in 2016. *Bacillus cereus* testing of dried infant formula and other dietary foods for less than 6 months infants (2.2.11) has not seen much change between the 2016 and 2019 audits: 10 OLs accredited compared to 9, respectively.

Egg products, shelled and shucked shellfish and fruit and vegetable products (2.3.1, 2.4.1 and 2.5.1 to 2.5.2, respectively) are tested by between 11 and 13 OLs for *Enterobacteriacae*, *E.coli*, CPS and *E.coli*, and these numbers are a slight improvement from the 2016 audit.

Challenges in microbiological testing: Q17 to Q19

In this audit, only 2 of 14 OLs noted that they experience difficulties in classifying, processing and/or interpreting results when testing certain food matrices. One OL noted novel vegan foods and the other stated the interpretation of STEC results, although the initial PCR and subsequent attempt at isolation of the strain were also found to be challenging. In relation to the first issue

(vegan foods), it should be noted that the UKHSA Food Water and Environmental Microbiology Service is conducting a survey of vegan foods (including plant-based substitutes for meat, fish and dairy products) between September 2022 and March 2023, with the aim of gaining a greater understanding of how to interpret results for these types of food in future.

A further problem was listed by an OL in that “bacterial contributions of raw vegetables and spice ingredients cannot be assessed with much confidence and are often not made clear in the food descriptions submitted”. The NRL will try to further clarify these queries listed under Q18 and Q19.

Participation in proficiency test schemes: Q20

Since 2014, the OLs have participated in the FEPTU’s European Food Microbiology Legislation (EFL) Scheme, which is agreed by UKHSA and FSA and funded by the NRL and allows direct comparisons of performance to be made between OLs. Participation in the EFL Scheme has been successful, with between 11 and 13 OLs (73% and 93%) registering on an annual basis. The NRL has monitored results and there is no evidence of continued periods of poor performance from any OL, which supports and gives confidence in the competence and reliability of the UK’s OLs.

Although most OLs have registered for the EFL Scheme, participation also occurs in other proficiency test schemes according to their needs and schedule of tests of the individual laboratory. Seven other FEPTU schemes are used, including the Standard Scheme (N=7) and the Environmental Swab Scheme (N=4), and 3 LGC schemes were also used. One OL used the FAPAS Food Microbiology Scheme, another was participating in the Don Whitley (spiral plater) scheme and one other recorded the Eurofins Bacterial Endotoxin Testing PT. Compared to the 2016 audit, PT participation has increased from the UK OLs.

Reporting unacceptable results: Q21 and Q22

The NRL requested information from the OLs regarding how unacceptable results are reported to the FSA. Most OLs replied by selecting more than one answer from what was available, therefore, responses will not add up to the 14 OLs. Ten OLs rely on their customer (usually local authorities, port health authorities or food business operators) to send details to FSA, 4 report the results using an electronic system (UKFSS) and 2 OLs use either email or telephone to contact FSA directly. Other routes that the OLs used included reporting via the director of FWEMS, using the Scottish Food Sampling Database or a combination of reporting to both the local authority and the FSA. This reveals that reporting of unacceptable results to the competent authority is inconsistent, but this is complex and is dependent on the nature of the

contamination and the reason for samples being tested (such as through routine testing, a targeted study or outbreak/food incident). Further consideration is recommended to ensure all unacceptable results are transmitted to the competent authority promptly and the level of response is commensurate to the situation. Clarifying to all OLs the most appropriate contact points within FSA and which results require escalating would be beneficial.

Provision of National Reference Laboratory services: Q23 to Q28

Several questions regarding NRL activities were included in the survey, in order to ascertain and improve the needs of the OLs. In 2019, 9 OLs found the National Methods useful and these are deposited on the GOV.UK website. Only 2 OLs were unaware of them, which has improved from the 2016 audit (n=5) and the NRL will work to update and expand their collection of National Methods and other relevant documents.

Focusing on delivering training and information through NRL events, the survey asked whether participants would like smaller discussion groups at the OL User Day. Only 3 of 14 OLs would like to see this, suggesting topics such as problems encountered with particular methods, food outbreak information and intelligence and capability of specific laboratories. From a multiple choice list, OLs selected a range of topics they would like the NRL to cover in future trainings either as practical laboratory training or online sessions. Eleven OLs selected ‘implications of new OCRs, EU 2017/625’ and 10 OLs chose ‘validation/verification of ISOs’. These have subsequently been topics of workshops either run by the FSA or by the NRL to the OLs. Other topics, such as ‘impact assessment of ISOs’, ‘PCR techniques’, ‘uncertainty of measurement’ and ‘ISO 17025:2017 accreditation’ were also selected by 7 to 4 OLs for which the NRL has also arranged workshops in the past few years. A new topic suggested by an OL was ‘rapid confirmation methods for example PCR, MALDI-TOF and other emerging technologies’, which the NRL can consider supporting in the future. Eight OLs selected ‘Interpretation of EC 2073/2005’, and this will be covered in a workshop in early 2023. The NRL continually requests feedback from the UK OL network and strives to address and respond to training and support needs of the OLs.

Regarding the NRL’s service, OLs gave free text comments and suggestions. These included:

- to increase the availability of the NRL meetings as online
- to clarify the mechanism to report failures
- to email notifications of relevant new legislation and guidelines
- to maintain a master list of all legislation and guidelines that can be used by all OLs, which is acceptable to UKAS

Audit questions sent in March 2022

As analysis of this 2019 audit commenced early in 2020, 2 events occurred soon after which impacted on the UK OLs significantly; the COVID-19 pandemic and UK leaving the EU. Therefore, a further set of questions were developed and sent to all the OLs in March 2022 to ascertain this impact. Twelve of the 14 OLs responded to these questions.

As the COVID-19 pandemic led to lockdowns, half of the OLs had to suspend testing; 3 OLs stopped all work for several weeks, 2 OLs suspended private work and reduced the level of work from the local authorities and another only performed work related to public health. Nine OLs have also been operating with reduced staff since the lockdown in March 2020 to when the questions were received (March 2022). Staffing levels varied from one OL quoting '2 staff down' to 3 OLs stating '50 to 80% reduced'. This would have impacted significantly on the operation of OLs during this time. Public Health England (now UKHSA) offered mutual aid to OLs during this time and one OL requested support.

The UK left the EU on 31 January 2020 and at the time of questioning, 9 OLs had problems acquiring provisions, such as media, testing kits and equipment. Most OLs resolved this by stockpiling before EU Exit, using alternatives (for example confirmation kits, plastic consumables) or sub-contracting testing to UK laboratories as it was difficult to transport samples to the EU. Combined with COVID-19 restrictions, the UK OL network was hampered with reduced levels of staffing, samples and laboratory consumables, resulting in a reduced capacity of microbiological testing in food. However, with no or reduced social interaction, the local authorities focussed on responding to the pandemic and as many food businesses closed, the demand for testing also diminished.

Since relaxation of lockdowns, 9 OLs resumed a full service, and 2 OLs stated a partial service and one OL selected that they haven't been fully functioning. Tests that have not been reinstated in some OLs include pool water testing and Legionella sampling, non-microbiological tests and not having the capacity to accept new clients. Other changes affecting OLs include the continuation of social distancing when working in the laboratory (11 OLs), increased costs of consumables (10 OLs), difficulty acquiring consumables (8 OLs) and seeing a reduction in official control samples being submitted (7 OLs). There are other changes that have affected OLs, which are detailed in the results section, question 2022: Q8 and 8a. At the time of writing this report, social distancing has been withdrawn as a recommendation, but rising costs of consumables continue to have an impact, along with reduced levels of official control samples, as the economic crisis has also affected the operation and testing of the OLs.

However, when asked, 4 OLs stated that there have been positive outcomes following the COVID-19 pandemic, such as working from home to focus on quality and safety work, using online meeting platforms to increase communications between laboratories and forging stronger team working, due to the increased planning and focused staff interactions which COVID-19 imposed.

Issues identified and recommended actions

The following issues from this report are summarised below, with the appropriate action to help resolve these issues.

Issue identified	Recommended action	Action implemented
Shelf-life testing a knowledge gap for OLs despite NRL holding a one-day workshop in October 2017	Further training and workshops are required	
Challenge testing performed in 7 out of 14 OLs (requiring separate work areas and different expertise)	Assess capabilitiy in OLs and other UK food laboratories against the demand from FBOs and local authorities	
Detection of STEC testing in 5 out of 14 OLs	NRL to organise laboratory training for OLs to implement method	
Enumeration of *Campylobacter* testing in 7 out of 14 OLs	NRL to organise laboratory training for OLs to implement method	
Interpreting novel vegan foods identified as challenging	Conduct a survey to assess appropriate testing for vegan foods	UKHSA FWEMS performed survey in 2022 to 2023, with findings to be disseminated
Interpretation of STEC results and isolation of organism is challenging	Training to be given to OLs to improve capability	
Reporting of unacceptable results is complex and inconsistent	To clarify most appropriate FSA contacts and when to escalate action	FSA provided contacts for reporting unacceptable results and has been shared with OLs
Various topics identified by OLs for training	‘Implications of new OCRs, EU 2017/625’, ‘validation/verification of ISOs’, ‘impact assessment of ISOs’, PCR techniques’, ‘uncretainty of measurement’ and ‘ISO 17025:2017 accreditation’ identifed to arrange training for OLs	Training has been led by NRL or FSA to address all topics identified

Issue identified	Recommended action	Action implemented
Training sought for ‘rapid confirmation methods for example PCR, MALDI-ToF’	NRL to arrange training for OLs	
Training sought for ‘interpretation of EC 2073/2005’	NRL to organise workshop for this area	NRL organised workshop in March 2023 to OLs
Continued evaluation of UK OLs capability and capacity	NRL to organise a repeat survey in 2023 to2024	

This audit has produced qualitative data concerning the capabilities and capacity of the OLs, including the impact of COVID-19 and EU Exit and the resilience of the UK OL network. The NRL will support the OLs on those areas identified and recommends that a repeat survey is performed to ascertain the full and lasting impact EU Exit and COVID-19 has had on the UK OL food microbiology network.

About the UK Health Security Agency

UKHSA is responsible for protecting every member of every community from the impact of infectious diseases, chemical, biological, radiological and nuclear incidents and other health threats. We provide intellectual, scientific and operational leadership at national and local level, as well as on the global stage, to make the nation heath secure.

UKHSA is an executive agency, sponsored by the Department of Health and Social Care.

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