COMMISSION IMPLEMENTING REGULATION (EU) 2022/1418

of 22 August 2022

amending Implementing Regulation (EU) 2015/1375 as regards *Trichinella* control in relation to cutting of carcases and alternative analytical methods

(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 rules for the performance of 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 pigs, and causes food-borne illness in humans when infected meat is consumed. Commission Implementing Regulation (EU) 2015/1375 ([2]) lays down specific rules on official controls for *Trichinella* in meat, including laboratory examination of meat samples of domestic swine.

(3) Implementing Regulation (EU) 2015/1375 allows the cutting of carcases of domestic swine into more than six parts before the result from *Trichinella* testing is known, subject to certain conditions. One of the conditions is that warm cutting is necessary for the production of specific products.

(4) The limitation to the production of specific products has proven to have no scientific basis. Besides, Regulation (EC) No 853/2004 of the European Parliament and of the Council ([3]) (hygiene of products of animal origin) does not provide for such limitation concerning warm cutting. This limitation should therefore be removed from Implementing Regulation (EU) 2015/1375.

(5) Commission Implementing Regulation (EU) 2020/1478 ([4]) amended Implementing Regulation (EU) 2015/1375, replacing in Chapter I of Annex I the detailed reference method of detection for the examination of samples for *Trichinella* by a cross-reference to the ISO 18743:2015. Chapter II of Annex I to Implementing Regulation (EU) 2015/1375 lays down equivalent alternative methods containing cross-references to specific aspects of the former reference methods. These cross-references should therefore be updated and replaced by references in the ISO 18743:2015.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([1]) OJ L 95, 7.4.2017, p. 1.

([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).

([3]) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

([4]) Commission Implementing Regulation (EU) 2020/1478 of 14 October 2020 amending Implementing Regulation (EU) 2015/1375 as regards sampling, the reference method for detection and import conditions related to *Trichinella* control (OJ L 338, 15.10.2020, p. 7).

HAS ADOPTED THIS REGULATION:

Article 1

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

(1) in Article 3(5)(b), point (ii) is replaced by the following:

'(ii) cutting or boning, prior to reaching the temperature referred to in point 2(b) of Chapter V of Section I of Annex III to Regulation (EC) No 853/2004, is applied in accordance with point 4 of Chapter V of Section I of Annex III to that Regulation;';

(2) Chapter II of Annex I is amended as follows:

(a) in point A.1:

(i) point (k) is replaced by:

'(k) A thermometer accurate to 0,5 °C within the range 20 °C to 70 °C.';

(ii) point (o) is replaced by:

'(o) Petri dishes of approximately 90 mm in diameter, gridded with squares of approximately 1 cm, or equivalent equipment for larval counting as in point 6.14 of the ISO 18743:2015.';

(iii) point (q) is replaced by:

'(q) Pepsin with the following strength:

— if powder or granular: 1:10 000 NF (US National Formulary) corresponding to 1:12 500 BP (British Pharmacopoeia) and to 2 000 FIP (Fédération internationale de pharmacie), or

— if liquid: stabilised liquid pepsin with minimum 660 European Pharmacopoeia units/ml.

Other pepsin activities can be used, provided the final activity in the digest fluid is equivalent to the activity of 10 g of 1:10 000 NF as stipulated in point 5.3 of the ISO 18743:2015.';

(iv) point (s) is replaced by:

'(s) Calibrated scale, for weighing samples and/or pepsin (accuracy ± 0,1 g).';

(b) point A.2 is replaced by the following:

'2. Collecting of specimens and quantity to be digested

As stipulated in point 4.2 of the ISO 18743:2015 (see also Annexes A and B thereto for further details).';

(c) in point A.3, points III and IV are replaced by the following:

'III. Recovery of larvae by sedimentation

— Ice (300 to 400 g of ice flakes, scaly ice or crushed ice) is added to the digestion fluid to bring its volume up to about 2 litres. The digestion fluid is then stirred until the ice has melted. In the case of smaller pools (see Section II(b)), the amount of ice must be reduced correspondingly.

— The chilled digestion fluid is transferred to a 2 litre separation funnel, equipped with a vibrator in an extra clamp.

— Sedimentation is allowed to proceed for 30 minutes, during which time the sedimentation funnel is vibrated intermittently, i.e. one minute vibration followed by a one-minute pause.

— After 30 minutes, a 60 ml sample of the sediment is quickly run off into a 100 ml measuring cylinder (the funnel is rinsed with detergent solution after use).

— The 60 ml sample is allowed to stand for at least 10 minutes, after which time the supernatant is withdrawn by suction to leave a volume of 15 ml, to be examined for presence of larvae.

— For suction, a disposable syringe, equipped with a plastic tube, can be used. The length of the tube must be such that 15 ml remains in the measuring cylinder when the flanges of the syringe rest on the cylinder's rim.

— The remaining 15 ml is poured into a petri dish or equivalent equipment for larval counting, and examined using a trichinoscope or stereo-microscope.

— The measuring cylinder is washed with 5 to 10 ml of tap water and the washings are added to the sample.

— Digests are to be examined as soon as they are ready. Under no circumstances is examination to be postponed until the following day.

Where the digests are unclear, they must be clarified as follows:

— the final sample of 60 ml is poured into a measuring cylinder and allowed to stand for 10 minutes; 45 ml of supernatant fluid is then removed by suction and the remaining 15 ml is made up to 45 ml with tap water,

— after a further settling period of 10 minutes, 30 ml of supernatant fluid is removed by suction and the remaining 15 ml is poured into a petri dish or equivalent equipment for larval counting and examined using a trichinoscope or stereo-microscope.

— the measuring cylinder is washed with 10 ml of tap water and these washings are added to the sample in the petri dish or equivalent equipment for larval counting and examined using a trichinoscope or stereo-microscope.

IV. Positive or doubtful results

Where examination of a collective sample produces a positive or uncertain result, a further 20 g sample is taken from each pig, as stipulated in point 4.2 of the ISO 18743:2015 (see also Annexes A and B thereto for further details). The 20 g samples from five pigs are pooled and examined using the method described in this Chapter. In this way samples from 20 groups of five pigs will be examined. When *Trichinella* is detected in a pooled sample from five pigs, further 20 g samples are collected from the individual pigs in the group and each is examined separately using the method described in this Chapter. Parasite samples are to be kept in 70-90 % (final concentration) ethyl alcohol for conservation and identification at species level at the EU or national reference laboratory. For decontamination procedure, see point 12 of the ISO 18743:2015.';

(d) point B.2 is replaced by the following:

'2. Collecting of specimens

As stipulated in point 4.2 of the ISO 18743:2015 (see also Annexes A and B thereto for further details).';

(e) point B.3 is amended as follows:

(i) point III (h) is replaced by the following:

'(h) After three minutes, the plastic bag, complete with filter disc and rennilase solution, is removed from the Stomacher and opened with scissors. The liquid contents are poured into a petri dish or equivalent equipment for larval counting. The bag is washed out with 5 to 10 ml of water, which is then added to the petri dish or equivalent equipment for larval counting and examined using a trichinoscope or stereo-microscope.';

(ii) point IV is replaced by the following:

'IV. Positive or doubtful results

As laid down in point IV of Section A(3).';

(f) point C.1 is amended as follows:

(i) point (f) is replaced by the following:

'(f) Pepsin with the following strength:

— if powder or granular: 1:10 000 NF (US National Formulary) corresponding to 1:12 500 BP (British Pharmacopoeia) and to 2 000 FIP (Fédération internationale de pharmacie), or

— if liquid: stabilised liquid pepsin with minimum 660 European Pharmacopoeia units/ml.

Other pepsin activities can be used, provided the final activity in the digest fluid is equivalent to the activity of 10 g of 1:10 000 NF as stipulated in point 5.3 of the ISO 18743:2015.';

(ii) point (g) is replaced by the following:

'(g) Calibrated scale, for weighing samples and/or pepsin (accuracy ± 0,1 g).';

(iii) point (m) is replaced by the following:

'(m) A thermometer accurate to 0,5 °C within the range 20 to 70 °C.';

(g) point C.2 is replaced by the following:

'2. Collecting of specimens

As stipulated in point 4.2 of the ISO 18743:2015 (see also Annexes A and B thereto for further details).';

(h) in point C.3, point VI is replaced by the following:

'VI. Positive or doubtful results

As laid down in point IV of Section A(3).';

(i) point D.1 is amended as follows:

(i) point (m) is replaced by the following:

'(m) Pepsin with the following strength:

— if powder or granular: 1:10 000 NF (US National Formulary) corresponding to 1:12 500 BP (British Pharmacopoeia) and to 2 000 FIP (Fédération internationale de pharmacie), or

— if liquid: stabilised liquid pepsin with minimum 660 European Pharmacopoeia units/ml.

Other pepsin activities can be used, provided the final activity in the digest fluid is equivalent to the activity of 10 g of 1:10 000 NF as stipulated in point 5.3 of the ISO 18743:2015.';

(ii) point (o) is replaced by the following:

'(o) Calibrated scale, for weighing samples and/or pepsin (accuracy ± 0,1 g).';

(iii) point (u) is replaced by the following:

'(u) A thermometer accurate to 0,5 °C within the range 20 to 70 °C.';

(j) point D.2 is replaced by the following:

'2. Collecting of specimens

As stipulated in point 4.2 of the ISO 18743:2015 (see also its Annexes A and B for further details).';

(k) in point D.3, points II and III are replaced by the following:

'II. Pools of less than 100 g as set out in in point 8 of the ISO 18743:2015

Where needed, up to 15 g can be added to a total pool of 100 g and examined together with these samples in accordance with Section I. More than 15 g must be examined as a complete pool. For pools of up to 50 g, the digestion fluid and the ingredients may be reduced to 1 litre of water, 8 ml of hydrochloric acid and 5 g of pepsin.

III. Positive or doubtful results

Where examination of a collective sample produces a positive or uncertain latex agglutination result, a further 20 g sample is taken from each swine in accordance with point 4.2 of the ISO 18743:2015 (see also Annexes A and B thereto for further details). The 20 g samples from five swine are pooled and examined using the method described in Section I. In this way samples from 20 groups of five swine must be examined.

When a positive latex agglutination is obtained from a group of five swine, further 20 g samples are collected from the individuals in the group and each is examined separately using the method described in Section I.

When a positive or uncertain latex agglutination result is obtained, at least 20 g of swine muscle must be sent to the national reference laboratory for confirmation using the ISO 18743:2015 or one of the equivalent methods as described above.

Parasite samples must be kept in 70-90 % (final concentration) ethyl alcohol for conservation and identification at species level at the EU or national reference laboratory.

After parasite collection, positive fluids must be decontaminated by heating to at least 60 °C.'.

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, 22 August 2022.

For the Commission
The President
Ursula VON DER LEYEN