# REGULATION (EU) No 438/2010 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

## of 19 May 2010

## amending Regulation (EC) No 998/2003 on the animal health requirements applicable to the non-commercial movement of pet animals

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(2) and Article 168(4)(b) thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Economic and Social Committee [1],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure [2],

Whereas:

(1) Regulation (EC) No 998/2003 of the European Parliament and of the Council [3] lays down the animal health requirements applicable to the non-commercial movement of pet animals and the rules applying to checks on such movement.

(2) Article 5 of Regulation (EC) No 998/2003 lays down provisions applicable to the movement between Member States of dogs, cats and ferrets as listed in Parts A and B of Annex I thereto. Pursuant to Article 5(1)(a) of that Regulation, those pet animals must be identified by means of an electronic identification system (transponder). For an eight-year transitional period from the date of entry into force of that Regulation, those pet animals are to be regarded as identified also where they bear a clearly readable tattoo.

(3) Article 4(1) and Article 14 of Regulation (EC) No 998/2003 provide that, where the transponder does not comply with ISO Standard 11784 or with Annex A to ISO Standard 11785, the owner or the natural person responsible for the pet animal on behalf of the owner must provide the means necessary for reading the transponder at the time of any inspection.

(4) In order to avoid any unnecessary disturbances, in particular as regards the movement of pet animals from third countries, it is necessary to make the references to those ISO Standards more precise before the use of transponders becomes mandatory. Due to the technical nature of those references, it is appropriate to include them in an Annex to Regulation (EC) No 998/2003 and amend Articles 4 and 14 of that Regulation accordingly.

(5) In addition, Article 5(1)(b) of Regulation (EC) No 998/2003 provides that dogs, cats and ferrets must be accompanied by a passport issued by a veterinarian authorised by the competent authority, certifying valid anti-rabies vaccination, in accordance with the recommendations of the manufacturing laboratory, carried out on the animal in question, with an inactivated anti-rabies vaccine of at least one antigenic unit per dose (WHO standard). Since the adoption of Regulation (EC) No 998/2003, recombinant vaccines have also become available for the purposes of anti-rabies vaccination.

(6) In order to allow the movement, in particular from third countries, of dogs, cats and ferrets vaccinated with recombinant vaccines, provision should also be made to authorise, for the purpose of Regulation (EC) No 998/2003, the use of such vaccines in accordance with certain technical requirements laid down in an Annex to that Regulation.

(7) If administered in a Member State, the vaccines should have been granted a marketing authorisation in accordance with either Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products [4] or Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [5].

(8) If administered in a third country, the vaccines should comply with the minimum standards for safety as laid down in the relevant Chapter of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE).

[1] OJ C 318, 23.12.2009, p. 121.
[2] Position of the European Parliament of 9 March 2010 (not yet published in the Official Journal) and Council Decision of 26 April 2010.
[3] OJ L 146, 13.6.2003, p. 1.
[4] OJ L 311, 28.11.2001, p. 1.
[5] OJ L 136, 30.4.2004, p. 1.

(9) In addition, science-based rules of a similar kind to those laid down for rabies should be adopted. They should provide for preventive health measures for the movement of pet animals regarding other diseases that may affect those animals, where those preventive measures are proportionate to the risk of spreading those diseases due to such movement.

(10) Article 6 of Regulation (EC) No 998/2003 provides that the entry of dogs and cats into Ireland, Malta, Sweden and the United Kingdom is to be subject to additional requirements, in view of the particular situation in those Member States with regard to rabies. That provision is to be applied as a transitional measure until 30 June 2010.

(11) In accordance with those additional requirements, dogs and cats entering the territory of those Member States must be identified by means of a transponder unless the Member State of destination also recognises that the animal may be identified by means of a clearly readable tattoo. In addition, those requirements include mandatory antibody titration before entry of those pet animals into the territory of those Member States, to confirm a protective level of anti-rabies antibodies.

(12) The Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union in respect of preventive health measures regarding diseases other than rabies, and modifications of technical requirements for the identification of animals and for the anti-rabies vaccination as laid down in the Annexes inserted, in accordance with this Regulation, into Regulation (EC) No 998/2003. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level.

(13) Article 8 of Regulation (EC) No 998/2003 lays down the conditions for the movement of dogs, cats and ferrets from third countries depending on the prevailing rabies situation in the third country of origin and in the Member State of destination.

(14) Article 8(1)(a)(ii) of Regulation (EC) No 998/2003 provides that, in cases where pet animals are moved from certain third countries to Ireland, Malta, Sweden and the United Kingdom, the additional requirements provided for in Article 6 of that Regulation are to apply. Those third countries are listed in Section 2 of Part B and in Part C of Annex II to that Regulation.

(15) Article 8(1)(b)(ii) of Regulation (EC) No 998/2003 provides that, in cases where pet animals are moved from other third countries, they are to be placed in quarantine unless they have been brought into conformity with the requirements of Article 6 of that Regulation after their entry into the Union.

(16) In addition, Article 16 of Regulation (EC) No 998/2003 provides that Finland, Ireland, Malta, Sweden and the United Kingdom as regards echinococcosis, and Ireland, Malta and the United Kingdom as regards ticks, may make the entry of pet animals into their territory subject to compliance with the special rules applicable on the date of entry into force of that Regulation. That provision is to be applied as a transitional measure until 30 June 2010.

(17) Article 23 of Regulation (EC) No 998/2003 provides that the Commission, after receipt of the opinion of the European Food Safety Authority (EFSA) on the need to maintain the serological test, and based on experience gained and on a risk evaluation, is to submit to the European Parliament and to the Council a report, together with appropriate proposals for determining the regime to be applied with effect from 1 July 2010 for Articles 6, 8 and 16 of that Regulation.

(18) In order to determine that regime, the Commission carried out an impact assessment based on various recent consultations and on the Commission report that was adopted on 8 October 2007 in connection with Article 23 of Regulation (EC) No 998/2003 and took into account the recommendations made by EFSA.

(19) On 11 December 2006, EFSA adopted an opinion entitled 'Assessment of the risk of rabies introduction into the UK, Ireland, Sweden, Malta, as a consequence of abandoning the serological test measuring protective antibodies to rabies' ([1]).

(20) Based on 2005 data, EFSA identified that certain Member States have a non-negligible prevalence of rabies in pet animals. In addition, EFSA recommended that risk-mitigating measures be implemented with respect to the movement of pet animals from countries with non-negligible prevalence of rabies in pet animals.

(21) Rabies in those Member States is primarily of sylvatic nature. Field evidence demonstrated that with the elimination of sylvatic rabies as a result of intensive programmes of oral vaccination of wildlife, the disease occurrence in domestic animals diminishes.

(22) The Community has approved a number of programmes for the eradication, control and monitoring of rabies in those Member States, pursuant to Article 24(5) of Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field ([2]). The Commission envisages ending EU support to national programmes in the territory of those Member States by the end of 2011.

([1]) The EFSA Journal (2006) 436, p. 1.
([2]) OJ L 224, 18.8.1990, p. 19.

(23) In view of the EFSA opinion of 11 December 2006 and of the Community-supported programmes for the eradication of rabies in certain Member States, the transitional measure provided for in Article 6 of Regulation (EC) No 998/2003 should be extended until 31 December 2011.

(24) On 18 January 2007, EFSA adopted an opinion entitled 'Assessment of the risk of echinococcosis introduction into the UK, Ireland, Sweden, Malta and Finland as a consequence of abandoning the national rules' ([1]).

(25) On 8 March 2007, EFSA adopted an opinion entitled 'Assessment of the risk of tick introduction into the UK, Ireland and Malta as a consequence of abandoning the national rules' ([2]).

(26) Those opinions show that the data available did not allow EFSA to demonstrate a particular status of the Member States applying the transitional measures with regard to certain ticks and the tapeworm Echinococcus multilocularis and to quantify the risk of pathogen introduction through the non-commercial movement of pet animals.

(27) In order to ensure consistency as regards the transitional measures, it is appropriate to extend the transitional measure provided for in Article 16 of Regulation (EC) No 998/2003 until 31 December 2011.

(28) Regulation (EC) No 998/2003 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

*Article 1*

Regulation (EC) No 998/2003 is hereby amended as follows:

1. In Article 4(1), the second subparagraph is replaced by the following:

'In the case referred to in point (b) of the first subparagraph, where the transponder does not comply with the requirements set out in Annex Ia, the owner or the natural person responsible for the pet animal on behalf of the owner must provide the means necessary for reading the transponder at the time of any inspection.';

2. Article 5(1) is amended as follows:

(a) Point (b) is replaced by the following:

'(b) be accompanied by a passport issued by a veterinarian authorised by the competent authority certifying that:

(i) a valid anti-rabies vaccination was carried out on the animal in question pursuant to Annex Ib,

(ii) where necessary, preventive health measures regarding other diseases were carried out on the animal in question.';

(b) The following subparagraph is added:

'In order to ensure the control of diseases other than rabies, likely to spread due to the movement of pet animals, the Commission may adopt, by means of delegated acts in accordance with Article 19b and subject to the conditions of Articles 19c and 19d, the preventive health measures referred to in point (b)(ii) of the first subparagraph. Those measures shall be scientifically justified and shall be proportionate to the risk of spreading those diseases due to such movement.';

3. In the first subparagraph of Article 6(1), the introductory part and the first indent is replaced by the following:

'1. Until 31 December 2011, the entry of the pet animals listed in Part A of Annex I into the territory of Ireland, Malta, Sweden and the United Kingdom shall be subject to the following requirements:

— they must be identified in accordance with point (b) of the first subparagraph of Article 4(1), unless, until the end of the eight-year transitional period provided for in Article 4(1), the Member State of destination also recognises identification in accordance with point (a) of the first subparagraph of Article 4(1), and';

4. Article 8(1) is amended as follows:

(a) In point (a), point (ii) is replaced by the following:

'(ii) until 31 December 2011, one of the Member States listed in part A of Annex II, either directly or after transit through one of the territories listed in part B of Annex II, satisfy the requirements of Article 6.'

([1]) The EFSA Journal (2006) 441, p. 1.
([2]) The EFSA Journal (2007) 469, p. 1.

(b) In point (b), point (ii) is replaced by the following:

'(ii) until 31 December 2011, one of the Member States listed in part A of Annex II, either directly or after transit through one of the territories listed in part B of Annex II, be placed in quarantine unless they have been brought into conformity with the requirements of Article 6 after their entry into the Union.';

5. In Article 14, the second paragraph is replaced by the following:

'In the case referred to in point (b) of the first subparagraph of Article 4(1), where the transponder does not comply with the requirements set out in Annex Ia, the owner or the natural person responsible for the pet animal on behalf of the owner must provide the means necessary for reading the transponder at the time of any inspection.';

6. Article 16 is replaced by the following:

'*Article 16*

Until 31 December 2011, Finland, Ireland, Malta, Sweden and the United Kingdom, as regards echinococcosis, and Ireland, Malta and the United Kingdom, as regards ticks, may make the entry of pet animals into their territory subject to compliance with the special rules applicable on the date of entry into force of this Regulation.';

7. The following Articles are inserted:

'*Article 19a*

1. In order to take account of technical progress, the Commission may adopt, by means of delegated acts in accordance with Article 19b and subject to the conditions of Articles 19c and 19d, amendments to the technical requirements for the identification as laid down in Annex Ia.

2. In order to take account of scientific and technical developments regarding anti-rabies vaccination, the Commission may adopt, by means of delegated acts in accordance with Article 19b and subject to the conditions of Articles 19c and 19d, amendments to the technical requirements for the anti-rabies vaccination as laid down in Annex Ib.

3. When adopting such delegated acts, the Commission shall act in accordance with the provisions of this Regulation.

*Article 19b*

1. The power to adopt the delegated acts referred to in Article 5(1) and Article 19a shall be conferred on the Commission for a period of 5 years following 18 June 2010. The Commission shall make a report in respect of the delegated powers not later than 6 months before the end of the 5 year period. The delegation of powers shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 19c.

2. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

3. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in Articles 19c and 19d.

*Article 19c*

1. The delegation of powers referred to in Article 5(1) and Article 19a may be revoked at any time by the European Parliament or by the Council.

2. The institution which has commenced an internal procedure for deciding whether to revoke the delegation of powers shall endeavour to inform the other institution and the Commission within a reasonable time before the final decision is taken, indicating the delegated powers which could be subject to revocation and possible reasons for a revocation.

3. The decision of revocation shall put an end to the delegation of the powers specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the *Official Journal of the European Union*.

*Article 19d*

1. The European Parliament or the Council may object to a delegated act within a period of two months from the date of notification.

At the initiative of the European Parliament or the Council this period shall be extended by two months.

2. If, on expiry of that period, neither the European Parliament nor the Council has objected to the delegated act, it shall be published in the *Official Journal of the European Union* and shall enter into force on the date stated therein.

The delegated act may be published in the *Official Journal of the European Union* and enter into force before the expiry of that period if the European Parliament and the Council have both informed the Commission of their intention not to raise objections.

3. If the European Parliament or the Council objects to a delegated act, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.';

8. Annexes Ia and Ib, as set out in the Annex to this Regulation, are inserted.

*Article 2*

This Regulation shall enter into force on the 20th day following 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 Strasbourg, 19 May 2010.

*For the European Parliament*
*The President*
J. BUZEK

*For the Council*
*The President*
D. LÓPEZ GARRIDO

*ANNEX*

*'ANNEX Ia*

**Technical requirements for the identification**

For the purposes of Article 4(1), the standard electronic identification system shall be a read-only passive radio frequency identification device ("transponder"):

1. complying with ISO Standard 11784 and applying HDX or FDX-B technology;

2. capable of being read by a reading device compatible with ISO Standard 11785.

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*ANNEX Ib*

**Technical requirements for the anti-rabies vaccination (Referred to in Article 5(1)(b)(i))**

For the purposes of Article 5(1), an anti-rabies vaccination shall be considered valid provided that the following requirements are complied with:

1. The anti-rabies vaccine must:

   (a) be a vaccine other than a live modified vaccine and fall within one of the following categories:

      (i) an inactivated vaccine of at least one antigenic unit per dose (WHO standard); or

      (ii) a recombinant vaccine expressing the immunising glycoprotein of the rabies virus in a live virus vector;

   (b) if administered in a Member State, have been granted a marketing authorisation in accordance with:

      (i) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (*); or

      (ii) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (**);

   (c) if administered in a third country, meet at least the requirements laid down in Part C of Chapter 2.1.13 of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, 2008 Edition, of the World Organisation for Animal Health.

2. An anti-rabies vaccination may only be considered valid if it meets the following conditions:

   (a) the vaccine was administered on a date indicated in:

      (i) Section IV of the passport; or

      (ii) the appropriate section of the accompanying animal health certificate;

   (b) the date referred to in point (a) must not precede the date of microchipping indicated in:

      (i) Section III(2) of the passport; or

      (ii) the appropriate section of the accompanying animal health certificate;

(*) OJ L 311, 28.11.2001, p. 1.
(**) OJ L 136, 30.4.2004, p. 1.

(c) at least 21 days must have elapsed since the completion of the vaccination protocol required by the manufacturer for the primary vaccination in accordance with the technical specification of the marketing authorisation referred to in point 1(b) for the anti-rabies vaccine in the Member State or third country in which the vaccination is administered;

(d) the period of validity of the vaccination, as prescribed in the technical specification of the marketing authorisation for the anti-rabies vaccine in the Member State or third country where the vaccine is administered, must have been entered by the authorised veterinarian in:

(i) Section IV of the passport; or

(ii) the appropriate section of the accompanying animal health certificate;

(e) a revaccination (booster) must be considered a primary vaccination if it was not carried out within the period of validity referred to in point (d) of a previous vaccination.'

**Statement of the European Parliament, the Council and the Commission on Article 290 TFEU**

The European Parliament, Council and Commission declare that the provisions of this Regulation shall be without prejudice to any future position of the institutions as regards the implementation of Article 290 TFEU or individual legislative acts containing such provisions.

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**Statement by the Commission**

The Commission has the intention to propose a revision of Regulation (EC) No 998/2003 in its entirety before 30 June 2011, and, in particular, the aspects of delegated and implementing acts.

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**Statement by the Commission concerning the notification of delegated acts**

The European Commission takes note that except in cases where the legislative act provides for an urgency procedure, the European Parliament and the Council consider that the notification of delegated acts, shall take into account the periods of recess of the institutions (winter, summer and European elections), in order to ensure that the European Parliament and the Council are able to exercise their prerogatives within the time limits laid down in the relevant legislative acts, and is ready to act accordingly.

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