LAB 33

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Assessment and Accreditation of UK Official Food and Feed Laboratories and National Reference Laboratories

Contents

Changes since last edition

Minor clarifications and corrections throughout.

Reference to retained EU regulation updated to assimilated law.

Flexible scope and official sample definitions under section 2 provided.

Clause 1.5 added to specify that responsibility lies with the Competent Authority to advise UKAS of any changes to official status held by a laboratory.

Hyperlink for Foods Standards Scotland official laboratory listing webpage corrected (clause 3.4).

Clause 5.1 expanded to comment on sampling as a laboratory-undertaken activity.

Clause 5.4 regarding derogation arrangements for the testing of official samples added.

Responsibility of official laboratories and national reference laboratories to advise UKAS of significant nonconforming work has been included in line with the UKAS customer agreement.

Expansion of competence expectations to specifically identify Continual Professional Development expectation for Public/Agricultural Analysts and Food Examiners.

Change in emphasis of responsibility from UKAS to official laboratories and national reference laboratories to communicate any sanctions on accreditation imposed by UKAS within a defined time period and the requirement to advise UKAS when so done (clauses 7.2 & 7.3).

1. Introduction

1.1 The Food Standards Agency (FSA) and Food Standards Scotland (FSS) are respectively designated as the Competent Authority (CA) within their area of responsibility for the purposes of Assimilated European Law (AEUL) Official Controls Regulation (OCR) 2017/625 and requirements under the Northern Ireland Protocol, and subsequent implementing Statutory Instruments thereafter. As CAs, FSA and FSS have responsibility for the designation of official laboratories (OLs) to carry out analyses, tests and diagnoses on samples taken in the context of official controls (feed and food) and other official activities, and for designating National Reference Laboratories (NRLs). OLs[1] and NRLs[2] are designated by the FSA/FSS and are covered in this publication. These include other OLs for specific areas of work as defined in the relevant Multi-Annual National Control plan for the United Kingdom.

1.2 The FSA/FSS may only designate a laboratory as an official laboratory if that laboratory:

"(a) has the expertise, equipment and infrastructure required to carry out analyses or tests or diagnoses on samples;

(b) has a sufficient number of suitably qualified, trained and experienced staff;

(c) ensures that the tasks conferred upon it are performed impartially and which is free from any conflict of interest as regards the exercise of its tasks as an official laboratory;

(d) can deliver in a timely manner the results of the analysis, test or diagnosis carried out on the samples taken during official controls and other official activities; and

(e) operates in accordance with the standard EN ISO/IEC 17025 and is accredited in accordance with that standard by a national accreditation body operating in accordance with Regulation (EC) No 765/2008, as amended."

1.3 The scope of the accreditation of an official laboratory:

"(a) shall include those methods of laboratory analysis, test or diagnosis required to be used by the laboratory for analyses, tests or diagnoses, when it operates as an official laboratory;

(b) may comprise one or more methods of laboratory analysis, test or diagnosis or groups of methods;

(c) may be defined in a flexible manner, so as to allow the scope of accreditation to include modified versions of the methods used by the official laboratory when the accreditation was granted or new methods in addition to those methods, on the basis of the laboratory's own validations without a specific assessment by the national accreditation body prior to the use of those modified or new methods."

1.4 The CA is required to organise audits of the OLs and NRLs they have designated on a regular basis and withdraw the designation where appropriate, either completely or for separate tasks, where an official laboratory fails to take appropriate and timely remedial action following the results of an audit, which disclose any of the following:

(a) it no longer complies with the conditions provided for in Article 37(4-5) of AEUL OCR 2017/625 and;

(b) it does not comply with the obligations provided for in Article 38 of AEUL OCR 2017/625;

(c) it is underperforming at inter-laboratory comparative tests referred to in Article 38 of AEUL OCR 2017/625.

[1] https://www.food.gov.uk/about-us/official-feed-and-food-control-laboratories
[2] https://www.food.gov.uk/about-us/national-reference-laboratories-nrls

1.5 Any change in designation following the outcome of the CA audits will be communicated to UKAS by the CA in order to permit schedules of accreditation for OLs/NRLs to be amended so that they continue to correctly reference test methods applicable to AEUL OCR 2017/625.

1.6 FSA/FSS have reached agreement with UKAS such that the outcome of ISO/IEC 17025 assessments of OLs and NRLs shall contribute to the CA's responsibility for auditing such designations under AEUL OCR 2017/625 and accordingly a memorandum of understanding (MoU) has been implemented between FSA/FSS and UKAS to facilitate the sharing of the outcomes of assessments relating to accredited OLs and NRLs activities as designated by the CA. This MoU is subject to periodic review, and any relevant updates may subsequently be reflected in this document.

1.7 Laboratories wishing to be assessed and accredited in accordance with the MoU must complete and return to UKAS the relevant permission form (UKAS Confidentiality Waiver Form F563) enabling UKAS to notify FSA/FSS as required. The FSA/FSS, where appropriate, will hold any documentation and information supplied under the terms of the MoU in confidence, subject to the law of the land.

1.8 Following successful assessment, status as an OL/NRL will be denoted on a laboratory's schedule of accreditation together with an indication of specific tests covered by its status.

1.9 For the purposes of implementing the MoU, it should be understood that existing designations of OL/NRL status by FSA/FSS will not be subject to any additional UKAS assessment at the commencement of the MoU. Instead, this publication sets out how UKAS will apply its assessment processes in accordance with ISO/IEC 17011 to determine conformity to ISO/IEC 17025 and in part, satisfy the CA need to fulfil Articles 37, 38 and Article 100 (2) of AEUL OCR 2017/625 when applied to organisations holding recognition as Official Feed and Food Laboratories and/or National Reference Laboratories. Laboratories shall also take account of any guidance and relevant information in other publications issued by UKAS or European co-operation for Accreditation (EA), to support laboratory accreditation to ISO/IEC 17025, particularly Eurachem/CITAC Guide for chemistry laboratories and Eurachem Accreditation for microbiology laboratories.

2. Definitions

Competent authority:
The central authority designated by the UK Government (and its devolved administrations) competent for the organisation of official controls or any other authority to which that competence has been conferred (e.g. Local Authorities); it shall include where appropriate, the corresponding authority of a third country.

Flexible scope:
The scope of accreditation expressed to allow conformity assessment bodies to make changes in methodology and other parameters which fall within the assessed competence of the laboratory in accordance with UKAS publication GEN 4.

Official control:
Any form of control that the competent authorities perform for the verification of compliance with feed and food law, animal health and animal welfare rules.

Official Laboratory (OL):
A laboratory that is designated as an Official Laboratory under AEUL OCR 2017/625 to undertake the laboratory analyses, tests and diagnoses on samples taken during official controls and other official activities.

Official sample:
FSA and FSS define samples for the purposes of official control testing as any sample taken for the purposes of inspection, partial inspection, audit, verification, monitoring and surveillance, whether taken in a formal or informal manner. For microbiological testing, this shall therefore also include environmental swabs.

National Reference Laboratory (NRL):
A specialist laboratory with responsibility for maintaining standards for the routine testing of feed, food and animal health, providing advice and support on methods for official control testing as set out under AEUL OCR 2017/625. NRLs are appointed by the FSA and FSS for the UK for food and feed, and Defra for Great Britain for animal health and live animals, with DAERA and FSA having equivalent appointing powers in Northern Ireland.

3. Regulatory requirements for food and feed analysis and examination

3.1 In the UK, the control of food safety, composition and consumer protection in relation to food is provided for by means of the Food Safety Act 1990 and supporting regulations. The Food Safety Act requires the appointment of Public Analysts and also provides for Food Examiners. The Food Safety (Sampling and Qualifications) Regulations 2013 define the minimum level of their qualifications and experience.

3.2 The Agriculture Act 1970 and supporting regulations provides for control of preparation and sale of animal feeding stuffs. The Act requires the appointment of Agricultural Analysts.

3.3 Under AEUL OCR 2017/625 and its Annexes, OLs shall be accredited and use appropriate test methods. For OLs the requirements became effective on 14 December 2019.

3.4 The FSA/FSS sets out its requirements concerning the use of Official Laboratories in Codes of Practice and holds the authoritative list of nominated laboratories. Details are available on the FSA and FSS websites at Feed and food official laboratories | Food Standards Agency, Official feed and food laboratories | Food Standards Scotland and National Reference Laboratories (NRLs) | Food Standards Agency.

4. Specific obligations on Official Feed and Food Laboratories when testing for official control and other official activities

4.1 Laboratories shall give permission in writing (according to clause 1.6) for UKAS to release to the FSA/FSS information relevant only to their status as official laboratories through provision of assessment report executive summaries and any other relevant report content. It will be for the CAs to determine an appropriate course of action should a laboratory not agree to UKAS releasing relevant information to the FSA/FSS.

4.2 For the purpose of the application of this document, the definition of official samples as given in section 2 of this publication shall be considered as an official control under AEUL OCR 2017/625.

4.3 OLs testing samples taken under Food Safety (Sampling and Qualifications) Regulations 2013 and The Animal Feed (Hygiene, Sampling etc. and Enforcement) Regulations as they apply to England, Wales, Northern Ireland, and Scotland, must employ appropriate personnel as Public Analysts, Agricultural Analysts and/or as Food Examiners with the requisite qualifications and experience as prescribed in SI 2013/264 and devolved equivalent regulations. This requirement however only applies to testing undertaken under these regulations. It does not apply to OLs testing official samples taken for official control monitoring activities.

4.4 OLs shall be accredited on a method-by-method basis for conformance with ISO/IEC 17025 for determinands relevant to their official activities. Only accredited methods may be used for the analysis or examination of official samples, unless covered under a derogation within the AEUL OCR 2017/625 (see Section 5).

4.5 OLs shall use methods of analysis or examination that are fully documented and have established performance characteristics demonstrating fitness for purpose noting OCR derogation articles 40 and 42.

4.6 In addition to any comparative tests organised by NRLs, OLs shall, where available, participate in relevant external proficiency testing schemes in line with UKAS Technical Policy Statement TPS 47.

4.7 For samples taken under the Food Safety Act 1990 and supporting regulations, OLs shall report their results for enforcement purposes, subject to such adaptations as circumstances may reasonably require, in the form set out in Schedule 3 of SI 2013/264 and devolved equivalent regulations.

4.8 OLs operating on two or more laboratory sites, but with a common scientific management and accredited as a multi-site laboratory, may transfer samples between those sites for analysis or examination for any of the above specific determinations. The OL transferring any such samples need not be accredited for the specific determination or the specific determinations to be carried out at that other OL, provided that the recipient laboratory is accredited for that specific analysis.

4.9 Where a laboratory receives samples submitted under the Food Safety Act and has subsequent need (e.g. lacks accreditation for the requested test) to transfer said samples to a laboratory independent of itself ('secondary' OL), then the receiving laboratory, whether or not it is in the same country as the original transferring laboratory, must be designated as an OL by the relevant CA for the testing required by the original laboratory (primary laboratory). Those tests that are being requested of the receiving laboratory need to be covered by accreditation and meet the requirements of ISO/IEC 17025 for the specific analysis and the analysis carried out "under the direction of" or via a "passing on" mechanism by the Public Analyst, Food Examiner or Agricultural Analyst, or as a consequence of "passing on" from the primary OL.

4.10 Where a laboratory is operating on two or more sites under multi-site accreditation, then, for the purposes of this publication, the multi-site group is deemed to be the OL.

5. Methods

5.1 Laboratories must have protocols defining the approaches to be adopted for processing and testing official samples and for all associated activities which should include sampling (whether accredited or otherwise, as the conduct of such an activity may influence the validity of subsequent testing).

5.2 Only accredited methods may be used for analysis and examination of official samples. If not prescribed by statute, methods published by, for example, ISO or CEN or methods with equivalent international recognition shall be used. If there are no such methods, others that have been suitably validated and demonstrated to be fit for purpose may be used.

5.3 OLs/NRLs may be accredited for specific and general methods. Specific methods are the determination of a particular parameter in a specified feed or food by a specified method; a general method is the determination of a particular parameter in a feed or food matrix by a specified method. In order to test unusual or infrequently received samples or for the determination of parameters for which accreditation for specific or general methods is not held, laboratories may also be accredited for the use of a flexible scope for the analysis or examination of feed or foodstuffs. This will require the documentation of protocols, which describe the basic components of a system or systems that may be used alone or in combination in order to carry out the required procedure. As necessary the protocols shall include, or shall cross reference, procedures relating to sample preparation techniques, measurement techniques and methods, use and maintenance of equipment, validation, circumstances under which exceptions may be permitted, staff training and experience requirements for the use of such procedures. Additional guidance on accreditation of flexible scopes is given in UKAS publication GEN 4.

5.4 Derogations from accreditation are provided in OCR Articles 40, 41 and 42. Provision is made for the adoption of derogations aimed at allowing laboratories not to be accredited for all the methods they use. Accreditation of a laboratory for all the methods that it should use as an OL might not be immediately available in cases where new or recently modified methods are to be used, in cases of

emerging risks or in emergency situations. OLs should give due consideration to the development of methodologies under flexible scope processes where granted by UKAS. Otherwise, under certain conditions, OLs may be allowed to carry out analyses/tests before they obtain the relevant accreditation. In all cases, derogation will be the sole responsibility of the CA. In these cases, UKAS' role in assessing conformity against ISO/IEC 17025 shall be to raise a nonconformity where unaccredited methods have found to have used for the testing of official samples when an OL is unable to demonstrate engagement with the CA concerning derogation from accreditation.

6. UKAS assessment procedures

6.1 General

6.1.1 Assessment shall follow the normal procedure as detailed in UKAS publication GEN 1 and shall aim to establish the laboratory's conformance with ISO/IEC 17025 for the specific activities of testing official samples. Other publications may also be relevant.

6.1.2 If, following UKAS assessment, any improvement action by the OL/NRL is identified as being necessary, then such action will be documented, and its effectiveness will be assessed by UKAS in accordance with and as part of its normal operation. The laboratory will be notified of the specified period of time in which it shall remedy the situation. Failure to take effective cause, effect and action within that time could lead to suspension or withdrawal of accreditation by UKAS.

6.1.3 Any impact on the designated status of a laboratory caused by UKAS-imposed suspension (part or full) or withdrawal of accreditation will be the responsibility of FSA/FSS. The remit of UKAS shall not extend to giving recommendations concerning the OL/NRL status.

6.1.4 Where a laboratory is operating on two or more sites, by a common scientific management under Multi-site Accreditation, then the multiple sites, collectively, are deemed by FSA/FSS to be the OL/NRL.

6.1.5 The performances of the OL/NRL in the recognised proficiency testing schemes will be monitored by UKAS on behalf of the FSA/FSS, along with the records of remedial actions taken by the laboratory to identify reasons for any unsatisfactory performance and the corrective actions undertaken.

6.1.6 The assessment team is required to record the extent of proficiency scheme participation in the Assessment Report.

6.1.7 OLs/NRLs will notify UKAS as soon as practicable following identification of any Significant Nonconformity as defined in the UKAS Customer Agreement. Upon investigation, UKAS will determine if the CA needs to be made aware.

6.2 Initial Assessment, Reassessment and Surveillance

6.2.1 The granting, renewal and maintenance of accreditation will be afforded only to a laboratory that complies with the requirements of ISO/IEC 17025 and any other relevant criteria of competence specified by UKAS, as is a requirement of AEUL OCR 2017/625 for official activities (unless otherwise covered by derogation Article 40 or a temporary derogation designated by the CA under Article 42). Regardless of assessment year in cycle, the assessment will specifically comment on:

- Assessment of the suitability of a representative selection of the test methods used for feed and/or food analysis or food examination according to OCR Article 34;
- Competence, training, authorisations, including qualifications, to operate official control test methods;

- Maintained competence of PA, AA and FE appointed laboratory personnel, including relevant CPD;
- Suitability of equipment sampled as part of the test method selection assessed;
- AQC/IQC and suitability of other relevant quality control processes;
- Appropriate participation in proficiency testing schemes and/or inter laboratory trials, results, and trend review;
- Development and implementation of test methods under flexible scope (as applicable);
- Maintenance of infrequently performed test methods;
- Subcontracted work falling under OCR if applicable.

6.2.2 In addition to the above aspects, UKAS assessment plans may include a requirement to conduct vertical audits covering all areas of enforcement work.

6.2.3 Where the designated activity of the OL or NRL represents a minority of the laboratory's overall accredited testing, it is unlikely that UKAS will assess all aspects listed in 6.2.1 on an annual basis where evident conformity is noted and overall risk is considered low. Performance in proficiency testing will be reviewed annually regardless.

7. Reporting to FSA/FSS

7.1 Under the arrangements of the MoU, UKAS will report to FSA/FSS on an annual basis to support the CA in fulfilling its obligations under AEUL OCR 2017/625. This annual report will summarise conformity to ISO/IEC 17025 in the areas outlined under 6.2 for all OLs/NRLs.

7.2 Where UKAS identifies of "serious effect on quality of the result". It may be recommended and upheld that:

a) part or all of a laboratory's OL activities is suspended;

b) UKAS deems that an extra assessment (including unannounced assessments) is required outside of the usual assessment programme;

c) permanent withdrawal of suspended activities is appropriate, otherwise suspended activities are reinstated.

7.3 It shall be the responsibility of the OL/NRL to communicate to the CA immediately of any suspension, or withdrawal of part or entire accreditation, related to the official control work, whether imposed or voluntary. The laboratory shall undertake to provide UKAS with evidence of such communication to the CA within 5 working days of the sanction being applied, otherwise UKAS shall communicate details of the sanction separately to the CA without further delay.

7.4 UKAS schedules of accreditation for OLs will identify those test methods that fall under AEUL OCR 2017/625, and it is the OL/NRL's responsibility to communicate required changes of schedules in a timely manner.

8. References

1. Agriculture Act 1970
2. CITAC/Eurachem “Guide to Quality in Analytical Chemistry - An Aid to Accreditation”, current edition
3. Eurachem “Accreditation for Microbiological Laboratories”, current edition
4. Food Safety Act 1990
5. Food Law Code of Practice (England), Food Standards Agency, and equivalents in Wales and Northern Ireland (https://www.food.gov.uk/about-us/food-and-feed-codes-of-practice)
6. Food Law Code of Practice (Scotland) (https://www.foodstandards.gov.scot/business-and-industry/safety-and-regulation/food-and-feed-law)
7. GEN 1, “General Principles for the Assessment of Conformity Assessment Bodies by the United Kingdom Accreditation Service”, current edition
8. GEN 4, “UKAS Policy and General Guidance on the Implementation and Management of Flexible Scopes of Accreditation”, current edition
9. https://www.food.gov.uk/about-us/official-feed-and-food-control-laboratories
10. https://www.food.gov.uk/about-us/national-reference-laboratories-nrls
11. ISO/IEC 17011, “Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies”
12. ISO/IEC 17025, “General Requirements for the Competence of Testing and Calibration Laboratories"
13. Assimilated European Law Official Controls Regulation 2017/625
14. Multi-Annual National Control Plan for the United Kingdom https://www.food.gov.uk/sites/default/files/media/document/ukmulti-nationalcontrolplan2013-2018.pdf
15. Requirements for accreditation and market surveillance relating to the marketing of products Regulation (EC) No 765/2008
16. The Food Safety (Sampling and Qualifications) (England) Regulations 2013 (http://www.legislation.gov.uk/uksi/2013/264/made)
17. The Food Safety (Sampling and Qualifications) (Wales) Regulations 2013 (http://www.legislation.gov.uk/wsi/2013/479/contents)
18. The Food Safety (Sampling and Qualifications) Regulations (Northern Ireland) 2013 (http://www.legislation.gov.uk/nisr/2013/66/contents/made)
19. The Food Safety (Sampling and Qualifications) (Scotland) Regulations 2013 (https://www.legislation.gov.uk/ssi/2013/84/contents/made)
20. TPS 47, “UKAS Policy on Participation in Proficiency Testing”, current edition