FEPTU
Food & Environmental Proficiency Testing Unit
Operated by UK Health Security Agency

UKHSA Food and Water PT Schemes:

A participants guide: UKHSA proficiency testing schemes for food and water microbiology

UKAS PROFICIENCY TESTING
0006

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Introduction
This participants guide is designed to help participants gain maximum benefit from UK Health Security Agency (UKHSA) proficiency testing schemes (external quality assessment (EQA) schemes) for food, water and environmental microbiology.

1.0 Organisation

The schemes are organised by the Food and Environmental Proficiency Testing Unit (FEPTU) based at Colindale. FEPTU is part of the External Quality Assessment Service which also has responsibility for providing the UK NEQAS (United Kingdom National External Quality Assessment Service) EQA schemes for clinical microbiology. Further information is available from the website: https://www.feptu.org.uk/

The organisers within FEPTU are supported by a Steering Group for Food and Water Microbiology Schemes, which includes participant representatives, scheme consultants/advisors with expertise in specific aspects of food and/or water microbiology and representatives from the food and water industries. The Steering Group meets twice every year; participants are contacted by email prior to each meeting and invited to submit queries and comments regarding scheme development and strategy for consideration by the Group. The remit of the Steering Group is available on request.

FEPTU is accredited to ISO/IEC ISO 17043:2010 (Conformity assessment – General requirements for proficiency testing) by the United Kingdom Accreditation Service (UKAS) for the provision of the food and water microbiology PT schemes. The schedule of accreditation is available from the UKAS website at 0006 Proficiency Testing Single (ukas.com). Certificate of accreditation is available on FEPTU - certificate.

FEPTU is committed to safeguarding all confidential information obtained during its operations. It will always ensure that decisions made are based on objective evidence, is unbiased and free from any undue influences. Any actions taken should not result in discrimination against the participant.

2.0 Quality systems

Proficiency testing (PT) is also referred to as external quality assessment (EQA), particularly in the clinical field, and is only one component of a quality system. The following definitions may help to define the relationships between the components:

- *Quality assurance* is the total process whereby the quality of laboratory results can be guaranteed.
- The *quality control (QC)* programme comprises the processes undertaken to check that media, reagents and equipment are performing within specifications
- *Proficiency testing or external quality assessment* is the challenge of the effectiveness of a laboratory's quality system with samples of known but undisclosed content.

A comprehensive quality assurance system will cover such areas as provision and control of standard operating procedures, education and training, planned maintenance and calibration of equipment, monitoring of response times, monitoring of suppliers etc. There is also a growing trend towards formal accreditation of laboratories for food, water and environmental examinations to acknowledge conformance with defined and objective quality standards, in particular those contained in ISO/IEC 17025:2017 (General requirements for the competence of testing and calibration laboratories) and ISO 15189:2022 (Medical laboratories - Requirements for quality and competence).

Laboratories may expect to report results of a consistently good quality only after all the components of the quality system are in place. It is important to consider the following limitations when designing a quality system for a laboratory:

- PT is not a substitute for other components of the quality system and cannot replace the QC programme.

- PT is of limited value without at least some of the other quality components such as adequate documentation, training of staff and the QC programme.

- PT helps to identify problems with testing; it does not solve the problems.

3.0 Management issues

PT schemes aim to provide the laboratory management with an insight into the quality of the routine work of their laboratories. The following qualifying factors apply:

- PT results will only provide an effective insight into routine results if the PT samples are treated in the same way as routine samples.

- If PT samples are treated differently from routine samples then the PT results may be excellent but nothing will be learnt about the quality of the routine service.

There are several ways in which PT samples may be given 'special' treatment. They may be handled by more experienced staff than those who examine typical routine samples, subjected to more rigorous checking procedures than normal, or results and information from other participants (collusion) may be sought before reporting. These practices must be discouraged by laboratory management.

To help to prevent malpractice and in order to gain maximum benefit from PT, management are advised to deal with situations where results for PT samples are incorrect in a sensitive manner. Problems may result from general failures in the quality system rather than from errors by individual staff. If incorrect PT results are not handled with sensitivity, staff may become defensive and will make more effort with PT samples in future to avoid further criticism. It is essential to involve staff closely in the process of quality system development. A positive approach to PT will help to reassure staff; guidance for helping to investigate incorrect results is provided in 19.0.

4.0 Scheme participation

UKHSA PT samples are grouped into schemes; each scheme is described on the website https://www.feptu.org.uk/schemes/ (the correct website URLs for each scheme is listed on page 3 of this document). The schedules for each scheme are also available from the website and a booklet summarising all the schedules (Ref. FEPTU483) is sent to all participants at the beginning of each distribution year. FEPTU staff are able to provide advice regarding the most appropriate scheme for laboratories.

The schemes are open to microbiology laboratories that can provide assurance that their facilities and expertise are adequate to ensure the safe handling and disposal of the samples. The terms and conditions of participation are available at the time of registration and in section 24.0. A reminder that laboratories failing to have adequate processes in place to safely dispose of any biological material can lead to regulatory policies being breach and safe unworking conditions.

Laboratories are encouraged to participate in all distributions (rounds) of a scheme, although some flexibility is allowed for all of the schemes. On some occasions, other bodies such as retail groups or accreditation bodies may advise on frequency of your participation. Further guidance may also be sought from the scheme organisers.

If a participant wants to submit more than one result per sample, for example in order to challenge two different methods, then they must register for a second laboratory identification number if the scheme has not been set up to allow for method variation by sample/examination.

5.0 Registration and fees

If you are a new participant wanting to enrol to our services, please complete the information in this link: https://www.feptu.org.uk/about-us/contact-us/. For existing participants to annually register your laboratory's requirement information will be sent around January either directly from FEPTU or via a distributor if this arrangement is in place for your country. Registration is subject to agreeing to the terms and conditions in 24.0.

The fees for participating in the PT schemes are reviewed annually; participants are advised, in advance, of any changes to registration fees. Price lists are also available from the scheme organisers on request, or from distributors in some countries outside the United Kingdom. Listed prices include PT samples, reports, repeat samples and advice as required. They do not include dispatch fees for laboratories outside the United Kingdom which will be included when an invoice is issued by UKHSA.

6.0 Confidentiality

All participants are allocated a unique laboratory identification number when they register for a UKHSA PT scheme. The same laboratory identification number will be used for participation in multiple UKHSA food and water microbiology schemes. The laboratory identification numbers are known only to the participating laboratory and the relevant UKHSA staff. This system enables results to be reported without divulging participant identity. Participants may reveal their identification number to other bodies if they choose to do so; UKHSA will never under normal circumstances reveal the identification numbers or performance of individual laboratories to any other organisations unless expressly instructed to, in writing, by the participant. If either a participant or a member of UKHSA staff has any concerns that anonymity has been compromised, then a new laboratory identification number will be issued.

7.0 Falsification and collusion

Collusion and/or falsification of records is prevented by FEPTU by not releasing any results until after the distribution has been closed. Result amendments after the closing date are also not accepted. Participants are reminded that the purpose of the PT schemes is to provide an independent assessment of their quality of their services. If collusion is suspected e.g. whistleblowing or internal monitoring of results, an internal inquiry will be conducted on the suspected participants. This will involve reviewing the performance history of the laboratory and further investigation will be conducted under strict confidentiality. This process will be conducted without bias and conclusions made will be on factual evidence. If there is strong evidence to suggest collusion or falsification of results, the report of the investigation If there is strong evidence suggesting collusion or falsification of results, the report will be shared with the UKHSA legal team for advice on further actions. The participants involved will be notified and can appeal the results of the investigation.

Falsification of results and/or collusion may result in but not limited to suspension of participating in future schemes, indefinitely banned from participating in future schemes and potentially losing accreditation/licences as a result of the relevant regulatory authorities being notified.

8.0 Sample dispatch

The PT samples are dispatched in compliance with the relevant international regulations. Instructions for storage of samples on receipt are printed on the request/report forms and outside of the boxes; the dispatch boxes are not intended for reuse. Request/report forms also describe the examinations required and includes links to the website for the instruction sheets, safety data sheets, these documents are sent via email to the laboratories prior to dispatch. Participants are reminded that failure to store the samples correctly on arrival or process the PT samples as instructed could affect the integrity/stability of the samples. Thereby impacting a laboratory's final PT result reported and associated performance.

The dispatch dates are included in the booklet summarising all the schedules (Ref FEPTU483). Forwarding laboratories are used in some countries outside the United Kingdom to reduce the cost of dispatch; those laboratories receive all the samples for a country in a single over-pack for onward dispatch using the most appropriate local system. All participants are advised that if they do not receive their samples within seven days of the dispatch date then they should contact FEPTU so an investigation can be initiated. If PT samples are damaged or lost in transit, then they are normally replaced without further cost to the participant.

9.0 PT samples

There are two sample formats for the PT samples: freeze-dried micro-organisms in evacuated glass vials and LENTICULE® discs. The sample format used depends on the purpose of the individual scheme. Storage and instructions for rehydration of the samples prior to testing are available from the website under the relevant scheme information: https://www.feptu.org.uk/schemes/.

Instruction sheets are available in a number of European languages (where available).

The samples are prepared in advance and are subjected to an array of control tests prior to dispatch. The sample contents are designed to ensure that participating laboratories will receive a wide range of different target micro-organisms; where enumerations/quantifications are required, the samples will be designed in such a way as to ensure that participation over a distribution year will allow a challenge to a laboratory's accuracy with a range of different levels.

Homogeneity testing: Batch homogeneity is an essential requirement of PT samples. Due to the differing nature of the specimens included in the FEPTU schemes different approaches are needed to ensure the specimens are homogeneous. All methods of establishing homogeneity are based on quantitatively testing a minimum of 10 randomly prepared samples in duplicate, this determines the variation between and within batches using statistical data. This homogeneity data is used to assess batch acceptance. All testing methodologies are selected to demonstrate repeatability over time and fitness for use by the laboratory.

Stability testing: The stability of PT samples is critical for ensuring that the materials maintain their integrity and diagnostic value over time. Stability refers to the ability of PT samples to preserve their intended characteristics (molecular composition, concentration, and activity) under defined conditions for a specified period. Factors affecting stability include but not limited to are temperature fluctuations, light exposure, humidity and time. Triplicate sets of samples are returned through the post from various laboratories in the UK and these are tested in the organising laboratory. It is not possible to state categorically that every single sample is in perfect condition, as quite random events can occur such as loss of vacuum in a freeze-dried specimen. It is, however, certain from the quality control sampling that the probability of random events occurring is low and therefore laboratories are unlikely to receive unsuitable samples.

The samples are mostly straightforward; they are not designed to be 'tricky' or to 'catch people out'. On most occasions, the samples will reflect what is likely to be found in routine samples submitted to food, water and environmental microbiology laboratories, although the proportion of positive results is significantly greater with the PT samples. Occasionally, a sample will be included that contains unusual micro-organisms to give participants the opportunity to gain experience.

10.0 Non-conforming products

Despite the rigorous quality control tests that are undertaken, occasionally against all expectations, quality control checks during the distribution period reveal unexpected changes in the sample to an extent where the likelihood of obtaining a correct result is significantly reduced. Participants will be informed as soon as possible if such a situation arises, with an explanation of how or if their results will be analysed. The outcome will be dependent on the specific situation.

11.0 Safety

Samples prepared for general microbiological examinations that may contain a mixture of micro-organisms, these organisms are classified as hazard group 2. A hazard group 2 organism may cause human disease and may be a hazard to laboratory workers but is unlikely to spread to the community. Laboratories must have the required facilities to handle PT samples and must be treated with the same degree of caution as real food and water samples. They must not be passed on to a third party. Samples are issued to participants on the understanding that they will be used for PT and that they will be handled by staff trained to handle equivalent routine samples. The samples are not designed for use in other applications e.g. for teaching, and participants are cautioned that their use for such purpose may pose

safety hazards. Samples are prepared in two formats; freeze dried and LENTICULE discs. Safety data sheets are available on the website: https://www.feptu.org.uk/schemes/sample-formats-and-storage/.

UK participants are asked to note that some microorganisms distributed as part of the PT services may include those included in the schedule 5 list of controlled substance. These organisms must not be stored locally and must be discarded once the examination of the PT has been completed.

12.0 Sample examinations

Participants are advised to read the instruction sheets for sample reconstitution for every distribution of samples in case there are any changes from previous distributions. A link on the latest instruction to follow is provided on the request/report forms which are sent electronically to all laboratories, or they are available under each specific scheme on the website. After the samples have been reconstituted participants should use their routine methods for undertaking the testing. PT results will only provide an effective insight into routine results if the PT samples are treated in the same way as routine samples. Some schemes, such as the Shellfish and European Food Microbiology Legislation schemes, are designed for processes where a particular method may be stipulated in EU legislation. In most cases participants should use the method they believe to be most appropriate; method analyses are undertaken on some occasions to provide background information. The FEPTU senior microbiologists are sufficiently experienced to be able to provide advice about the impact of different methods on participant results. Comments will be included in the distribution reports if this is a sample-specific effect; more general advice for individual participants will be provided on request.

For some of the scheme there will be enough material after the sample has been reconstituted for at least two/three members of staff to perform all the tests required. However, one result must be nominated for statistical calculations when reporting the PT results.

13.0 Reporting results

Results must be reported to FEPTU by the deadline date noted on the request/report form. Sample contents will not normally be revealed to any participants before the deadline date to prevent collusion and falsification of results. Extensions to the deadline dates cannot normally be accommodated; late results (results received after the deadline date) will not be included in the reports.

For some schemes, more than one set of results may be reported. However, one result for each test must be nominated and reported to FEPTU for statistical calculations. One of the reasons for this is to prevent multiple results from a single laboratory skewing the statistical calculations. If more than one member of staff (or staff team) examines a sample, it should be decided in advance which set of results will be submitted. The sets of results should not be combined as this may mask an individual's poor performance.

14.0 Notification of intended results

Intended results are published within three working days following the close of each distribution (unless otherwise advised usually through an email). Email notification of the intended results is sent to participants who have supplied their email address. The intended results are derived from the results obtained in the FEPTU laboratory and are provided as guidance. The results for detection of micro-organisms are very unlikely to change prior to the final report, although the expected ranges for enumeration/quantification results in the reports are derived from participant consensus data so may show minor differences from the initial intended results. Participants should compare their results with the intended results and decide if any repeat samples need to be ordered to investigate discrepancies. They should decide whether immediate action is necessary or whether investigations should wait until the distribution summary report is received (usually within three weeks). Generally, it is advisable to perform an initial investigation as soon as possible.

15.0 Establishing assigned values (intended results)

The assigned values for qualitative examinations (detection or presence/absence examinations) are derived from the sample contents; the samples are designed in such a manner that it is statistically unlikely that a participant will report an incorrect result for a qualitative examination by chance.

The assigned values for quantitative examinations (enumerations/quantifications) are derived from participants' results (irrespective of method used) using robust statistical methods including calculation of the median, calculation of the median absolute deviation from the median, percentile ranges and standard deviations from the median values. The median is used in preference to the mean because the median is less affected by extreme outlying results. In practice the two values are usually very similar. The methods used are dependent on factors such as the purpose of the scheme, the levels of micro-organisms to be enumerated/quantified and the number of participants reporting enumeration/quantification results for a particular parameter. A description of the statistical methods used for each scheme is provided on the web-site: https://www.feptu.org.uk/schemes/scoring/.

16.0 Allocation of scores and performance assessments

The allocation of scores is a means of drawing attention to differences between a participant's result and what has been designated as the intended result or the 'assigned value'. Scores may help participants to identify whether there is a problem with their testing, although low scores do not always mean that this is the case. There will always be differences in laboratory practice; this means that the score allocated for the PT results may not be totally applicable to a particular situation. For example, a participant may report an outlying result for an enumeration because they use a method that results in a higher recovery than methods used in most other laboratories. In this situation, the low score does not indicate a problem, but this should be documented, indicating that no corrective actions are required.

Participants are advised that if they report outlying results for enumerations and are allocated low scores on single occasions only then they should not be unduly alarmed, although they should still assess the reason(s) for the outlying result. This is particularly important for samples that are likely to contain very low levels of micro-organisms, such as for the Drinking Water, Bottled and Mineral Water, Endoscope Rinse Water, *Mycobacterium* spp., Dialysis Water and Hospital Tap Water Schemes.

The allocation of scores is provided as a management tool to help assess performance; it cannot replace assessment of PT results in the context of the individual laboratory. Methods should never be amended for the sole purpose of achieving better scores with PT samples.

17.0 Reports

Distribution scheme reports are provided after every distribution, normally within three weeks of the deadline date (depending on the scheme) for return of results and includes the expected content and results for each sample and a comparison of an individual participant's results together with those of all the other laboratories that participated in the distribution. Note that occasionally enumeration/quantification results are often converted to $\log_{10}$ values.

Sample-specific comments are often included in reports, as appropriate. Scores and an overarching assessment of performance over time for some schemes and the scoring system used, are also included, together with statistical data, and bar charts or scatter graphs to demonstrate the range of enumeration/quantification results reported. FEPTU contact details, the names of the FEPTU staff who contributed to the distribution and the person who authorised the report are provided for all reports. In addition, basic quality control testing undertaken is also included.

18.0 Trend analysis and performance data:

For some distributions the scheme reports provide information about performance over an extended period of time, participants are still advised to monitor their own results to identify trends that may not be apparent from the reports. FEPTU does not identify poor performing laboratories, this is down to the laboratory to establish this. However, FEPTU are always willing to help and support laboratories when performance in PT needs addressing. Trend analysis charts are available directly from the FEPTU via email. Trend charts allow the laboratory to plot its own result for an enumeration test against the participants' median result. The ensuing graph can then be examined for the presence of any trends or bias. The laboratory should investigate the reasons if these are found.

It should be noted that participation in proficiency testing schemes is one of the few ways that the laboratory's bias can be determined.

The UKHSA schemes always publish the number of colony forming units per gram or per litre for detection (presence/absence) tests such as *Salmonella*. This information can be used by the laboratory when compiling performance data including its lower limit of detection for each detection method.

19.0 Response to incorrect results

A common initial response to incorrect results with a PT sample may be that 'there was probably something wrong with the sample'. While it not possible to demonstrate that every single sample of a PT batch is representative, stringent manufacturing practices, past experience, homogeneity and stability testing, and general sampling of the batch by the FEPTU laboratory provides good assurance that it is unlikely that a participant will receive an unrepresentative sample. If a participant does receive such a sample by chance, it is statistically extremely unlikely that they will receive a series of them.

Where incorrect results have been identified, it is advisable to consider, at an early stage, whether any actions are necessary. Repeat PT samples are normally available after every distribution, on request, and are provided free of charge and sent with the next distribution the laboratory is taking. Laboratories can order a repeat sample either by email, through a distributor (if this is in place) or on https://www.feptu.org.uk/support/. Appropriate actions following incorrect results may include:

i) **Assessing methods:** *Is the laboratory using standard or validated, clearly documented methods for isolation, identification and enumeration?*

ii) **Assessing QC procedures:** *Are there sufficient and appropriate QC procedures in place?*

iii) **Assessing equipment:** *Is all the equipment used for the procedures (incubators, refrigerators, measuring instruments, spiral platers etc.) calibrated and monitored regularly?*

iv) **Assessing staff training:** *Are the staff who perform the examinations fully trained and familiar with all the procedural steps?*

v) **Assessing laboratory practice:** *Do staff adhere to good laboratory practice (GLP) at all times?*

vi) **Assessing clerical procedures:** *Are the laboratory numbering and clerical procedures adequate?*

Participants must note that a single PT sample is not fully representative of the materials that are examined routinely in a food, water and environmental laboratory; also individual bacterial strains vary in factors such as growth requirements, antigenic structure and biochemical characteristics. For these reasons, it is inadvisable to make major changes, such as to suppliers or use of culture media, on the basis of results with single PT samples. Such changes may give better results with an individual PT sample but worse results with the majority of the routine food, water and environmental samples. Therefore, it is necessary to confirm that the problem revealed is general in nature, and this will require further investigation with real samples, before such changes are made.

It is important also to remember the impact of incorrect results if they arise with routine samples. Some examples are provided below:

False negative results: where a laboratory does not report micro-organisms that are present in a sample; this may have serious public health implications.

False positive results: where a laboratory reports incorrectly the presence of micro-organisms that are not present in a sample; this may result in unnecessary product withdrawal for a foodstuff, or inappropriate treatment of a water system, with serious financial implications.

Incorrect results for enumerations/quantifications: where a laboratory reports results that are consistently higher or lower than would be expected; this may result in a misleading impression of hygiene conditions, or of the severity of the risk associated with the sample.

20.0 Complaints process

Complaints arise when a participant expresses dissatisfaction about one or more aspects of the PT service. If you have a complaint about our services (excluding scoring issues) then the laboratory can

contact FEPTU by email as per details on page 1. Your complaint will be logged as part of our quality management system and a unique reference number provided. This will then be forwarded to a relevant member of staff who will consider your complaint and may request for more information before an outcome is concluded. Straightforward complaints such as leaking specimens, specimens not received will be dealt with immediately and a response provided back within 2 working days. Complaints requiring more evidence to be submitted by the complainant and one that requires expert input before a conclusion is made may take up to 10 working days to resolve. If there are delays in addressing your complaint, then we will inform you of this and the reason for the delay. All decisions made are based on objective evidence and free from any undue influences. All complaints are monitored locally for progress as part of our quality management system. Any actions taken should not result in discrimination against the participant.

21.0 Appeal process for scoring

A laboratory may wish to appeal against their score and must contact us by email as per details on page 1. Your appeal will be given unique reference number and assigned to a Scheme Coordinator for consideration who will analyse the evidence and decide on an outcome. If your appeal is rejected, then a rationale for this conclusion will be provided. If your appeal is upheld, then you will be informed and actions will be taken accordingly. Actions required will be locally tracked and monitored for progress as part of our quality management system.

Any errors made by FEPTU in assigning your results will be rectified and an amended report issued. A participant requesting alteration of results will only be considered if the published report is less than three months old, as this is deemed sufficient time for laboratories to analyse their performance. Normally, outcomes for appeals are provided back to the participant within 10 working days. All decisions made are based on objective evidence and free from any undue influences. Any disagreements with your appeal based on our scoring policy that cannot be resolved by discussion with the Scheme Coordinator will be referred to the Steering Committee for further advice. This appeal process can take up to nine months to resolve due to the infrequency these meetings are held. Any actions taken should not result in discrimination against the participant.

22.0 Conferences

Open scientific conferences that cover aspects of the PT schemes and provide updates about new and emerging issues in food and water microbiology are organised regularly (approximately every 18 months). The conferences allow further opportunity for participants to meet FEPTU staff and other colleagues working in their field to discuss the schemes and other food and water microbiology issues.

23.0 Scheme consultants

The UKHSA food and water PT schemes are supported by a number of consultants who are experts, with many years of experience, in the relevant field of proficiency testing, food microbiology and/or water microbiology. Most of the consultants are, or were, employed by the UKHSA and are internationally recognised; they are all members of the Steering Group on Food and Water Microbiology Schemes. The consultants not only provide advice for the scheme organisers but are also able to respond to participant queries that are submitted via FEPTU, as required.

24.0 Terms and Conditions of participation

1. Samples distributed as part of the Schemes may contain microbiological pathogens of Hazard Groups 1 and 2 as defined by the Advisory Committee on Dangerous Pathogens (2004) “The Approved List of biological agents”. Participants must ensure that their laboratory facilities and expertise are adequate to ensure the safe handling and disposal of these organisms during their participation in the Schemes.
2. Membership of the Schemes is on an annual basis commencing on 1 April each year and terminating on 31 March in the next year. A participant is required to renew its participation in the Scheme each year. If a participant fails to renew, its membership in the Scheme will be terminated automatically. If a participant joins part way through the annual period, a reduced fee is payable reflecting the number of samples to be supplied for that part year. A participant may withdraw from the schemes at any time on giving 30 days' written notice, but no refund will be given of fees paid.

3. UK Health Security Agency (UKHSA) reserves the right to decline renewal of participant's membership at the end of each annual period or to change the annual fee.
4. Process for re-registration of the Schemes starts in January every year. Participants must complete the re-registration process to continue participating and receiving the Schemes.
5. Membership of a Scheme is offered with the understanding that participants will process quality assessment samples in the same way as their routine samples. This is necessary to achieve the primary purpose of the schemes, which is to allow participants an insight into their levels of performance in routine work.
6. Each laboratory will be registered under a unique code number. This code number and the assessment of individual performance is confidential to the participant and will not be released by UKHSA to third parties other than under any written agreement. Participants are free to release information concerning their own individual performance to whoever they wish. The fact of actual participation in the Schemes is not regarded as confidential and may be revealed by UKHSA to those with legitimate reasons for knowing.
7. All reports, and the data they contain, issued by the Quality Assessment Schemes are Crown Copyright and may not be published in any form without permission of UKHSA.
8. Participants in the Schemes have entire responsibility for all samples distributed to them under the Schemes and all activities carried out by them or any third party in relation to the samples from the time of delivery of the samples.
9. The liability of UKHSA to the participant in any annual period resulting from or in connection with the provision of the Scheme by UKHSA to the participant shall under no circumstances exceed the amount of the annual fee paid by the participant in respect of that annual period.
10. In case of the transfer of all or a substantial part of UKHSA's activities to another government body, UKHSA shall, notwithstanding any provisions to the contrary in this agreement, be entitled to transfer its rights and obligations hereunder to such other government body.
11. An invoice will be raised for the whole year's membership and payment terms are 30 days of the date of the invoice. Invoices will be issued in GBP and payments to be made in GBP.

I understand that the Scheme samples are likely to contain virulent pathogenic organisms of ACDP categories 1 & 2 and confirm that my laboratory facilities and staff expertise are adequate for safe handling and disposal of these organisms. I understand also that the Scheme samples are supplied on the basis that they will not be re-sold or supplied to any organisation or individuals outside the purchasing authority.