



EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

amending Annex I to Implementing Regulation (EU) 2015/1375 as regards the reference method and the authorisation of lumiVAST *Trichinella* as an equivalent method for detection of *Trichinella* in meat of domestic swine

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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)¹, and in particular Article 18(8), point (a), thereof,

Whereas:

- (1) Regulation (EU) 2017/625 lays down, inter alia, specific rules on official controls and for action to be taken by the competent authorities in relation to the production of products of animal origin intended for human consumption.
- (2) *Trichinella* is a parasite that may be present in the meat of susceptible species, such as domestic swine and causes food-borne illness in humans when infected meat is consumed. Commission Implementing Regulation (EU) 2015/1375² lays down specific rules on official controls for *Trichinella* in meat, including rules on laboratory examination of samples of carcasses of domestic swine.
- (3) Annex I to Implementing Regulation (EU) 2015/1375 sets out the detection methods for *Trichinella*, and Chapter I of that Annex provides that the reference method of detection for the examination of samples for *Trichinella* is ISO 18743:2015.
- (4) ISO 18743:2015 reference method does not specify the weight of the sample to be taken in the case of whole carcasses and cuts of meat of domestic swine. To ensure the sensitivity of the method and a harmonised approach, these weights should be laid down. In addition, ISO 18743:2015 was updated in 2023 to ISO 18743:2015/Amd1:2023. It

¹ OJ L 95, 7.4.2017, p. 1, ELI: <http://data.europa.eu/eli/reg/2017/625/oj>.

² 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, ELI: http://data.europa.eu/eli/reg_impl/2015/1375/oj).

should be ensured that reference is made to this most recent version of the ISO method. Chapter I of Annex I to Implementing Regulation (EU) 2015/1375 should be amended accordingly.

- (5) Furthermore, Chapter II of Annex I to Implementing Regulation (EU) 2015/1375 lists equivalent methods that are authorised for the detection in examining samples for *Trichinella*.
- (6) For reasons of consistency, in Chapter II of Annex I, references to the ISO method should also refer to its most recent version and reference to Chapter I of that Annex should be made to ensure that the introduced weight of the samples also applies in case of testing using an equivalent method.
- (7) On 3 September 2024, the European Reference Laboratory for Parasites forwarded a report to the Commission on the validation of lumiVAST *Trichinella* for the examination of samples of meat of domestic swine for *Trichinella*. The report concludes that: ‘according to the results of the validation rounds, the lumiVAST *Trichinella* is suitable to detect *Trichinella spp.* larvae in muscle samples of pigs. The use of this method is restricted to pork meat inspection only, as the kit has been not validated for other animal species’.
- (8) The lumiVAST *Trichinella* should therefore be authorised as an equivalent method for the examination of samples from carcasses of domestic swine for *Trichinella*. It should also be laid down how to carry out further investigations in the case of the examination of a collective sample that produces a positive or uncertain result. Chapter II of Annex I to Implementing Regulation (EU) 2015/1375 should therefore be amended accordingly.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Implementing Regulation (EU) 2015/1375 is amended as follows:

- (1) Chapter I is replaced by the following:

‘CHAPTER I

REFERENCE METHOD OF DETECTION

1. The reference method of detection for the examination of samples for *Trichinella*, shall be [ISO 18743:2015/Amd1:2023](#).

2. The following rules shall apply only to the examination of meat of domestic swine:

- (a) In the case of whole carcasses of domestic swine other than breeding sows and boars, a specimen weighing at least 1g shall be taken from a pillar of the diaphragm at the transition to the sinewy part. Special trichinae forceps may be used provided that an accuracy of between 1,00 and 1,15g can be guaranteed.

In the case of whole carcasses of breeding sows and boars, a larger sample weighing at least 2g shall be taken from a pillar of the diaphragm at the transition to the sinewy part.

In the absence of diaphragm pillars, a specimen of 2g shall be taken from the rib part or the breastbone part of the diaphragm, or from the jaw muscle, tongue or abdominal muscles of domestic swine other than breeding sows and boars, and a specimen of 4g shall be taken from the same tissues of breeding sows and boars.

- (b) For cuts of meat, a sample weighing at least 5g of striated muscle, and containing little fat shall be taken, where possible from close to bones or tendons. A sample of the same size shall be collected from meat that is not intended to be cooked thoroughly or other types of post-slaughter processing.’;

(2) Chapter II is amended as follows:

- (a) the wording ‘ISO 18743:2015’ is replaced by ‘ISO 18743:2015/Amd1:2023’ in the following provisions:

- (i) Part A, point 1(o) and (q), second paragraph;
- (ii) Part A, point 3.IV, first and final sentences;
- (iii) Part C, point 1(f), second paragraph;
- (iv) Part D, point 1(m), second paragraph;
- (v) Part D, point 3.II, heading; and
- (vi) Part D, point 3.III, first and third paragraphs;

- (b) the wording in Part A, point 2, Part B, point 2, Part C, point 2, and Part D, point 2 is replaced by the following:

‘2. Collecting of specimens and quantity to be digested

As stipulated in Chapter I of this Regulation and in point 4.2 of the ISO 18743:2015/Amd1:2023 (see also Annexes A and B thereto for further details).’;

- (c) the following point F is added:

‘F. **Automated detection of *Trichinella* spp. using the lumiVAST *Trichinella* method.**

This method shall only be considered equivalent for the testing of meat of domestic swine.

Sample preparation and analysis shall be carried out in accordance with the instructions provided by the manufacturer.

Where examination of a collective sample produces a positive or uncertain result, a further 20g sample shall be taken from a pillar of the diaphragm or other tissue of each swine in accordance with Chapter I.

The 20g samples from 5 swine shall be pooled and examined using the same method.

When a positive result is obtained from a group of 5 swine, a further 20g samples shall be collected from the individuals in the group and each shall be examined separately using the same method.

When a positive or uncertain result is obtained, at least 20g of swine muscle shall be sent to the national reference laboratory for confirmation using the reference method laid down in Chapter I.

Parasite samples shall be kept in 70 to 90 % ethyl alcohol for conservation and identification at species level at the EU or national reference laboratory.’.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN