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

This is the first edition of this publication.

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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 retained Regulation (EU) 2017/625 on Official Feed and Food Controls (OCR) 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 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".

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 are 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 retained Regulation (EU) 2017/625 and;

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

(c) it is underperforming at inter-laboratory comparative tests referred to in Article 38 of retained Regulation (EU) 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

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1.5 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 retained Regulation (EU) 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.

1.6 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.

1.7 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.

1.8 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 OCR 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.

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 retained Regulation (EU) 2017/625 to undertake the laboratory analyses, tests and diagnoses on samples taken during official controls and other official activities.

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 retained Regulation (EU) 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.

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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 retained Regulation (EU) 2017/625 and its Annexes, OLs shall be accredited and use appropriate test methods. For OLs the requirements became effective on the 14th 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 https://www.food.gov.uk/about-us/official-feed-and-food-control-laboratories, https://www.foodstandards.gov.scot/business-and-industry/local-authorities-gateway/official-feed-and-food-control-laboratories and https://www.food.gov.uk/about-us/national-reference-laboratories-nrls.

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. 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, all samples that are examined by an official lab for food and feed law compliance shall be considered as an official control under retained Regulation (EU) 2017/625. Samples taken for regulatory monitoring purposes shall be considered an official activity.

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 retained Regulation (EU) 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.

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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 and shall notify UKAS in the event of continued unacceptable performance.

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.

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.

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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.

6.2 Initial Assessment, Reassessment and Surveillance

6.2.1 The granting, renewal and maintenance of accreditation will be afforded only to a laboratory that continually complies with the requirements of ISO/IEC 17025 and any other relevant criteria of competence specified by UKAS, as is a requirement of retained Regulation (EU) 2017/625 for official activities (unless otherwise covered by derogation Art 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;
- 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.

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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 retained Regulation (EU) 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 Additionally, UKAS will advise FSA/FSS of details of any ”serious effect on quality of the result”. This will include:

a) all instances where accreditation for part or all of a laboratory’s OL activities is recommended and upheld for suspension;

b) instances where UKAS deems that an extra assessment (including unannounced assessments) is required outside of the usual assessment programme due to concerns over ongoing conformity with meeting the requirements of ISO/IEC 17025;

c) reinstatement or permanent withdrawal of suspended activities.

7.3 UKAS schedules of accreditation for OLs will identify those test methods that fall under retained Regulation (EU) 2017/625 and UKAS will request cooperation from laboratories to communicate required changes of schedules in a timely manner.

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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. Official Controls Regulation (EU) 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

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