

COMMISSION DELEGATED REGULATION (EU) No 1152/2011

of 14 July 2011

supplementing Regulation (EC) No 998/2003 of the European Parliament and of the Council as regards preventive health measures for the control of *Echinococcus multilocularis* infection in dogs

(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 998/2003 of the European Parliament and of the Council of 26 May 2003 on the animal health requirements applicable to the non-commercial movement of pet animals and amending Council Directive 92/65/EEC⁽¹⁾, and in particular the second subparagraph of Article 5(1) thereof,

Whereas:

- (1) Regulation (EC) No 998/2003 lays down animal health requirements applicable to the non-commercial movement of pet animals. In particular, it lays down rules applicable to non-commercial movements into Member States of dogs, cats and ferrets and provides, where necessary, for preventive health measures to be adopted by means of delegated acts to ensure the control of diseases, other than rabies, likely to be spread due to the movement of those animals. Those measures are to be scientifically justified and proportionate to the risk of the spread of those diseases by such movements.
- (2) In addition, Regulation (EC) No 998/2003 provides that pet animals are to be accompanied by a passport issued by a veterinarian authorised by the competent authority certifying, where necessary, that preventive health measures regarding diseases other than rabies were carried out on the animal in question.
- (3) Alveolar echinococcosis is a parasitic disease caused by the tapeworm *Echinococcus multilocularis*. Where the disease is established, the typical transmission cycle of the parasite in Europe is wildlife-based and involves wild carnivores as definitive hosts and several species of mammals, notably small rodents, as intermediate hosts which become infected by ingesting eggs disseminated with the faeces of definitive hosts into the environment.
- (4) Although of secondary importance for the persistence of the life cycle of the parasite in endemic settings, dogs can be infested by ingesting infected rodents. As potential definitive hosts and due to close contacts to human, they may serve as a source of infection for humans as well as a source of contamination of the environment, including parasite-free areas behind natural barriers.

There are no reports of ferrets being definitive hosts and according to the current knowledge, the contribution of cats to the transmission cycle is doubtful.

- (5) Where humans are affected as aberrant intermediate hosts by the larval form of the tapeworm, severe clinical and pathological signs of the disease are observed after a long incubation period and in untreated or in inadequately treated patients, mortality may be more than 90 %. The increasing prevalence of the disease in wildlife, and in parallel in humans, in certain parts of Europe causes serious concern for public health authorities in many Member States.
- (6) While *Echinococcus multilocularis* infection in animals occurs in the northern hemisphere, including central and northern parts of Europe, Asia and North America, it has never been recorded in domestic and wild definitive hosts in certain areas of the European Union despite ongoing surveillance of wildlife and unrestricted access of dogs.
- (7) The transboundary movement of infected wildlife has been identified by the European Food Safety Authority (EFSA), in a scientific opinion on the Assessment of the risk of echinococcosis introduction into the United Kingdom, Ireland, Sweden, Malta and Finland as a consequence of abandoning national rules⁽²⁾, as the main potential route of incursion of the *Echinococcus multilocularis* parasite, especially in areas lacking effective physical barriers, such as open seas. The EFSA considers that the epidemiological role of dogs in endemic settings is of limited importance for the life cycle of the parasite.
- (8) However, the EFSA considers that the risk of the transmission cycle of the *Echinococcus multilocularis* parasite being established in suitable wild intermediate and definitive hosts in previously parasite-free areas is greater than negligible, where the parasite is introduced through the movement of infected dogs shedding eggs of the tapeworm.
- (9) According to the EFSA, the risk of introducing the *Echinococcus multilocularis* parasite into previously parasite-free areas could be mitigated if dogs from endemic areas are treated. In order to prevent re-infection, such treatment should be applied as soon as possible prior to entry into the areas free of that parasite. However, a minimum post-treatment period of 24 hours is necessary to prevent the shedding of residual amounts of infectious eggs in the environment of the parasite-free area.

⁽¹⁾ OJ L 146, 13.6.2003, p. 1.

⁽²⁾ The EFSA Journal (2006) 441, 1-54 (<http://www.efsa.europa.eu/en/efsajournal/doc/441.pdf>).

- (10) To ensure their effectiveness for the control of *Echinococcus multilocularis* infection in dogs, the medicinal products 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 ⁽¹⁾ 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 the European Medicines Agency ⁽²⁾, or should have been approved or licensed by the competent authority of the third country of origin of the animal.
- (11) Article 16 of Regulation (EC) No 998/2003 provides that Finland, Ireland, Malta, Sweden and the United Kingdom, as regards echinococcosis, 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. Because Article 16 of that Regulation applies only until 31 December 2011, it is necessary to adopt measures before that date, in order to ensure continuous protection of those Member States mentioned in that Article that claim to have remained free of the parasite as a result of applying national rules.
- (12) Experience has shown that the 24 to 48 hour treatment window required by some Member States under national rules in accordance with Article 16 of Regulation (EC) No 998/2003 may be very burdensome or even not feasible for pet owners especially when the treatment has to be carried out during weekends and public holidays or when the departure after treatment is delayed for reasons beyond the control of the owner.
- (13) Given the experience of some other Member States which permit a longer treatment window under national rules in accordance with Article 16 of Regulation (EC) No 998/2003 and have remained free from the parasite, a reasonable increase in that treatment window to a 24 to 120 hour period should not significantly enhance the risk of re-infection of treated dogs from endemic areas with the *Echinococcus multilocularis* parasite.
- (14) The preventive health measures for the control of *Echinococcus multilocularis* infections in dogs should therefore consist in the documented administration by a veterinarian of an effective authorised or licensed medicinal product which guarantees the timely elimination of the intestinal forms of the *Echinococcus multilocularis* parasite.
- (15) The treatment should be documented in the relevant section of the passport as established by Commission Decision 2003/803/EC of 26 November 2003 establishing a model passport for the intra-Community movements of dogs, cats and ferrets ⁽³⁾ or the health certificate established by Commission Decision 2004/824/EC of 1 December 2004 establishing a model health certificate for non-commercial movements of dogs, cats and ferrets from third countries into the Community ⁽⁴⁾.
- (16) Considering that the preventive health measures are burdensome, they should be applied proportionately to the risk of the spread of *Echinococcus multilocularis* infection through the non-commercial movements of pet dogs. Therefore, it is appropriate to mitigate such risks by applying the preventive health measures provided for in this Regulation to non-commercial movements of dogs entering the territory of Member States or parts thereof in which the infection was not recorded, namely those Member States listed in Part A of Annex I to this Regulation.
- (17) In addition, and for a strictly limited period of time, the preventive health measures should be also applied to prevent the re-introduction of the *Echinococcus multilocularis* parasite into Member States or parts thereof with a low prevalence of that parasite and where a compulsory programme for its eradication in wild definitive hosts is being implemented, namely those Member States listed in Part B of Annex I to this Regulation.
- (18) Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A(I) to Directive 90/425/EEC ⁽⁵⁾ lays down, amongst others, animal health rules for trade in and imports from third countries of dogs. The health requirements in Articles 10 and 16 of that Directive refer to Regulation (EC) No 998/2003. Therefore, in the interests of consistency of Union legislation, it is appropriate that the programmes for the eradication of *Echinococcus multilocularis* infection in wild definitive hosts be drawn up and presented to the Commission outlining in particular the elements in Article 14(1) of Directive 92/65/EEC.
- (19) As the movement of dogs from an area free of the *Echinococcus multilocularis* parasite presents a negligible risk of spreading the disease, the preventive health measures should not be required for dogs coming from Member States or parts thereof listed in Part A of Annex I to this Regulation.
- (20) Sweden has reported cases of *Echinococcus multilocularis* infection in wildlife since January 2011, while Ireland, Finland and the United Kingdom have submitted to the Commission results of their surveillance for the *Echinococcus multilocularis* parasite in wild definite hosts which support their claim of the absence of the parasite in their respective ecosystems.

⁽¹⁾ OJ L 311, 28.11.2001, p. 1.

⁽²⁾ OJ L 136, 30.4.2004, p. 1.

⁽³⁾ OJ L 312, 27.11.2003, p. 1.

⁽⁴⁾ OJ L 358, 3.12.2004, p. 12.

⁽⁵⁾ OJ L 268, 14.9.1992, p. 54.

- (21) Malta has submitted evidence that suitable definitive wildlife host animals are missing on the island, that the *Echinococcus multilocularis* parasite has never been recorded in indigenous domestic definitive hosts and that the environment does not support a significant population of potential intermediate host animals.
- (22) From the information submitted by Ireland, Malta, Finland and the United Kingdom, it is clear that those Member States comply with one of the conditions for being listed in Part A of Annex I to this Regulation for the whole of their territory. Accordingly, they should be permitted to apply the preventive health measures provided for in this Regulation from 1 January 2012, when the transitional measure provided for in Article 16 of Regulation (EC) No 998/2003 expires.
- (23) According to the EFSA's opinion of 2006, the shedding of infectious eggs of the *Echinococcus multilocularis* parasite does not commence until 28 days after ingestion of an infected intermediate host. Therefore, this Regulation should lay down the conditions for granting derogations in the case of dogs residing for less than 28 days following the application of preventive health measures on the territory of Member States or parts thereof listed in Annex I to this Regulation, since those dogs do not represent a risk of introducing that parasite,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

This Regulation establishes preventive health measures for the control of *Echinococcus multilocularis* infection in dogs intended for non-commercial movements into the territories of the Member States or parts thereof, which are determined on the basis of:

- (a) the absence of the *Echinococcus multilocularis* parasite in definitive host animals; or
- (b) the implementation of a programme for the eradication of the *Echinococcus multilocularis* parasite in wild definitive host animals, within a defined timescale.

Article 2

Geographical application of preventive health measures

1. Member States listed in Annex I shall apply the preventive health measures provided for in Article 7 ('the preventive health measures') to dogs intended for non-commercial movements entering into the territory of those Member States or parts thereof listed in that Annex.

2. Member States listed in Part A of Annex I shall not apply the preventive health measures to the dogs intended for non-commercial movements coming directly from another Member State or parts thereof listed in that Part.

3. Member States listed in Part B of Annex I shall not apply the preventive health measures to dogs intended for non-commercial movements coming directly from another Member State or parts thereof listed in Part A.

Article 3

Conditions for listing Member States or parts thereof in Part A of Annex I

Member States shall be listed in Part A of Annex I, for the whole or parts of their territory, where they have submitted to the Commission an application documenting compliance with at least one of the following conditions:

- (a) they have declared, in accordance with the procedure recommended in paragraph 3 of Article 1.4.6 of Chapter 1.4 of the Terrestrial Animal Health Code, 2010 Edition, Volume 1, of the World Organisation for Animal Health (OIE), the whole or part of their territory to be free from *Echinococcus multilocularis* infection in definitive host animals, and rules are in place for *Echinococcus multilocularis* infection in host animals to be compulsorily notifiable under national law;
- (b) during the 15 years prior to the date of that application and without applying a pathogen-specific surveillance programme they have not recorded any occurrence of *Echinococcus multilocularis* infection in host animals provided that during the 10 years prior to the date of that application the following conditions have been met:
- (i) rules have been in place for *Echinococcus multilocularis* infection in host animals to be compulsorily notifiable under national law;
- (ii) an early detection system for *Echinococcus multilocularis* infection in host animals has been in place;
- (iii) appropriate measures to prevent the introduction of the *Echinococcus multilocularis* parasite through domestic definitive host animals have been in place;
- (iv) infection with the *Echinococcus multilocularis* parasite has not been known to be established in the wild host animals on their territory;
- (c) they have implemented, for three 12-month periods prior to the date of that application, a pathogen-specific surveillance programme which complies with the requirements of Annex II and has not recorded any occurrence of *Echinococcus multilocularis* infection in wild definitive host animals, and such occurrences are compulsorily notifiable under national law.

Article 4

Conditions for listing Member States or parts thereof in Part B of Annex I

Member States shall be listed in Part B of Annex I for not more than five 12-month surveillance periods where they have submitted to the Commission an application documenting that:

- (a) a compulsory programme, in line with the indents in Article 14(1) of Directive 92/65/EEC, for the eradication of *Echinococcus multilocularis* infection in wild definitive host animals has been implemented in the whole or part of their territory to be listed in that Part;
- (b) rules are in place for *Echinococcus multilocularis* infection in host animals to be compulsorily notifiable under national law.

Article 5

Obligations of Member States listed in Annex I

1. Member States listed in Annex I shall have in place:
 - (a) rules for *Echinococcus multilocularis* infection in host animals to be compulsorily notifiable under national law;
 - (b) an early detection system for *Echinococcus multilocularis* infection in host animals.
2. Member States listed in Annex I shall implement a pathogen-specific surveillance programme which is drawn up and carried out in accordance with Annex II.
3. Member States listed in Annex I shall immediately notify to the Commission and the other Member States the detection of any *Echinococcus multilocularis* infection in samples taken from wild definitive host animals:
 - (a) during the previous 12-month surveillance period, in the case of Member States or parts thereof listed in Part A of Annex I; or
 - (b) after the first 24-month period following the beginning of the compulsory programme provided for in Article 4 for the eradication of *Echinococcus multilocularis* infection in wild definitive host animals in Member States or parts thereof listed in Part B of Annex I.
4. Member States listed in Annex I shall report to the Commission the results of the pathogen-specific surveillance programme referred to in paragraph 2 by 31 May following the end of each 12-month surveillance period.

Article 6

Conditions for delisting Member States or parts thereof from Annex I

The Commission shall remove Member States or parts thereof from the respective list set out in Annex I when:

- (a) the conditions set up in Article 5(1) no longer apply; or
- (b) the occurrence of any *Echinococcus multilocularis* infection in definitive host animals has been detected during the surveillance periods referred to in Article 5(3); or
- (c) the report referred to in Article 5(4) has not been supplied to the Commission within the set deadline provided for in Article 5(4); or
- (d) the eradication programme provided for in Article 4 has been terminated.

Article 7

Preventive health measures

1. Dogs intended for non-commercial movements into Member States or parts thereof listed in Annex I shall be treated against mature and immature intestinal forms of the *Echinococcus multilocularis* parasite within a period of not more than 120 hours and not less than 24 hours before the time of their scheduled entry into such Member States or parts thereof.
2. The treatment provided for in paragraph 1 shall be administered by a veterinarian and shall consist of a medicinal product:
 - (a) which contains the appropriate dose of:
 - (i) praziquantel; or
 - (ii) pharmacologically active substances, which alone or in combination, have been proven to reduce the burden of mature and immature intestinal forms of the *Echinococcus multilocularis* parasite in the host species concerned;
 - (b) which has been granted:
 - (i) a marketing authorisation in accordance with Article 5 of Directive 2001/82/EC or Article 3 of Regulation (EC) No 726/2004; or
 - (ii) an approval or a licence by the competent authority of the third country of provenance of the dog intended for non-commercial movement.
3. The treatment provided for in paragraph 1 shall be certified by:
 - (a) the administering veterinarian in the relevant section of the model passport established by Decision 2003/803/EC, in the case of intra-Union non-commercial movements of dogs; or
 - (b) an official veterinarian in the relevant section of the model animal health certificate established by Decision 2004/824/EC, in the case of non-commercial movements of dogs from a third country.

Article 8

Derogation from the application of the preventive health measures

1. By way of derogation from Article 7(1), the non-commercial movement into Member States or parts thereof listed in Annex I shall be permitted for dogs which have been subjected to the preventive health measures as provided for:
 - (a) in Article 7(2) and Article 7(3)(a), at least twice at an interval of a maximum of 28 days and the treatment is repeated thereafter at regular intervals not exceeding 28 days;
 - (b) in Article 7(2) and (3), not less than 24 hours before the time of entering, and not more than 28 days prior to the date of completing the transit, in which case those dogs must pass through a travellers' point of entry listed by that Member State in accordance with Article 13 of Regulation (EC) No 998/2003.

2. The derogation provided for in paragraph 1 shall only apply to movements of dogs entering those Member States or parts thereof listed in Annex I which have:

- (a) notified the Commission of the conditions for the control of such movements; and
- (b) made such conditions publicly available.

Article 9

Revision

The Commission shall:

- (a) review this Regulation no later than 5 years following the date of its entry into force in the light of scientific developments regarding *Echinococcus multilocularis* infection in animals;

- (b) submit the results of its review to the European Parliament and to the Council.

The review shall, in particular, assess the proportionality and the scientific justification of the preventive health measures.

Article 10

Entry into force and application

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 January 2012.

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

Done at Brussels, 14 July 2011.

For the Commission

The President

José Manuel BARROSO

ANNEX I

PART A

List of Member States or parts thereof complying with the conditions laid down in Article 3

ISO code	Member State	Part of territory
FI	FINLAND	Whole territory
GB	UNITED KINGDOM	Whole territory
IE	IRELAND	Whole territory
MT	MALTA	Whole territory

PART B

List of Member States or parts thereof complying with the conditions laid down in Article 4

ISO code	Member State	Part of territory

ANNEX II

Requirements for the pathogen-specific surveillance programme provided for in point (c) of Article 3

1. The pathogen-specific surveillance programme shall be designed to detect per epidemiologically relevant geographical unit in the Member State or part thereof a prevalence of not more than 1 % at confidence level of at least 95 %.
 2. The pathogen-specific surveillance programme shall use appropriate sampling, either risk-based or representative, that ensures detection of the *Echinococcus multilocularis* parasite if present in any part of the Member State at the design prevalence specified at point 1.
 3. The pathogen-specific surveillance programme shall consist in the ongoing collection, during the 12-month surveillance period, of samples from wild definitive hosts or, in the case where there is evidence of the absence of wild definitive hosts in the Member State or part thereof, from domestic definitive hosts, to be analysed by examination of:
 - (a) intestinal contents for the detection of the *Echinococcus multilocularis* parasite by the sedimentation and counting technique (SCT), or a technique of equivalent sensitivity and specificity; or
 - (b) faeces for the detection of species-specific deoxyribonucleic acid (DNA) from tissue or eggs of the *Echinococcus multilocularis* parasite by polymerase chain reaction (PCR), or a technique of equivalent sensitivity and specificity.
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