

## COMMISSION REGULATION (EU) No 216/2014

of 7 March 2014

amending Regulation (EC) No 2075/2005 laying down specific rules on official controls for *Trichinella* in meat

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption <sup>(1)</sup>, and in particular points 6, 8, 10 and 12 of Article 18 thereof,

Whereas:

- (1) Commission Regulation (EC) No 2075/2005 of 5 December 2005 laying down specific rules on official controls for *Trichinella* in meat <sup>(2)</sup> lays down rules for the sampling of carcasses of species susceptible to *Trichinella* infection, for the determination of the status holdings and regions and conditions for import of meat into the Union. It also provides for reference methods and equivalent methods of detection of *Trichinella* in samples of carcasses.
- (2) The European Food Safety Authority (EFSA) adopted on 3 October 2011 a Scientific Opinion on the public health hazards to be covered by inspection of meat (swine) <sup>(3)</sup>. In that opinion EFSA identified *Trichinella* as a medium risk for public health related to the consumption of pig meat and concludes that with respect to inspection methods for biological hazards, a pork carcass safety assurance, with a range of preventive measures and controls applied both on-farm and at slaughterhouse in an integrated way is the only way to ensure an effective control of the main hazards.
- (3) EFSA identified certain epidemiological indicators in relation to *Trichinella*. Depending on the purpose and the epidemiological situation of the country the indicators may be applied at national, regional, slaughterhouse or holding level.
- (4) EFSA recognises the sporadic presence of *Trichinella* in the Union, mainly in free-ranging and backyard pigs. EFSA also identified that the type of production system is the single main risk factor for *Trichinella* infections. In addition, available data demonstrate that the risk of *Trichinella* infection in pigs from officially recognised controlled housing conditions is negligible.

- (5) A negligible risk status for a country or region is no longer recognised in an international context by the World Animal Health Organisation (OIE). Instead, such recognition is linked to compartments of one or more holdings applying specific controlled housing conditions.
- (6) For reasons of consistency with international standards, and in order to enhance a control system in accordance with the actual public health risks, the *Trichinella* risk mitigation measures, including import conditions, at slaughterhouses and the conditions for determination of the *Trichinella* infection status of countries, regions or holdings should be adapted, rationalised and simplified.
- (7) Belgium and Denmark notified in 2011 a *Trichinella* negligible risk for their territory in accordance with Regulation (EC) No 2075/2005. Such negligible risk status for a country or region is however no longer recognised. Nevertheless, holdings and compartments in Belgium and Denmark which comply with the conditions for controlled housing at the date of entry into force of this Regulation should be allowed to apply the derogation for such holdings and compartments without additional prerequisites such as further requirements of post-official recognition by the competent authority.
- (8) The EU Reference Laboratory for parasites has recommended clarifying the text of the Regulation in relation to the procedure of certain equivalent methods for *Trichinella* testing.
- (9) It should be provided that the operators must ensure that dead animals are collected, identified and transported without undue delay in accordance with Articles 21 and 22 of Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) <sup>(4)</sup> and with Annex VIII to Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive <sup>(5)</sup>.

<sup>(1)</sup> OJ L 139, 30.4.2004, p. 206.

<sup>(2)</sup> OJ L 338, 22.12.2005, p. 60.

<sup>(3)</sup> EFSA Journal 2011; 9(10):2351[198 pp.], published 3 October 2011.

<sup>(4)</sup> OJ L 300, 14.11.2009, p. 1.

<sup>(5)</sup> OJ L 54, 26.2.2011, p. 1.

- (10) The number of cases (imported and autochthonous) of *Trichinella* in humans, including epidemiological data should be reported in accordance with Commission Decision 2000/96/EC of 22 December 1999 on the communicable diseases to be progressively covered by the Community network under Decision No 2119/98/EC of the European Parliament and of the Council <sup>(1)</sup>.
- (11) Regulation (EC) No 2075/2005 should therefore be amended accordingly.
- (12) The requirements provided for in this Regulation involve an adaptation of current practices both for food business operators and competent authorities. It is therefore appropriate to allow a delayed application of some of the provisions of this Regulation.
- (13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

#### Article 1

Regulation (EC) No 2075/2005 is amended as follows:

- (1) Article 1 is replaced by the following:

‘Article 1

#### Definitions

For the purposes of this Regulation, the following definitions shall apply:

- (1) “*Trichinella*” means any nematode belonging to the species of the genus *Trichinella*;
- (2) “controlled housing conditions” means a type of animal husbandry where swine are kept at all times under conditions controlled by the food business operator with regard to feeding and housing;
- (3) “compartment” means a group of holdings which apply controlled housing conditions. All holdings applying controlled housing conditions in a Member States, may be considered as one compartment.’
- (2) Articles 2 and 3 are replaced by the following:

‘Article 2

#### Sampling of carcasses

1. Carcasses of domestic swine shall be sampled in slaughterhouses as part of the post-mortem examination as follows:

- (a) all carcasses of breeding sows and boars or at least 10 % of carcasses of animals sent in for slaughter each year from each holding being officially recognised as applying controlled housing conditions, shall be examined for *Trichinella*;

- (b) all carcasses from holdings not being officially recognised as applying controlled housing conditions shall be systematically examined for *Trichinella*.

A sample shall be collected from each carcass and the sample shall be examined for *Trichinella*, in a laboratory designated by the competent authority, using one of the following methods of detection:

- (a) the reference method of detection set out in Chapter I of Annex I; or
- (b) an equivalent method of detection set out in Chapter II of Annex I.

2. Pending the results of the *Trichinella* examination and provided full traceability is guaranteed by the food business operator, such carcasses may be cut up into a maximum of six parts in a slaughterhouse or in a cutting plant on the same premises as the slaughterhouse (the premises).

By way of derogation from the first subparagraph and following approval by the competent authority, such carcasses may be cut up at a cutting plant attached to or separate from the slaughterhouse provided that:

- (a) the procedure is under supervision by the competent authority;
- (b) a carcass or the parts thereof have not more than one cutting plant as its destination;
- (c) the cutting plant is situated within the territory of the Member State; and
- (d) in case of a positive result all the parts are declared unfit for human consumption.

3. Carcasses of horses, wild boar and other farmed and wild animal species susceptible to *Trichinella* infestation shall be systematically sampled in slaughterhouses or game-handling establishments as part of the post-mortem examination.

A sample shall be collected from each carcass and the sample shall be examined in accordance with Annexes I and III in a laboratory designated by the competent authority.

Article 3

#### Derogations

1. By way of derogation from Article 2(1), meat of domestic swine that has undergone a freezing treatment in accordance with Annex II under the supervision of the competent authority shall be exempt from *Trichinella* examination.

2. By way of derogation from Article 2(1), carcasses and meat of not weaned domestic swine less than five weeks of age shall be exempt from *Trichinella* examination.

<sup>(1)</sup> OJ L 28, 3.2.2000, p. 50.

3. By way of derogation from Article 2(1), carcases and meat of domestic swine may be exempt from *Trichinella* examination where the animals come from a holding or a compartment officially recognised as applying controlled housing conditions in accordance with Annex IV, if:

- (a) no autochthonous *Trichinella* infestations in domestic swine kept in holdings officially recognised as applying controlled housing conditions have been detected in the Member State in the past three years, during which time continuous testing has been conducted in accordance with Article 2; or
- (b) historical data on continuous testing carried out on slaughtered swine population provide at least 95 % confidence that the prevalence of *Trichinella* does not exceed 1 per million in that population; or
- (c) the holdings applying controlled housing conditions are located in Belgium or Denmark.

4. Where a Member State implements the derogation provided for in paragraph 3, the Member State concerned shall inform the Commission and the other Member States at the Standing Committee of the Food Chain and Animal Health and submit an annual report to the Commission containing the information referred to in Chapter II of Annex IV. The Commission shall publish on its website the list of Member States implementing the derogation.

Where a Member State fails to submit that annual report or the annual report is unsatisfactory for the purposes of this Article, then the derogation shall cease to apply to that Member State.;

(3) Articles 8 to 12 are replaced by the following:

'Article 8

#### **Official recognition of holdings applying controlled housing conditions**

1. For the purpose of this Regulation, the competent authority may officially recognise a holding or a compartment applying controlled housing conditions where the requirements laid down in Annex IV are complied with.

2. Holdings or a compartment applying controlled housing conditions in Denmark or Belgium in accordance with Article 3, paragraph 3(c) at the date of application of this Regulation are considered to be officially recognised applying controlled housing conditions as listed in Annex IV to this Regulation.

Article 9

#### **Obligation on food business operators to inform**

Food business operators of holdings officially recognised as applying controlled housing conditions shall inform the

competent authority of any requirement as laid down in Annex IV that is no longer fulfilled or of any other change that might affect holdings' *Trichinella* status.

Article 10

#### **Audits of holdings officially recognised as applying controlled housing conditions**

The competent authority shall ensure that audits are carried out periodically of holdings officially recognised as applying controlled housing conditions.

The frequency of audits shall be risk-based, taking account of disease history and prevalence, previous findings, the geographical area, local susceptible wildlife, animal husbandry practices, veterinary supervision and farmers' compliance.

The competent authority shall verify that domestic swine coming from those holdings are examined in accordance with Article 2(1).

Article 11

#### **Monitoring programmes**

The competent authority may implement a monitoring programme covering the population of domestic swine coming from a holding or a compartment officially recognised as applying controlled housing conditions, in order to verify that *Trichinella* is effectively absent in that population.

The frequency of testing, the number of animals to be tested and the sampling plan shall be laid down in the monitoring programme. To that end, meat samples shall be collected and examined for presence of *Trichinella* parasites in accordance with Chapter I or II of Annex I.

The monitoring programme may include serological methods as an additional tool once a suitable test is validated by the EU reference laboratory.

Article 12

#### **Withdrawal of official recognition of holdings as applying controlled housing conditions**

1. Where the results of the audits carried out in accordance with Article 10 show that the requirements of Annex IV are no longer fulfilled, the competent authority shall withdraw the holdings official recognition without delay.

2. Where domestic swine from a holding officially recognised as applying controlled housing conditions test positive to *Trichinella*, the competent authority shall without delay:

- (a) withdraw the holding's official recognition;
- (b) examine all domestic swine of that holding at the time of slaughter;
- (c) trace and test all breeding animals that arrived on the holding and, as far as possible, all those that left the holding in at least the six months preceding the positive finding; to that end, meat samples shall be collected and examined for presence of *Trichinella* parasites using the detection methods laid down in Chapters I and II of Annex I;
- (d) when relevant, as far as is feasible, investigate the spread of parasite infestation due to the distribution of meat from domestic swine slaughtered in the period preceding the positive finding;
- (e) inform the Commission and the other Member States;
- (f) When relevant, initiate an epidemiological investigation to elucidate the cause of infestation;
- (g) take appropriate measures where any infested carcass cannot be identified at the slaughterhouse, including:
  - (i) increasing the size of each meat sample collected for testing of the suspect carcasses; or
  - (ii) declaring the carcasses unfit for human consumption;
  - (iii) taking appropriate measures for the disposal of suspect carcasses or parts thereof and those testing positive.

3. Following withdrawal of recognition, holdings may be officially recognised again once the problems identified have been solved and the requirements laid down in Annex IV are fulfilled to the satisfaction of the competent authority.

4. If the inspection identified a lack of compliance with Article 9 or positive testing in a holding of a compartment, the holding concerned should be removed from the compartment until compliance is re-established.;

- (4) Article 13 is replaced by the following:

*'Article 13*

#### **Import health requirements**

Meat of animal species that may be carriers of *Trichinella*, containing striated muscles and coming from a third country may only be imported into the Union if examination for *Trichinella* has been performed in accordance with Articles 2 and 3 in that third country before export.;

- (5) Article 14 is deleted;
- (6) Article 15 is replaced by the following:

*'Article 15*

#### **Documents**

The health certificate accompanying imports of meat as referred to in Article 13 shall be endorsed with a statement by the official veterinarian to the effect that the examination for *Trichinella* in the third country of origin has been performed in accordance with Article 13.

That document shall accompany the meat in the original unless an exemption has been granted in accordance with Article 14(4) of Regulation (EC) No 854/2004.;

- (7) Annex I is amended in accordance with Annex I to this Regulation;
- (8) Annex IV is replaced by the text in Annex II to this Regulation.

#### *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*.

It shall apply from 1 June 2014.

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

Done at Brussels, 7 March 2014.

For the Commission  
The President  
José Manuel BARROSO

## ANNEX I

Annex I to Regulation (EC) No 2075/2005 is amended as follows:

(1) in Chapter I, point 3. Procedure, the following paragraph is added:

IV. Cleaning and decontamination procedure after a positive or doubtful result

When the examination of a collective or individual sample produces a positive or doubtful latex agglutination result, all material in contact with meat (blender bowl, beaker, stirring rod, temperature sensor, conical filtration funnel, sieve and forceps) must be carefully decontaminated by soaking for few seconds in warm water (65 to 90 °C). Meat residues or inactivated larvae that could remain on their surface may be removed with a clean sponge and tap water. If required, a few drops of detergent can be added for degreasing equipment. It is then recommended to rinse each piece thoroughly to remove all traces of detergent.;

(2) Part D, of Chapter II, point 3 is replaced by the following:

3. Procedure

I. For complete pools (100 g of samples at a time)

- (a)  $16 \pm 0,5$  ml of 25 % hydrochloric acid (0,2 % final) is added to a 3 litre beaker containing 2,0 litres  $\pm 200$  ml of tap water, preheated to 46 to 48 °C; a stirring rod is placed in the beaker, the beaker is placed on the preheated plate and the stirring is started.
- (b)  $10 \pm 1$  g of powder pepsin (or  $30 \pm 3$  ml of liquid pepsin) is added.
- (c) 100-115 g of samples collected in accordance with point 2 are chopped in the blender, with  $150 \pm 15$  ml of preheated digestion buffer.
- (d) The chopped meat is transferred to the 3 litre beaker containing the water, pepsin and hydrochloric acid.
- (e) The mincing insert of the blender is immersed repeatedly in the digestion fluid in the beaker and the blender bowl is rinsed with a small quantity of digestion fluid to remove any meat still adhering.
- (f) The beaker is covered with aluminium foil.
- (g) The magnetic stirrer must be adjusted so that it maintains a constant temperature of 44 to 46 °C throughout the operation. During stirring, the digestion fluid must rotate at a sufficiently high speed to create a deep whirl without splashing.
- (h) The digestion fluid is stirred until the meat particles disappear (approximately 30 minutes). The stirrer is then switched off and the digestion fluid is poured through the sieve into the sedimentation funnel. Longer digestion times may be necessary (not exceeding 60 minutes) in the processing of certain types of meat (tongue, game meat, etc.).
- (i) The digestion process is considered satisfactory if not more than 5 % of the starting sample weight remains on the sieve.
- (j) The 20 microns nylon mesh filter is placed on the filtration support. The conical filtration steel funnel is fixed to the support with the block system and the steel sieve of 180 microns mesh size is placed on the funnel. The vacuum pump is connected with the filtration support and with the metal or plastic tank, to collect the digestive fluid.
- (k) Stirring is stopped and the digestion fluid is poured into the filtration funnel through the sieve. The beaker is rinsed with approximately 250 ml of warm water. The rinsing liquid is poured into the filtration ramp after the digested fluid has been successfully filtrated.
- (l) The filtration membrane is taken with the forceps, holding it by an edge. The filtration membrane is folded (minimal) in four and put in the 15 ml conical tube. The choice of conical tube must be adapted to the pestle.

- (m) The filtration membrane is pushed at the bottom of the 15 ml conical tube with the help of the pestle and strongly pressed by doing approximately 20 successive back and forth movements with the pestle which should be positioned inside the filtration membrane folding according to the manufacturer's instructions.
- (n) 0,5 ± 0,01 ml of sample diluents is added into the 15 ml conical tube by pipette and the filtration membrane is homogenised with the pestle by doing successive low amplitude back and forth movements for approximately 30 seconds, avoiding abrupt movements to limit liquid splashes according to the manufacturer's instructions.
- (o) Each sample, the negative control, and the positive control, are dispensed into different fields of the agglutination card by pipettes, according to the manufacturer's instructions.
- (p) The latex beads are added into each field of the agglutination card by a pipette, according to the manufacturer's instructions, without making them come into contact with the sample/s and controls. In each field, the latex beads are then gently mixed with a disposable stick until the homogeneous liquid covers the entire field.
- (q) The agglutination card is put on the 3D rocker and is rocked for 10 ± 1 minutes according to the manufacturer's instructions.
- (r) After the time established by the manufacturer's instructions, the rocking is stopped and the agglutination card is put on a plane surface and the reaction results are read immediately, according to the manufacturer's instructions. In the case of a positive sample, the beads aggregates must appear. In the case of a negative sample, the suspension remains homogeneous without beads aggregates.

#### II. Pools of less than 100 g as set out in Chapter I(3)(II)

For pools of less than 100 g, the procedure set out in Chapter I(3)(II) must be followed.

#### 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 Chapter I(2)(a). 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 one of the methods described in Chapter I.

Parasite samples must be kept in 90 % 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.

#### IV. Cleaning and decontamination procedure after a positive or doubtful result.

When the examination of a collective or individual sample produces a positive or doubtful latex agglutination result, all material in contact with meat (blender bowl, beaker, stirring rod, temperature sensor, conical filtration funnel, sieve and forceps) must be carefully decontaminated by soaking for few seconds in warm water (65 to 90 °C). Meat residues or inactivated larvae that could remain on their surface may be removed with a clean sponge and tap water. If required, a few drops of detergent can be added for degreasing equipment. It is then recommended to rinse each piece thoroughly to remove all traces of detergent.

## ANNEX II

## ANNEX IV

## CHAPTER I

**OFFICIAL RECOGNITION OF A HOLDINGS OR A COMPARTMENT AS APPLYING CONTROLLED HOUSING CONDITIONS**

- A. The following requirements must be met by food business operators to obtain official recognition of holdings:
- (a) the operator must have taken all practical precautions with regard to building construction and maintenance in order to prevent rodents, any other kind of mammals and carnivorous birds from having access to buildings where animals are kept;
  - (b) the operator must apply a pest-control programme, in particular for rodents, effectively to prevent infestation of pigs. The operator must keep records of the programme to the satisfaction of the competent authority;
  - (c) the operator must ensure that all feed has been obtained from a facility that produces feed in accordance with the principles described in Regulation (EC) No 1831/2003 of the European Parliament and of the Council (\*);
  - (d) the operator must store feed intended for *Trichinella* susceptible species in closed silos or other containers that are impenetrable to rodents. All other feed supplies must be heat-treated or produced and stored to the satisfaction of the competent authority;
  - (e) the operator must ensure that dead animals are collected, identified and transported without undue delay in accordance with Articles 21 and 22 of Regulation (EC) No 1069/2009 of the European Parliament and of the Council (\*\*), and with Annex VIII to Commission Regulation (EU) No 142/2011 (\*\*\*);
  - (f) if a rubbish dump is located in the neighbourhood of the holding, the operator must inform the competent authority. Subsequently, the competent authority must assess the risks involved and decide whether the holding is to be recognised as applying controlled housing conditions;
  - (g) the operator must ensure that piglets coming onto the holding from outside and pigs purchased are born and bred under controlled housing conditions;
  - (h) the operator must ensure that pigs are identified so each animal can be traced back to the holding;
  - (i) the operator may introduce new animals onto the holding only if they come from holdings also officially recognised as applying controlled housing conditions;
  - (j) none of the animals has access to outdoor facilities unless the food business operator can show by a risk analysis to the satisfaction of the competent authority that the time period, facilities and circumstances of outdoor access do not pose a danger for introduction of *Trichinella* in the holding.
- B. Food business operators of holdings officially recognised as applying controlled housing conditions shall inform the competent authority where any of the requirements laid down in point A is no longer fulfilled or where any other change has occurred that might affect the status of the holding.
- C. The competent authorities in Member States may only recognise a holding or a category of holdings provided that they have verified that the requirements laid down in point A are met.

## CHAPTER II

**REPORTING ON TRICHINELLA SITUATION**

- (a) The number of cases (imported and autochthonous) of *Trichinella* in humans, including epidemiological data shall be reported in accordance with Commission Decision 2000/96/EC (\*\*\*\*).
- (b) The number of tests and the results of testing for *Trichinella* in domestic swine, wild boar, horses, game and any other susceptible animals shall be submitted in accordance with Annex IV to Directive 2003/99/EC. Data on domestic swine shall, at least, provide specific information related to:
- (i) tests on animals raised under controlled housing conditions;
  - (ii) tests on breeding sows, boars and fattening pigs.

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(\*) OJ L 35, 8.2.2005, p. 1.

(\*\*) OJ L 300, 14.11.2009, p. 1.

(\*\*\*) OJ L 54, 26.2.2011, p. 1.

(\*\*\*\*) OJ L 28, 3.2.2000, p. 50.

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