Commission Implementing Regulation (EU) No 176/2012 of 1 March 2012 amending Annexes B, C and D to Council Directive 90/429/EEC as regards animal health requirements for brucellosis and Aujeszky's disease (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 176/2012

of 1 March 2012

amending Annexes B, C and D to Council Directive 90/429/EEC as regards animal health requirements for brucellosis and Aujeszky's disease

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 90/429/EEC of 26 June 1990 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species[(1)], and in particular Article 17 thereof,

Whereas:

(1) Directive 90/429/EEC lays down the animal health conditions governing intra-Union trade in and imports from third countries of semen of domestic animals of the porcine species.

(2) Directive 90/429/EEC provides that semen intended for trade must have been collected from domestic animals of the porcine species whose health status complies with Annex B to that Directive. Chapter I of Annex B sets out conditions applying to the admission of animals to approved semen collection centres. Chapter II of that Annex sets outs compulsory routine tests for animals kept at an approved semen collection centre.

(3) In addition, Directive 90/429/EEC provides that semen intended for trade must have been collected, processed, stored and transported in accordance with Annex C to that Directive. That Annex sets out conditions which semen collected at approved centres must satisfy for the purposes of intra-Union trade. Point 4 of Annex C to Directive 90/429/EEC provides that Member States may refuse admission of semen from collection centres where boars vaccinated against Aujeszky's disease are admitted to their territory, or to a region of their territory, when it has been recognised as free of Aujeszky's disease.

(4) Finally, Annex D to Directive 90/429/EEC establishes a model animal health certificate for trade in that commodity.

(5) Commission Decision 2008/185/EC of 21 February 2008 on additional guarantees in intra-Community trade of pigs relating to Aujeszky's disease and criteria to provide information on this disease[(2)] lays down additional guarantees applicable to intra-Union trade in pigs relating to Aujeszky's disease. In the interest of consistency of Union legislation, the animal health requirements applicable to donor male animals of the

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porcine species and their semen set out in Annex B to Directive 90/429/EEC should be aligned with Decision 2008/185/EC.

(6) Equally should a provision be inserted in point 4 of Annex C to Directive 90/429/EEC obliging Member States to inform the other Member States and the Commission when they use the right to refuse porcine semen produced in the semen collection centres keeping animals of the porcine species vaccinated against Aujeszky's disease.

(7) The Commission requested the European Food Safety Authority (EFSA) to assess the suitability of the buffered *Brucella* antigen test (rose Bengal test) which currently is the only authorised test for brucellosis diagnosis in Annex B to Directive 90/429/EEC and to provide a scientific opinion on the suitability of other available diagnostic tests for inclusion in that Annex.

(8) On 5 June 2009, EFSA adopted a Scientific Opinion of the Panel on Animal Health and Welfare (AHAW) on a request from the Commission on porcine brucellosis (*Brucella suis*)[(3)]. EFSA concluded that a competitive enzyme-linked immunosorbent assay (cELISA) and an indirect enzyme-linked immunosorbent assay (iELISA) for the detection of antibodies to a *Brucella suis* infection may be considered for the purpose of testing donor animals of the porcine species for admission to the semen collection centres and for compulsory routine testing during the stay or on exit from such centres. Therefore, these tests should be included in Annex B to Directive 90/429/EEC along with the current buffered *Brucella* antigen test (rose Bengal test).

(9) In addition, it is necessary to revise the protocol provided for in Chapter I of Annex B to Directive 90/429/EEC to rule out or confirm a suspicion of brucellosis on admission of animals to the semen collection centres and to provide in Chapter II of that Annex that the re-establishment of the health status of a semen collection centre shall be carried out under the responsibility of the competent authority of a Member State.

(10) It is also necessary to align the model animal health certificate for intra-Union trade in semen of animals of the porcine species provided for in Annex D to Directive 90/429/EEC with the amendments in Annexes B and C. The model animal health certificate should also be presented in accordance with the standardised layout of veterinary certificates as set out in Commission Regulation (EC) No 599/2004 of 30 March 2004 concerning the adoption of a harmonised model certificate and inspection report linked to intra-Community trade in animals and products of animal origin[(4)].

(11) Annexes B, C and D to Directive 90/429/EEC should therefore be amended accordingly.

(12) To avoid any disruption of trade, the use of animal health certificates issued in accordance with Annex D to Directive 90/429/EEC, before the amendments introduced by this Regulation, should be authorised during a transitional period subject to certain conditions.

(13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee of the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

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Article 1

Annexes B, C and D to Directive 90/429/EEC are replaced by the text set out in the Annex to this Regulation.

Article 2

For a transitional period until 31 July 2012, Member States may authorise trade in semen of domestic animals of the porcine species accompanied by an animal health certificate issued not later than 31 May 2012 in accordance with the model set out in Annex D to Directive 90/429/EEC in its version prior to the amendments introduced by this Regulation.

Article 3

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 June 2012.

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

Done at Brussels, 1 March 2012.

For the Commission

The President

José Manuel BARROSO

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ANNEX

ANNEX BCHAPTER IConditions for the admission of domestic animals of the porcine species to a semen collection centre1.All domestic animals of the porcine species ('animals') admitted to the semen collection centre must, prior to admission:

2.

All tests must be carried out in an approved laboratory.

3.

Animals may only be admitted to the semen collection centre with the express permission of the centre veterinarian. All animal movements, entering and exiting the semen collection centre, must be recorded.

4.

No animal admitted to the semen collection centre may show any clinical sign of disease on the date of admission.

5.All animals must, without prejudice to point 6, have come directly from the quarantine accommodation which, on the date of consignment, fulfils the following conditions:

6.Animals may be transferred directly from one semen collection centre to another of equal health status without quarantine or testing, provided that the conditions set out in point 5 are satisfied and the compulsory routine tests referred to in Chapter II have been carried out during the 12 months prior to the date of transfer.

Such animals must not come into direct or indirect contact with cloven-hoofed animals of a lower health status and the means of transport used must have been cleansed and disinfected before use.

7.For the purpose of point 6 and in case of trade between Member States, animals must be accompanied by an animal health certificate for animals of the porcine species for breeding in conformity with the Model 2 in Annex F to Directive 64/432/EEC, with one of the following additional guarantees, corresponding to their status, being certified by adding the following to Section C of that certificate:

CHAPTER II

Compulsory routine tests for animals kept at a semen collection centre

1. Compulsory routine testing must be carried out as follows:

1.1. all animals kept at a semen collection centre must be subjected to the following tests with negative results:

(a) as regards brucellosis, a buffered *Brucella* antigen test (rose Bengal test), or a cELISA or an iELISA;

(b) as regards Aujeszky's disease:

(i) in the case of non-vaccinated animals, an ELISA detecting antibodies to the whole Aujeszky's disease virus or to its glycoprotein B (ADV-gB) or glycoprotein D (ADV-gD) or a serum neutralisation test;

(ii) in the case of animals vaccinated with a gE deleted vaccine, an ELISA detecting antibodies to Aujeszky's disease virus glycoprotein E (ADV-gE);

(c) as regards classical swine fever, an antibody ELISA or a serum neutralisation test;

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1.2. the tests set out in point 1.1 must be carried out on samples taken:

(a) from all animals immediately prior to leaving the semen collection centre, or upon arrival at the slaughterhouse, and in no case later than l2 months after the date of admission to the semen collection centre; or

(b) from at least 25 % of the animals in the semen collection centre every 3 months and the centre veterinarian must ensure that the sampled animals are representative of the total population of that centre, in particular with respect to age groups and housing;

1.3. where the testing is carried out in accordance with 1.2(b), the centre veterinarian must ensure that all animals are tested in accordance with point 1.1 at least once during their stay at the semen collection centre and at least every 12 months from the date of admission, if their stay exceeds 12 months.

2. All tests must be carried out in an approved laboratory.

3. If any of the tests set out in point 1.1 proves positive, the animals must be isolated and the semen collected from them since the last negative test may not be the subject of intra-Union trade.

Semen collected from each animal at the semen collection centre since the date of that animal's last negative test must be held in separate storage and may not be the subject of intra-Union trade until the health status of that centre has been re-established under responsibility of the competent authority of the Member State.

ANNEX C

Conditions for semen collected at a semen collection centre and intended for intra-Union trade

1. Semen must be obtained from animals which:

(a) show no clinical signs of disease on the date the semen is collected;

(b) have not been vaccinated against foot-and-mouth disease;

(c) satisfy the requirements of Chapter I of Annex B;

(d) are not allowed to serve naturally;

(e) are kept in semen collection centres which must not be situated in a restricted area defined under the provisions of Union legislation due to the emergence of an infectious or contagious disease in domestic pigs, including foot-and-mouth disease, swine vesicular disease, vesicular stomatitis, classical swine fever and African swine fever;

(f) are kept in semen collection centres in which no clinical, serological, virological or pathological evidence of Aujeszky's disease has been detected in the 30-day period immediately prior to the date of collection.

2. An effective combination of antibiotics, in particular against leptospires, must be added to the semen after final dilution or to the diluent.

In the case of frozen semen, antibiotics must be added before the semen is frozen.