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)

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

Changes to legislation: *There are outstanding changes not yet made to Commission Delegated Regulation (EU) 2018/772. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(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 predating 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.

(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[(2)] pursuant to Regulation (EC) No 998/2003 of the European Parliament and of the Council[(3)] 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)[(4)]

(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.

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(10) Moreover, according to EFSA's opinion on *Echinococcus multilocularis* infection in animals[(4)], 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[(5)] 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.

(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.

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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

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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;