Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (Text with EEA relevance)

TITLE II

OFFICIAL CONTROLS AND OTHER OFFICIAL ACTIVITIES [F1]...

CHAPTER IV

Sampling, analyses, tests and diagnoses

Article 34

Methods used for sampling, analyses, tests and diagnoses

1 Methods used for sampling and for laboratory analyses, tests and diagnoses during official controls and other official activities shall comply with **[**[F1]legislation in force in the relevant constituent territory of Great Britain**]** establishing those methods or the performance criteria for those methods.

2 In the absence of [F2]... rules as referred to in paragraph 1, and in the context of official controls and other official activities, official laboratories shall use one of the following methods according to the suitability for their specific analytical, testing and diagnostic needs:

a available methods complying with relevant internationally recognised rules or protocols [F3]...; or

relevant methods developed or recommended by the European Union **[**[F4]or British**]** reference laboratories and validated in accordance with internationally accepted scientific protocols;

b in the absence of the suitable rules or protocols, as referred to in point (a), methods which comply with relevant rules established **[**[F5]in the relevant constituent territory of Great Britain**]**, or, if no such rules exist, relevant methods developed or recommended by national reference laboratories and validated in accordance with internationally accepted scientific protocols; or

relevant methods developed and validated with inter or intra-laboratory methods validation studies in accordance with internationally accepted scientific protocols.

3 Where laboratory analyses, tests or diagnoses are urgently needed and none of the methods referred to in paragraphs 1 and 2 of this Article exists, the relevant national reference laboratory or, if no such national reference laboratory exists, any other laboratory designated in accordance with Article 37(1) may use methods other than those referred to in paragraphs 1 and 2 of this Article until the validation of an appropriate method in accordance with internationally accepted scientific protocols.

4 Wherever possible, methods used for laboratory analyses shall be characterised by the relevant criteria set out in Annex III.

5 Samples shall be taken, handled and labelled in such a way as to ensure their legal, scientific and technical validity.

6 The **[**F6appropriate authority may make regulations laying**]** down rules on:

a the methods to be used for sampling and for laboratory analyses, tests and diagnoses;

b performance criteria, analysis, test or diagnosis parameters, measurement uncertainty and procedures for the validation of those methods;

c the interpretation of analytical, testing and diagnostic results.

F7 …

Textual Amendments

F1 Words in Art. 34(1) substituted (31.12.2020) by The Official Controls (Animals, Feed and Food, Plant Health etc.) (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1481), regs. 1, **8(1)(a)** (with reg. 46)

F2 Words in Art. 34(2) omitted (31.12.2020) by virtue of The Official Controls (Animals, Feed and Food, Plant Health etc.) (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1481), regs. 1, **8(1)(b)(i)** (with reg. 46)

F3 Words in Art. 34(2)(a) omitted (31.12.2020) by virtue of The Official Controls (Animals, Feed and Food, Plant Health etc.) (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1481), regs. 1, **8(1)(b)(ii)(aa)** (with reg. 46)

F4 Words in Art. 34(2)(a) inserted (31.12.2020) by The Official Controls (Animals, Feed and Food, Plant Health etc.) (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1481), regs. 1, **8(1)(b)(ii)(bb)** (with reg. 46)

F5 Words in Art. 34(2)(b) substituted (31.12.2020) by The Official Controls (Animals, Feed and Food, Plant Health etc.) (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1481), regs. 1, **8(1)(b)(iii)** (with reg. 46)

F6 Words in Art. 34(6) substituted (31.12.2020) by The Official Controls (Animals, Feed and Food, Plant Health etc.) (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1481), regs. 1, **8(1)(c)(i)** (with reg. 46)

F7 Words in Art. 34(6) omitted (31.12.2020) by virtue of The Official Controls (Animals, Feed and Food, Plant Health etc.) (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1481), regs. 1, **8(1)(c)(ii)** (with reg. 46)

Article 35

Second expert opinion

1 The competent authorities shall ensure that operators, whose animals or goods are subject to sampling, analysis, test or diagnosis in the context of official controls, have the right to a second expert opinion, at the operator’s own expense.

The right to a second expert opinion shall entitle the operator to request a documentary review of the sampling, analysis, test or diagnosis by another recognised and appropriately qualified expert.

2 Where relevant, appropriate and technically feasible, having regard in particular to the prevalence and distribution of the hazard in the animals or goods, to the perishability of the samples or the goods and to the amount of available substrate, the competent authorities shall:

a when taking the sample, and if so requested by the operator, ensure that a sufficient quantity is taken to allow for a second expert opinion and for the review referred to in paragraph 3, should this prove necessary; or

b where it is not possible to take a sufficient quantity as referred to in point (a), inform the operator thereof.

This paragraph shall not apply when assessing the presence of quarantine pests in plants, plant products or other objects for the purpose of verifying compliance with the rules referred to in point (g) of Article 1(2).

3 **[**[F8]The appropriate authority**]** may decide that, where there is a dispute between the competent authorities and the operators that is based on the second expert opinion referred to in paragraph 1, the operators may request, at their own expense, the documentary review of the initial analysis, test or diagnosis and, where appropriate, another analysis, test or diagnosis by another official laboratory.

4 The application by the operator for a second expert opinion under paragraph 1 of this Article shall not affect the obligation of competent authorities to take prompt action to eliminate or contain the risks to human, animal and plant health, or to animal welfare or, as regards GMOs and plant protection products, also to the environment, in accordance with this Regulation and with the rules referred to in Article 1(2).

Textual Amendments

F8 Words in Art. 35(3) substituted (31.12.2020) by The Official Controls (Animals, Feed and Food, Plant Health etc.) (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1481), regs. 1, **8(2)** (with reg. 46)

Article 36

Sampling of animals and goods offered for sale by means of distance communication

1 In the case of animals and goods offered for sale by means of distance communication, samples ordered from operators by the competent authorities without identifying themselves may be used for the purposes of an official control.

2 Competent authorities, once they are in possession of the samples, shall take all steps to ensure that the operators from whom these samples have been ordered in accordance with paragraph 1:

a are informed that such samples have been taken in the context of an official control and, where appropriate, are analysed or tested for the purposes of such official control; and

b where the samples referred to in that paragraph are analysed or tested, are able to exercise the right to a second expert opinion, as provided for in Article 35(1).

3 Paragraphs 1 and 2 shall apply to delegated bodies and natural persons to which certain official controls tasks have been delegated.

Article 37

Designation of official laboratories

1 The competent authorities shall designate official laboratories **[**F9, which may be in any part of the United Kingdom,**]** to carry out the laboratory analyses, tests and diagnoses on samples taken during official controls and other official activities **[**F10in Great Britain.**]**

2 Competent authorities may designate as an official laboratory a laboratory located in **[**F11a third country**]**, subject to compliance with the following conditions:

a appropriate arrangements are in place under which the competent authorities are enabled to perform the audits and inspections referred to in Article 39(1)F12...; and

b that laboratory is already designated as an official laboratory by the competent authorities of the **[**F13country**]** on whose territory it is located.

3 The designation of an official laboratory shall be in writing and shall include a detailed description of:

a the tasks that the laboratory carries out as an official laboratory;

b the conditions under which it carries out the tasks referred to in point (a); and

c the arrangements necessary to ensure efficient and effective coordination and collaboration between the laboratory and the competent authorities.

4 The competent authorities may only designate as an official laboratory a laboratory which:

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 as set out in paragraph 1 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.

5 The scope of the accreditation of an official laboratory as referred to in point (e) of paragraph 4:

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.

6 Where no official laboratory designated in the **[**F14United Kingdom or in a third country,**]** has the expertise, equipment, infrastructure and staff necessary to perform new or

particularly uncommon laboratory analyses, tests or diagnoses, the competent authorities may request a laboratory or diagnostic centre which does not comply with one or more of the requirements set out in paragraphs 3 and 4 to carry out those analyses, tests and diagnoses.

Textual Amendments

F9 Words in Art. 37(1) inserted (31.12.2020) by The Official Controls (Animals, Feed and Food, Plant Health etc.) (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1481), regs. 1, **8(3)(a)(i)** (with reg. 46)

F10 Words in Art. 37 substituted (31.12.2020) by The Official Controls (Animals, Feed and Food, Plant Health etc.) (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1481), regs. 1, **8(3)(b)** (with reg. 46)

F11 Words in Art. 37(2) substituted (31.12.2020) by The Official Controls (Animals, Feed and Food, Plant Health etc.) (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1481), regs. 1, **8(3)(c)(i)** (with reg. 46)

F12 Words in Art. 37(2)(a) omitted (31.12.2020) by virtue of The Official Controls (Animals, Feed and Food, Plant Health etc.) (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1481), regs. 1, **8(3)(c)(ii)** (with reg. 46)

F13 Word in Art. 37(2)(b) substituted (31.12.2020) by The Official Controls (Animals, Feed and Food, Plant Health etc.) (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1481), regs. 1, **8(3)(c)(iii)** (with reg. 46)

F14 Words in Art. 37(6) substituted (31.12.2020) by The Official Controls (Animals, Feed and Food, Plant Health etc.) (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1481), regs. 1, **8(3)(d)** (with reg. 46)

Article 38

Obligations of official laboratories

1 Where the results of an analysis, test or diagnosis carried out on samples taken during official controls or other official activities indicate a risk to human, animal or plant health, or, as regards GMOs and plant protection products, also to the environment, or point to the likelihood of non-compliance, official laboratories shall inform immediately the competent authorities which designated them for that analysis, test or diagnosis and, where relevant, delegated bodies or natural persons to which tasks have been delegated. However, specific arrangements between the competent authorities, delegated bodies or natural persons to which tasks have been delegated and the official laboratories may specify that this information is not required to be provided immediately.

2 Upon request by **[**F15a**]** national reference laboratory, official laboratories shall take part in inter-laboratory comparative tests or proficiency tests that are organised for the analyses, tests or diagnoses they perform as official laboratories.

3 Official laboratories shall, upon request of the competent authorities, make available to the public the names of the methods used for analyses, tests or diagnoses performed in the context of official controls and other official activities.

4 Official laboratories shall indicate, at the request of the competent authorities, together with the results, the method used for each analysis, testing or diagnosis, performed in the context of official controls and other official activities.

Textual Amendments

F15 Word in Art. 38(2) substituted (31.12.2020) by The Official Controls (Animals, Feed and Food, Plant Health etc.) (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1481), regs. 1, **8(4)** (with reg. 46)

Article 39

Audits of official laboratories

1 The competent authorities shall organise audits of the official laboratories they have designated in accordance with Article 37(1) on a regular basis and any time they consider that an audit is necessary, unless they find such audits to be redundant considering the accreditation assessment referred to in point (e) of Article 37(4).

2 The competent authorities shall immediately withdraw the designation of an official laboratory, either completely or for certain tasks, where it fails to take appropriate and timely remedial action following the results of an audit provided for in paragraph 1 which disclose any of the following:

a it no longer complies with the conditions provided for in Article 37(4) and (5);

b it does not comply with the obligations provided for in Article 38;

c it is underperforming at inter-laboratory comparative tests referred to in Article 38(2).

Article 40

Derogations from the condition for the mandatory accreditation for certain official laboratories

1 By way of derogation from point (e) of Article 37(4), competent authorities may designate the following as official laboratories irrespective of whether they fulfil the condition provided for in that point:

a laboratories:

(i) whose sole activity is the detection of *Trichinella* in meat;

(ii) that only use the methods of detection of *Trichinella* referred to in Article 6 of Commission Implementing Regulation (EU) 2015/1375[(1)];

(iii) that carry out the detection of *Trichinella* under the supervision of the competent authorities or of an official laboratory designated in accordance with Article 37(1) and accredited in accordance with the standard EN ISO/IEC 17025 for the use of the methods referred to in point (ii) of this point; and

(iv) that participate regularly and have satisfactory performance in the inter-laboratory comparative tests or proficiency tests organised by the national reference laboratories for the methods they use for the detection of *Trichinella*;

b laboratories which only carry out analyses, tests or diagnoses in the context of other official activities, provided that they:

(i) only use the methods of laboratory analysis, test and diagnosis referred to in Article 34(1) and point (a) or (b) of Article 34(2);

(ii) carry out the analyses, tests or diagnoses under the supervision of the competent authorities or of the national reference laboratories in relation to the methods they use;

(iii) participate regularly and have satisfactory performance in the inter-laboratory comparative tests or proficiency tests organised by the national reference laboratories in relation to the methods they use; and

(iv) have a quality assurance system in place to ensure sound and reliable results from the methods for laboratory analysis, test and diagnosis used.

2 Where the methods used by the laboratories referred to in point (b) of paragraph 1 of this Article require confirmation of the result of the laboratory analysis, test or diagnosis, the confirmatory laboratory analysis, test or diagnosis shall be carried out by an official laboratory which complies with the requirements set out in point (e) of Article 37(4).

3 The official laboratories designated in accordance with paragraph 1 shall be located in the **[**[F16]United Kingdom.**]**

Textual Amendments

F16 Words in Art. 40(3) substituted (31.12.2020) by The Official Controls (Animals, Feed and Food, Plant Health etc.) (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1481), regs. 1, **8(5)** (with reg. 46)

Article 41

Powers to adopt derogations from the condition for the mandatory accreditation of all the methods of laboratory analysis, test and diagnosis used by official laboratories

The **[**[F17]appropriate authority may make regulations**]** to supplement this Regulation concerning the cases where, and the conditions under which, competent authorities may designate as official laboratories, in accordance with Article 37(1), laboratories which do not fulfil the conditions referred to in point (e) of Article 37(4) in relation to all the methods they use for official controls or other official activities, provided that such laboratories comply with the following conditions:

(a) they operate and are accredited in accordance with the standard EN ISO/IEC 17025 for the use of one or more methods which are similar to and representative of the other methods they use; and

(b) they make regular and significant use of the methods for which they have obtained the accreditation referred to in point (a) of this Article; except, as regards the area governed by the rules referred to in point (g) of Article 1(2), where a validated method for the detection of the particular pests of plants referred to in Article 34(1) and (2) does not exist.

Textual Amendments

F17 Words in Art. 41 substituted (31.12.2020) by The Official Controls (Animals, Feed and Food, Plant Health etc.) (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1481), regs. 1, **8(6)** (with reg. 46)

Article 42

Temporary derogations from the conditions of the mandatory accreditation for official laboratories

1 By way of derogation from point (a) of Article 37(5), the competent authorities may temporarily designate an existing official laboratory as an official laboratory in accordance with Article 37(1) for the use of a method of laboratory analysis, test or diagnosis for which it has not obtained the accreditation referred to in point (e) of Article 37(4):

a when the use of that method is newly required by **[**F18legislation in force in the relevant constituent territory of Great Britain**]**;

b when changes to a method in use require a new accreditation or an extension of the scope of the accreditation obtained by the official laboratory; or

c in cases where the need for the use of the method results from an emergency situation or an emerging risk to human, animal or plant health, animal welfare or, as regards GMOs and plant protection products, also to the environment.

2 The temporary designation referred to in paragraph 1 shall be subject to the following conditions:

a the official laboratory is already accredited in accordance with the standard EN ISO/IEC 17025 for the use of a method which is similar to the one not included within the scope of its accreditation;

b a quality assurance system is in place in the official laboratory to ensure sound and reliable results by using a method which is not included within the scope of the existing accreditation;

c the analyses, tests or diagnoses are carried out under the supervision of the competent authorities or the national reference laboratory for that method.

3 The temporary designation provided for in paragraph 1 shall not exceed a period of one year. It may be renewed once for a further period of one year.

4 The official laboratories designated in accordance with paragraph 1 shall be located in the **[**F19United Kingdom.**]**

Textual Amendments

F18 Words in Art. 42(1)(a) substituted (31.12.2020) by The Official Controls (Animals, Feed and Food, Plant Health etc.) (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1481), regs. 1, **8(7)(a)** (with reg. 46)

F19 Words in Art. 42(4) substituted (31.12.2020) by The Official Controls (Animals, Feed and Food, Plant Health etc.) (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1481), regs. 1, **8(7)(b)** (with reg. 46)

(**1**) Commission Implementing Regulation (EU) 2015/1375 of 10 August 2015 laying down specific rules on official controls for Trichinella in meat (OJ L 212, 11.8.2015, p. 7).

Status:
Point in time view as at 31/12/2020.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) 2017/625 of the European Parliament and of the Council, CHAPTER IV.