

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2018/772

of 21 November 2017

supplementing Regulation (EU) No 576/2013 of the European Parliament and of the Council with regard to preventive health measures for the control of *Echinococcus multilocularis* infection in dogs, and repealing Delegated Regulation (EU) No 1152/2011

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 576/2013 of the European Parliament and of the Council of 12 June 2013 on the non-commercial movement of pet animals and repealing Regulation (EC) No 998/2003 ⁽¹⁾, and in particular the first subparagraph of Article 19(1) thereof,

Whereas:

- (1) Regulation (EU) No 576/2013 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. It also provides, where necessary, for preventive health measures to be adopted by means of delegated acts for controlling diseases or infections other than rabies that are likely to be spread due to movements of those animals. Those measures are to be based on adequate, reliable and validated scientific information and are to be applied proportionately to the risk to public or animal health of spreading those diseases or infections via cross-border movements of dogs, cats or ferrets.
- (2) In addition, the categorisation of Member States in view of their eligibility to apply those preventive health measures is to be based on compliance with certain requirements with respect to the animal health status of the country and the surveillance and reporting systems with regard to certain diseases or infections other than rabies.
- (3) Regulation (EU) No 576/2013 also provides that dogs, cats or ferrets moved into Member States are to be accompanied by an identification document attesting, inter alia, compliance with any preventive health measures for diseases or infections other than rabies adopted pursuant to that Regulation.
- (4) *Echinococcus multilocularis* infection in dogs falls under the category of diseases or infections other than rabies that require preventive health measures for its control to be adopted by the Commission by means of a delegated act in accordance with Regulation (EU) No 576/2013. *Echinococcus multilocularis* is a tapeworm which in its larval stage causes alveolar echinococcosis, a zoonotic disease considered as one of the most severe human parasitic diseases in non-tropical areas. Where the disease is established, the typical transmission cycle of the parasite in Europe involves wild carnivores, notably red foxes, as definitive hosts and small rodents, as intermediate hosts.
- (5) Domestic dogs and cats having access to outdoors may sporadically contract the infection when preying on infected rodents. However, current knowledge suggests that the contribution of cats to the *Echinococcus multilocularis* life cycle is low, and there are no reports of ferrets being definitive hosts. *Echinococcus multilocularis* infection in animals has so far not been detected, despite ongoing surveillance, in definitive hosts in Ireland, Malta, Finland and the United Kingdom.

⁽¹⁾ OJ L 178, 28.6.2013, p. 1.

- (6) Since the movement of domestic definitive hosts with a pre-patent or patent infection is considered an important introduction pathway, the treatment of dogs prior to entry into countries where no findings of the parasite have been recorded and where appropriate definitive and intermediate hosts exist to support the *Echinococcus multilocularis* cycle is recommended in order to mitigate the risk of introducing the infection into such countries through the movement of dogs.
- (7) The Commission adopted Delegated Regulation (EU) No 1152/2011 ⁽¹⁾ pursuant to Regulation (EC) No 998/2003 of the European Parliament and of the Council ⁽²⁾ in order to ensure continuous protection of Ireland, Malta, Finland and the United Kingdom that claimed to be free of the parasite *Echinococcus multilocularis* as a result of applying national rules until 31 December 2011 in accordance with Article 16 of Regulation (EC) No 998/2003. Delegated Regulation (EU) No 1152/2011 has remained in force after Regulation (EC) No 998/2003 was repealed and replaced by Regulation (EU) No 576/2013.
- (8) Delegated Regulation (EU) No 1152/2011 provides that the Commission is to review that 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, and to submit the results of its review to the European Parliament and to the Council. The review is in particular to assess the proportionality and the scientific justification of the preventive health measures. In this respect, the Commission asked for the opinion of the European Food Safety Authority (EFSA) ⁽³⁾
- (9) The results of the Commission's review show that Delegated Regulation (EU) No 1152/2011 provides an adequate framework for the effective protection of Member States claiming freedom from *Echinococcus multilocularis* parasite. For that reason the main provisions of Delegated Regulation (EU) No 1152/2011 should be taken into account in this Regulation. In particular, the timely and documented treatment of dogs with an effective approved or licensed medicinal product prior to movement into the territory of Member States which have demonstrated continuous absence of the parasite or of those Member States with low prevalence which have implemented for a strictly limited period of time a programme for the eradication of the parasite in the suitable animal population, as well as the conditions for granting derogations from that treatment, should be incorporated in this Regulation.
- (10) Moreover, according to EFSA's opinion on *Echinococcus multilocularis* infection in animals ⁽³⁾, there is no evidence that dogs can maintain the *Echinococcus multilocularis* life cycle in the absence of red foxes. Therefore, in Member States where the dog is reported as the only candidate definitive host, the *Echinococcus multilocularis* infection cannot become established.
- (11) However, the introduction of contaminated dog faeces through the movement of dogs from endemic areas into Member States where the infection cannot become established constitutes a risk of human infection which otherwise would not exist in that location and which can be mitigated by the application of preventive health measures on dogs entering such Member States. In order to be eligible for such preventive health measures, Member States claiming absence of red foxes likely to harbour the *Echinococcus multilocularis* parasite should however provide regular evidence of that absence by implementing a programme for the early detection of the presence of red foxes in any part of the Member State.
- (12) The review also highlights the importance of surveillance activities to be implemented in Member States claiming freedom from the parasite. The review found that certain aspects regarding the surveillance activities should be reconsidered. Therefore, the existing rules in Delegated Regulation (EU) No 1152/2011 on surveillance activities should be adapted accordingly.
- (13) Article 14(1) of Council Directive 92/65/EEC ⁽⁴⁾ sets out certain elements regarding the documentation to be provided for the recognition of a compulsory programme of a Member State for the eradication of the disease. Provision should be made in order to include those elements in this Regulation.
- (14) The Terrestrial Animal Health Code of the World Organisation for Animal Health should be used for the declarations by Member States which claim that their territory is free of *Echinococcus multilocularis* parasite.

⁽¹⁾ 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 (OJ L 296, 15.11.2011, p. 6).

⁽²⁾ 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 (OJ L 146, 13.6.2003, p. 1).

⁽³⁾ http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4373.pdf

⁽⁴⁾ 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 (OJ L 268, 14.9.1992, p. 54).

- (15) The models of animal identification documents should be used for documenting the preventive health measures.
- (16) To ensure legal certainty it is necessary to repeal Delegated Regulation (EU) No 1152/2011,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

This Regulation lays down rules for the application of preventive health measures for the control of *Echinococcus multilocularis* infection in dogs intended for non-commercial movement into the territory or parts of the territory of certain Member States.

Article 2

Rules for the categorisation of Member States in view of their eligibility for preventive health measures

1. Member States may apply to the Commission for the categorisation with respect to preventive health measures under the conditions laid down in paragraphs 2, 3 and 4.
2. Where a Member State can demonstrate that the infection with the *Echinococcus multilocularis* parasite has not been established because of the absence of wild red foxes in the whole of its territory, it shall submit to the Commission documentation attesting compliance with the following conditions:
 - (a) it has implemented for three consecutive 12-month periods prior to the date of application, a national observation programme, which describes:
 - (i) the techniques allowing the detection of a species' presence, the type and frequency of surveys implemented, the different categories of actors involved and record-keeping of results of surveys,
 - (ii) the procedures for monitoring the implementation of the programme;
 - (b) it has not recorded the presence of wild red foxes in any part of its territory.
3. Where a Member State can demonstrate that wild definitive host animals likely to harbour the *Echinococcus multilocularis* parasite are present in the whole or parts of its territory and that occurrence of the infection with this parasite has not been recorded in those animals, it shall submit to the Commission documentation attesting compliance with at least one of the following conditions:
 - (a) it has declared, in accordance with the procedures for self-declaration set out in the Terrestrial Animal Health Code of the World Organisation for Animal Health, the whole or part of its territory free from *Echinococcus multilocularis* infection in wild definitive host animals, and rules are in place for *Echinococcus multilocularis* infection in wild definitive host animals to be compulsorily notifiable under national law;
 - (b) during the 15 years prior to the date of application and without applying a pathogen-specific surveillance programme it has not recorded any occurrence of *Echinococcus multilocularis* infection in wild definitive host animals provided that during the 10 years prior to the date of application the following conditions have been met:
 - (i) rules have been in place for *Echinococcus multilocularis* infection in wild definitive host animals to be compulsorily notifiable under national law,
 - (ii) an early detection system for *Echinococcus multilocularis* infection in wild definitive 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 definitive host animals on their territory;

- (c) it has implemented, for three consecutive 12-month periods prior to the date of application, a pathogen-specific surveillance programme which complies with the requirements of Annex I to this Regulation and has not recorded any occurrence of *Echinococcus multilocularis* infection in wild definitive host animals, and such occurrences are compulsorily notifiable under national law.
4. Where a Member State has drawn up a compulsory programme for the eradication of *Echinococcus multilocularis* infection in wild definitive host animals within a defined timescale for the whole or parts of its territory, it shall submit to the Commission documentation outlining in particular:
- (a) the rules that are in place for *Echinococcus multilocularis* infection in wild definitive host animals to be compulsorily notifiable under national law;
 - (b) the distribution of the infection in its territory;
 - (c) the reasons for undertaking the programme, taking into account the significance of the disease in humans and its impact on public health;
 - (d) the geographical area in which the programme is to be implemented;
 - (e) the programme monitoring procedures, including the extent of the hunters' involvement in implementing the programme;
 - (f) the measures to be taken if the results of the tests carried out under the programme are positive.

Article 3

Eligibility for preventive health measures

1. Following the examination of the application by a Member State in accordance with Article 2(1), the Commission shall determine whether that Member State complies with the rules for the categorisation for the whole or parts of its territory, and the Commission shall include, where compliant, that Member State or parts thereof in the appropriate list to be established in accordance with the procedure provided for in Article 20 of Regulation (EU) No 576/2013.
2. A Member State or parts thereof in a list referred to in paragraph 1 are eligible for the application of the preventive health measures provided for in this Regulation.

Article 4

Conditions to be fulfilled in order to remain eligible for preventive health measures

1. Member States categorised as compliant with the rules laid down in Article 2(2) for the whole of their territory shall remain eligible for the application of the preventive health measures where the following conditions are met:
- (a) they have a national observation programme in place to detect the presence of wild red foxes;
 - (b) they immediately notify the Commission and the other Member States of the detection of the presence of wild red foxes during each 12-month observation period;
 - (c) they report to the Commission the results of the national programme referred to in point (a) by 31 May following the end of each 12-month observation period.
2. Member States categorised as compliant with the rules laid down in Article 2(3) for the whole or parts of their territory shall remain eligible for the application of the preventive health measures where the following conditions are met:
- (a) they have in place rules for *Echinococcus multilocularis* infection in wild definitive host animals to be compulsorily notifiable under national law;
 - (b) they have in place an early detection system for *Echinococcus multilocularis* infection in wild definitive host animals;
 - (c) they implement a pathogen-specific surveillance programme in wild definitive host animals that is drawn up and carried out in accordance with the requirements set out in Annex I;

- (d) they immediately notify to the Commission and the other Member States the detection of any *Echinococcus multilocularis* parasite in samples taken from wild definitive host animals during each 12-month surveillance period;
- (e) they report to the Commission the results of the pathogen-specific surveillance programme referred to in point (c) by 31 May following the end of each 12-month surveillance period.
3. Member States categorised as compliant with the rules laid down in Article 2(4) for the whole or parts of their territory shall remain eligible for the application of the preventive health measures for not more than five consecutive 12-month surveillance periods where the following conditions are met:
- (a) they have in place rules for *Echinococcus multilocularis* infection in wild definitive host animals to be compulsorily notifiable under national law;
- (b) they have in place an early detection system for *Echinococcus multilocularis* infection in wild definitive host animals;
- (c) after the first two consecutive 12-month surveillance periods following the beginning of the compulsory eradication programme provided for in Article 2(4),
- (i) they implement a pathogen-specific surveillance programme in wild definitive host animals that is drawn up and carried out in accordance with the requirements set out in Annex I;
- (ii) they immediately notify to the Commission and the other Member States of the detection of any *Echinococcus multilocularis* parasite in samples taken from wild definitive host animals during each 12-month surveillance period;
- (iii) they report to the Commission the results of the pathogen-specific surveillance programme referred to in point (i) by 31 May following the end of each 12-month surveillance period.
4. Member States referred to in paragraph 3 shall remain eligible for the application of the preventive health measures after not more than five consecutive 12-month surveillance periods if they have presented an application to the Commission documenting compliance with the rules for the categorisation laid down in point (c) of Article 2(3) for the whole or parts of their territory and until the Commission has determined in accordance with Article 3 that they comply with those rules for the whole or parts of their territory.

Article 5

Failure to fulfil the conditions provided for in Article 4

1. Member States categorised as compliant with the rules laid down in Article 2(2) are no longer eligible for the application of the preventive health measures to dogs moved into their territory where:
- (a) the condition laid down in point (a) of Article 4(1) is no longer met; or
- (b) the presence of at least one wild red fox has been detected during the 12-month observation periods referred to in point (b) of Article 4(1) and the Member State concerned has not presented to the Commission an application documenting compliance with the rules for categorisation laid down in point (c) of Article 2(3) for the whole or parts of its territory; or
- (c) the report referred to in point (c) of Article 4(1) has not been supplied to the Commission within the set deadline.
2. Member States categorised as compliant with the rules laid down in Article 2(3) are no longer eligible for the application of the preventive health measures to dogs moved into their territory or into parts of their territory where:
- (a) any of the conditions laid down in points (a), (b) and (c) of Article 4(2) are no longer met; or
- (b) the occurrence of any *Echinococcus multilocularis* infection in wild definitive host animals has been detected during the surveillance periods referred to in point (d) of Article 4(2); or
- (c) the report referred to in point (e) of Article 4(2) has not been supplied to the Commission within the set deadline.
3. Member States categorised as compliant with the rules laid down in Article 2(4) are no longer eligible for the application of the preventive health measures to dogs moved into their territory or into parts of their territory where:
- (a) any of the conditions laid down in points (a) and (b) of Article 4(3) and point (i) of Article 4(3)(c) are no longer met; or

- (b) the occurrence of any *Echinococcus multilocularis* infection in wild definitive host animals has been detected during the surveillance periods referred to in point (ii) of Article 4(3)(c); or
 - (c) the report referred to in point (iii) of Article 4(3)(c) has not been supplied to the Commission within the set deadline; or
 - (d) the compulsory eradication programme provided for in Article 2(4) has ended and the Member State concerned has not presented to the Commission an application documenting compliance with the rules for categorisation laid down in point (c) of Article 2(3) for the whole or parts of its territory.
4. In any of the cases referred to in paragraphs 1, 2 and 3, the Commission shall adapt the list of Member States referred to in Article 3.

Article 6

Preventive health measures

1. The owner or authorised person as defined in points (c) and (d) of Article 3 of Regulation (EU) No 576/2013 shall ensure that dogs moved into the territory or into the parts of the territory of a Member State referred to in Article 3 of this Regulation have undergone a treatment against mature and immature intestinal forms of the *Echinococcus multilocularis* parasite.
2. The treatment referred to in paragraph 1 shall be carried out within a period of not more than 120 hours and not less than 24 hours before the time of the dog's scheduled entry into the territory or into parts of the territory of such Member State in accordance with paragraphs 3 and 4 of this Article.
3. The treatment referred to 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) other 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 dogs at least as effectively as praziquantel; and
 - (b) which has been granted:
 - (i) a marketing authorisation in accordance with Article 5 of Directive 2001/82/EC of the European Parliament and of the Council ⁽¹⁾ or Article 3 of Regulation (EC) No 726/2004 of the European Parliament and of the Council ⁽²⁾, or
 - (ii) an approval or a licence by the competent authority of the third country of dispatch of the dog intended for non-commercial movement.
4. The treatment referred to in paragraph 1 shall be certified by:
 - (a) the administering veterinarian in the relevant section of the passport laid down in accordance with the model set out in:
 - (i) Part 1 of Annex III to Commission Implementing Regulation (EU) No 577/2013 ⁽³⁾, in the case of non-commercial movements of dogs into the territory or into parts of the territory of a Member State referred to in Article 3 of this Regulation from another Member State or entry into a Member State after movement to or transit through a territory or a third country from a Member State in accordance with point (b) of Article 27 of Regulation (EU) No 576/2013; or

⁽¹⁾ 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 (OJ L 311, 28.11.2001, p. 1).

⁽²⁾ 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 (OJ L 136, 30.4.2004, p. 1).

⁽³⁾ Commission Implementing Regulation (EU) No 577/2013 of 28 June 2013 on the model identification documents for the non-commercial movement of dogs, cats and ferrets, the establishment of lists of territories and third countries and the format, layout and language requirements of the declarations attesting compliance with certain conditions provided for in Regulation (EU) No 576/2013 of the European Parliament and of the Council (OJ L 178, 28.6.2013, p. 109).

- (ii) Part 3 of Annex III to Implementing Regulation (EU) No 577/2013, in the case of non-commercial movements of dogs into the territory or into parts of a Member State referred to in Article 3 of this Regulation from a territory or third country listed in Part 1 of Annex II to that Implementing Regulation; or
- (b) an official veterinarian of the territory or third country of provenance, or an authorised veterinarian and subsequently endorsed by the competent authority of the territory or third country of provenance, in the relevant section of the animal health certificate laid down in accordance with the model set out in Part 1 of Annex IV to Implementing Regulation (EU) No 577/2013, in the case of non-commercial movement of dogs into the territory or into parts of a Member State referred to in Article 3 of this Regulation from a territory or third country other than those listed in Part 1 of Annex II to that Implementing Regulation.

Article 7

Derogation from the application of the preventive health measures

1. By way of derogation from Article 6, a Member State referred to in Article 3 shall authorise the non-commercial movement into its territory or into parts of its territory of dogs which have not been subjected to the preventive health measures provided those dogs are moved directly from:
 - (a) the territory of another Member State referred to in Article 3 that complies with the rules for the categorisation laid down in Article 2(2) for the whole of its territory; or
 - (b) the territory or part of the territory of another Member State referred to in Article 3 that complies with the rules for the categorisation laid down in Article 2(3) for the whole or parts of its territory.
2. By way of derogation from Article 6(2) a Member State referred to in Article 3 may authorise the non-commercial movement into its territory or into parts of its territory of dogs which have been subjected to the preventive health measures provided for:
 - (a) in Article 6(3) and in point (a) of Article 6(4), 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 6(3) and (4), not less than 24 hours before the time of entering, and not more than 28 days prior to the date of leaving the Member State referred to in Article 3, in which case those dogs must enter and leave that Member State through a travellers' point of entry designated by that Member State for the purposes of the checks referred to in Article 34(1) of Regulation (EU) No 576/2013.
3. Member States referred to in Article 3 making use of the derogation provided for in paragraph 2 shall establish the conditions for the control of such movements and make them publicly available.

Article 8

Repeal

Delegated Regulation (EU) No 1152/2011 is repealed.

References to the repealed Regulation shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex II.

Article 9

Entry into force and application

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

Article 8 shall apply from 1 July 2018.

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

Done at Brussels, 21 November 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

Requirements for the pathogen-specific surveillance programme provided for in Articles 2(3)(c), 4(2)(c) and Article 4(3)(c)(i)

1. The pathogen-specific surveillance programme, using appropriate risk-based or representative sampling, shall be designed to detect per epidemiologically relevant geographical unit in the Member State or part thereof the *Echinococcus multilocularis* parasite in the wild definitive host population, if present in any part of the Member State at a prevalence of not more than 1 % at a confidence level of at least 95 %.
 2. The pathogen-specific surveillance programme shall describe the target wild definitive host population, including the density, age structure, geographical and gender distribution, taking into account the relative risks of infection with the *Echinococcus multilocularis* parasite in different species and subpopulations of the target wild definitive host population.
 3. The pathogen-specific surveillance programme shall consist in the ongoing collection, during the 12-month surveillance period, of samples from wild definitive hosts to be analysed using:
 - (a) the sedimentation and counting technique (SCT), or a technique of equivalent sensitivity and specificity, by examination of intestinal contents for the detection of the *Echinococcus multilocularis* parasite; or
 - (b) polymerase chain reaction (PCR) methods, or a technique of equivalent sensitivity and specificity, by examination of intestinal contents or faeces for the detection of species-specific deoxyribonucleic acid (DNA) from tissue or eggs of the *Echinococcus multilocularis* parasite.
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ANNEX II

Correlation table referred to in Article 8

Delegated Regulation (EU) No 1152/2011	This Regulation
Article 1	Article 1
Article 2(1)	Article 3
Article 2(2)	Article 7(1)(b)
Article 2(3)	Article 7(1)(b)
Article 3(a)	Article 2(3)(a)
Article 3(b)	Article 2(3)(b)
Article 3(c)	Article 2(3)(c)
Article 4	Articles 2(4) and 4(3)
Article 5(1)(a)	Article 4(2)(a)
Article 5(1)(b)	Article 4(2)(b)
Article 5(2)	Article 4(2)(c)
Article 5(3)(a)	Article 4(2)(d)
Article 5(3)(b)	Article 4(3)(c)
Article 5(4)	Article 4(2)(e)
Article 6(a)	Article 5(2)(a)
Article 6(b)	Article 5(2)(b)
Article 6(c)	Article 5(2)(c)
Article 6(d)	Article 5(3)(d)
Article 7(1)	Article 6(1) and (2)
Article 7(2)	Article 6(3)
Article 7(3)(a)	Article 6(4)(a)(i)
Article 7(3)(b)	Article 6(4)(b)
Article 8(1)	Article 7(2)
Article 8(2)	Article 7(3)
Article 9	—
Article 10	Article 9
Annex I	—
Annex II	Annex I