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COMMISSION STAFF WORKING DOCUMENT

on the results of the review of 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 the preventive health measures for the control of Echinococcus multilocularis infection in dogs

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1. PURPOSE OF THE DOCUMENT

This document fulfils the Commission's obligation to review Delegated Regulation (EU) No 1152/2011[1] (the Regulation) in accordance with Article 9 thereof in the light of scientific developments regarding *Echinococcus multilocularis* (*EM*) infection in animals and to submit the results of its review to the European Parliament and to the Council.

Its purpose is to present the findings of this review which seeks in particular to assess the proportionality and the scientific justification of the preventive health measures laid down in the Regulation. The review is built on the conclusions drawn from the European Food Safety Authority (EFSA) scientific opinion on *EM* infection and assessment reports of surveillance programmes submitted by Finland, Ireland, Malta and the United Kingdom, and on comments raised during the Member State consultation on those EFSA publications.

2. GENERAL ASPECTS

2.1. Legal background

The Commission adopted the Regulation as regards preventive health measures for the control of *EM* infection in dogs to supplement Regulation (EC) No 998/2003 of the European Parliament and of the Council[2], which conferred on the Commission the power to adopt preventive health measures for the control of diseases other than rabies, under the condition that those measures are scientifically justified and proportionate to the risk of spreading those diseases due to non-commercial movements of pet animals.

Published on 15 November 2011, the Regulation entered into force on 5 December 2011 and applied from 1 January 2012. Regulation (EC) No 998/2003 has since been repealed and replaced by Regulation (EU) No 576/2013 of the European Parliament and of the Council[3] without prejudice to the maintenance in force of the Regulation. Article 19 of Regulation (EU) No 576/2013 provides for the adoption by means of a delegated act of species-specific preventive health measures for controlling diseases or infections other than rabies that are likely to be spread due to the movement of pet animals.

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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 the preventive health measures for the control of *Echinococcus multilocularis* infection in dogs (OJ L 296, 15.11.2011, p. 6).
http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R1152&qid=1457109363651&from=EN

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).
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2003R0998:20141120:EN:PDF

3 Regulation (EU) No 576/2013 of the European Parliament and of the Council on the non-commercial movement of pet animals and repealing Regulation (EC) No 998/2003 (OJ L 178, 28.6.2013, p. 1)
http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013R0576&qid=1457109564830&from=EN

The purpose of the Regulation was to establish harmonised rules in order to ensure continuous protection of Finland, Ireland, Malta and the United Kingdom that claim to have remained free of *EM* parasite as a result of applying national rules until 31 December 2011 in accordance with Article 16 of Regulation (EC) No 998/2003.

The Regulation was based on an EFSA scientific opinion delivered on the Commission's request on 26 January 2007 and addressing *the assessment of the risk of Echinococcosis introduction into the United Kingdom, Ireland, Sweden, Malta and Finland as a consequence of abandoning the national rules*[4]. EFSA overall conclusion was that the risk of introducing *EM* from endemic areas into countries, where the intermediate host (arvicolid rodents) is present, but considered free from the disease on the basis of national surveys conducted, is greater than negligible and could be reduced if dogs are treated before movement.

2.2. Main provisions of Delegated Regulation (EU) No 1152/2011

The Regulation provides that dogs intended for non-commercial movements into Member States or parts thereof listed in its Annex I should be treated against *EM* parasite with the appropriate medicinal product within a set period before the time of their scheduled entry into one of those Member States or parts thereof. The treatment should be administered and certified by a veterinarian in the relevant identification document.

Finland, Ireland, Malta and the United Kingdom are listed in that Annex. In order to be maintained as listed, the Regulation includes the obligation for these Member States to implement a pathogen-specific surveillance programme aimed at detecting the parasite, if present in any part of those Member States, in accordance with certain requirements regarding the sampling and the detection techniques laid down in Annex II to the Regulation.

The Regulation also provides an obligation for those Member States to report to the Commission the results of the pathogen-specific surveillance programme by 31 May following the end of each 12-month surveillance period. Since the Regulation applies from 1 January 2012, the first Member States' reports were due by 31 May 2013 in order to cover the usual surveillance period, *i.e.* from September to April.

2.3. Legal obligation to review Delegated Regulation (EU) No 1152/2011

According to Article 9 of the Regulation the Commission shall review the Regulation no later than five years following the date of its entry into force, *i.e.* by 5 December 2016, in the light of scientific developments regarding *EM* infection in animals and submit the results of the review to the European Parliament and to the Council. The

[4] http://www.efsa.europa.eu/en/efsajournal/doc/441.pdf (EFSA-Q-2006-112)

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

In order to respond to the legal obligation to review the Regulation, the Commission officially consulted EFSA.

As some aspects of EFSA's mandate deal with issues which fall under the competence of the Committee for Medicinal Products for Veterinary Use (CVMP), such as efficacy of medicinal products and scientific basis for recommending treatment schemes, the European Medicines Agency (EMA) was officially consulted by EFSA.

Moreover, in order to produce a comprehensive review, the Commission also consulted the competent authorities of Member States in the framework of the Standing Committee on Plants, Animals, Food and Feed (PAFF) meetings.

Given that the Commission has not registered any complaints in relation to the Regulation, the Commission has not considered a public consultation on the Regulation as being relevant.

3. SCIENTIFIC REPORTS FROM EFSA – CONCLUSIONS

3.1. EFSA scientific and technical assistance in the analysis and critical assessment of surveillance programmes

3.1.1. Commission's request for assistance

In May 2012, in the context of Article 31 of Regulation (EC) No 178/2002 the Commission asked EFSA to assist in the analysis and critical assessment of the surveillance programmes submitted by Finland, Ireland, Malta and the United Kingdom in view of verifying compliance with the requirements laid down in the Regulation. Sampling strategy, data collected and detection methods used in the framework of the programmes were to be assessed. EFSA was asked to produce a report each year in October after reception of the Member States' reports by 31 May.

By 31 May 2015, Finland, Ireland, Malta and the United Kingdom supplied to the Commission documentation supporting the evidence of the absence of the parasite *EM* for three consecutive surveillance periods that was submitted to EFSA for assessment. Accordingly, EFSA produced three assessment reports and made them publicly available in October 2013[5], 2014[6] and 2015[7].

In view of the future mandate for a scientific opinion on *EM* infection in animals, the Commission's request for EFSA assistance also included a regular follow-up of the

5 http://www.efsa.europa.eu/en/efsajournal/doc/3465.pdf (2013 EFSA's assessment report)

6 http://www.efsa.europa.eu/en/efsajournal/doc/3875.pdf (2014 EFSA's assessment report)

7 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4310.pdf (2015 EFSA's assessment report)

literature regarding *EM* infection in animals in the European Union and adjacent countries, including its geographical distribution and prevalence. This part has been addressed by an Article 36 cooperation project of EFSA[8].

3.1.2. Approach

To address the Commission's request for assistance, EFSA identified the critical elements to be assessed in the Member States' *EM* surveillance reports following the guidelines for animal health surveillance of the World Organisation for Animal Health (OIE Code – Chapter 1.4)[9]. To this end, 2007 EFSA opinion[10], the external scientific report submitted to EFSA on the development of harmonised schemes for the monitoring and reporting of *Echinococcus* in animals and foodstuffs in the European Union (2010)[11] and additional relevant scientific literature were also consulted.

The principles and procedures established in EFSA's scientific report[12] aimed at facilitating reporting as well as assessment of reports, and EFSA's technical report[13] aimed at calculating the sample size needed to substantiate absence of disease and/or the surveillance system sensitivity once samples are collected, have been applied in the assessment of each of the surveillance reports submitted by Finland, Ireland, Malta and the United Kingdom.

In a first step, the description of the surveillance system was checked for completeness against the relevant elements that need to be addressed in assessing the quality of *EM* surveillance reports in the context of the Regulation (*i.e.* susceptible host population, timeframe of the surveillance data, relevant epidemiological unit of the surveillance system, geographical clustering of infection, case definition, sensitivity and specificity of tests used, type of survey, survey design, sampling methods, and sample size).

In a second step, the data reported on individual samples were assessed using the raw data submitted by the Member States via EFSA's Data Collection Framework (DCF) and descriptive statistics were calculated to check whether the requirements of the Regulation had been fulfilled.

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8 Article 36 of EFSA's Founding Regulation http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02002R0178-20140630&qid=1461317687010&from=EN

9 http://www.oie.int/fileadmin/Home/eng/Health_standards/tahc/2010/chapitre_surveillance_general.pdf

10 See footnote 4

11 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/36e.pdf

12 Scientific report of EFSA - Scientific and technical assistance on *Echinococcus multilocularis* infection in animals http://www.efsa.europa.eu/en/efsajournal/pub/2973.htm (26 November 2012) - Presented at SCFCAH meeting of 6 February 2013 (http://ec.europa.eu/food/animals/docs/reg-com_ahw_20130206_pres_echinococcus_multicocularis_efsa.pdf)

13 Technical report - A framework to substantiate absence of disease: the risk-based estimate of system sensitivity tool (RiBESS) using data collated according to the EFSA Standard Sample Description - An example on *Echinococcus multilocularis* http://www.efsa.europa.eu/en/supporting/pub/366e.htm (30 November 2012)

3.1.3. EFSA's conclusions on the surveillance reports submitted in 2013, 2014 and 2015

None of the four Member States who are operating an *EM*-specific surveillance programme aimed at detecting the parasite, if present in any part of those Member States, has detected *EM* through the surveillance activities reported in 2013, 2014 and 2015.

Under the assumption of an unbiased representative sampling and considering the sensitivity of the tests applied, Finland, Ireland and the United Kingdom have succeeded in implementing surveillance activities able to detect EM at 1% prevalence maximum with a 95% confidence level. In 2015, the overall area sensitivity of the Maltese surveillance system reached 0.942 which is below the required level of 0.95[14].

3.1.4. Main EFSA's recommendations on the surveillance reports submitted in 2013, 2014 and 2015

Surveillance of wildlife populations for the presence of *EM* presents many challenges. Collaboration between epidemiologists and wildlife experts would facilitate data collection and subsequent estimation of susceptible wildlife population parameters (e.g. the density and local distribution, age structure and gender distribution).

Surveillance activities in the isle of Ireland as a whole would be scientifically sensible and would reduce the total resources currently used for sampling and testing by Northern Ireland and Ireland.

For the risk-based surveillance option, due to the limited knowledge on risk factors for *EM* infection in animals, it is recommended to identify or perform additional scientific studies on potential risk factors affecting the probability of host animal species being infected with *EM*.

A robust estimation of the test sensitivity is required. It is recommended that each laboratory involved in a surveillance programme verify the sensitivity and specificity of in-house tests used to diagnose *EM* based on the positive test material which the European Union Reference Laboratory for Parasites (EURLP)[15] would supply.

3.2. EFSA's scientific opinion regarding *EM* infection in animals

3.2.1. Commission's request for an opinion

In October 2014, in accordance with Article 29 of Regulation (EC) No 178/2002, the Commission asked EFSA to issue an updated scientific opinion regarding *EM*

14 Explanation provided in paragraph 4.1.

15 http://www.iss.it/crlp/index.php

infection in animals and to make it available by the end of November 2015. That request was then mutually deferred to the end of December 2015.

EFSA delivered the updated scientific opinion and made it publicly available on 22 December 2015[16].

3.2.2. Terms of reference and method

EFSA was requested to:

- describe *EM* infection in animals in the European Union and adjacent countries: importance and role of the different host species, geographical distribution and prevalence, risk factors for and the probability of introduction and establishment of *EM* in areas where it is has never been recorded through the movement of infected domestic and wildlife species involved in the *EM* lifecycle;
- assess the current situation in the European Union and adjacent countries regarding monitoring and surveillance programmes of *EM* infection and programmes for the eradication of *EM* in wildlife host species;
- describe the current situation in the European Union and adjacent countries regarding the risk factors associated with human alveolar echinococccosis and the impact of *EM* infection in animals on public health;
- describe the efficacy of available *EM* drugs and the effectiveness of the current species-specific treatment protocols to protect domestic species against the parasite;
- assess the laboratory techniques for the detection of *EM* in live and dead animals, in terms of sensitivity, specificity, predictive values and practicability.

In line with those terms of reference, EFSA conducted a thorough review of the literature in order to be able to provide a sound, comprehensive and, if possible, quantitative assessment of *EM* infection in animals. To this end, EFSA awarded a special grant[17] to collect information on all the relevant aspects of the terms of reference resulting in EFSA's External Scientific Report[18] made publicly available on 22 December 2015.

16 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4373.pdf

17 http://www.efsa.europa.eu/sites/default/files/assets/gpefsaahaw201201guide.pdf

18 *Echinococcus multilocularis* infection in animals GP/EFSA/AHAW/2012/01 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/882e.pdf

3.2.3. Main elements of EFSA's conclusions

3.2.3.1. Description of *EM* infection in animals in the European Union and adjacent countries

- Importance and role of the different host species in the life cycle of the parasite

  The life cycle of the *EM* tapeworm is mostly sylvatic and is based on a predator–prey relationship between definitive hosts (DH) and intermediate hosts (IH).

  The red fox is considered to be the principal wild DH due to its high population densities, its high susceptibility to *EM* infection and the high worm burden detected in foxes compared to other potential DHs (raccoon dog, golden jackal, grey wolf). For these reasons the fox is considered the target species for surveillance. Raccoon dogs, golden jackals and grey wolves can act as DHs but there is no evidence that any of these species can maintain the lifecycle in the absence of red foxes.

  Domestic dogs and cats having access to outdoors can also be sporadically infected by predating on infected rodents in city parks or gardens. However, current knowledge suggests that the contribution of cats to the *EM* lifecycle is small and there is no evidence that dogs and cats can maintain the lifecycle in the absence of red foxes.

  In Europe, various vole species are confirmed as suitable IHs but the relative importance of individual species for maintenance of the lifecycle depends also on additional parameters like population densities and predation rate by DHs. This extreme variability does not make any of those potential IHs particularly suitable for surveillance purposes.

- Geographical distribution and prevalence

  Since the 1980s, the autochthonous presence of *EM* has been recorded in 17 "newly endemic" countries in Central-Eastern Europe where it cannot be excluded that the parasite had remained undetected. It may have expanded in the wake of population increases of red foxes with more observations of foxes living in urban areas. However, in some European countries the parasite has so far not been recorded despite ongoing surveillance in wildlife.

  The distribution of *EM* is not homogeneous, showing areas with high and low prevalence levels in foxes, including amongst countries, most frequently linked to anthropogenic landscape changes (*e.g.* deforestation and agricultural practices) which have led to more favourable conditions for the parasite's animal hosts, especially rodents.

- Risk factors for and the probability of introduction and establishment of *EM* in areas where it has never been recorded, through the movement of infected domestic and wildlife species involved in the *EM* lifecycle

  In principle, *EM* can be introduced by wild or domestic DHs with a pre-patent or patent infection, infected IHs and plants or other items contaminated with eggs. However, the knowledge on movement of wild DHs across borders is scarce and it is unlikely that a recent introduction of *EM* is detected due to its slow spread and resulting very low prevalence. Lack of compliance with the Regulation also represents a potential risk factor for the introduction of *EM* although the presence of border compliance checks always reduces the probability of introduction.

  The establishment of *EM* lifecycle after introduction of *EM* requires transmission from DHs to IHs and back to DHs to close the lifecycle. Appropriate DHs and IHs should therefore exist to support the life cycle and where no suitable wild DHs and no highly suitable IHs exist, such as in Malta, transmission and establishment is considered not to be possible.

  The exposure of IHs to a contaminated environment, the ingestion of infected IHs by DHs and survival of the parasite to patent infection in the DH are environmental factors influencing the persistence of the lifecycle and therefore the probability of establishment of the infection. However, the knowledge on the potential role of those environmental factors is scarce.

3.2.3.2. Assessment of the current situation in the European Union and adjacent countries regarding monitoring and surveillance programmes of *EM* infection and probability of detection if *EM* is introduced in areas where it has never been recorded

- Mandatory surveillance for *EM* in countries where no findings of the parasite have been recorded

  The *EM* surveillance programmes provided for in the Regulation are output-based, providing flexibility about the level of sampling required, the use of risk-based or representative strategies and the combination of tests which can be used to achieve the required confidence.

  Finland, Ireland and the United Kingdom draw a representative sample from wild DHs present in their territory. The targeted susceptible wild DH population is defined as red foxes in Ireland and the United Kingdom and as red foxes and racoon dogs in Finland.

  Known wild DH species should be able to survive in the Maltese ecosystem but their presence has never been reported and the environment does not support a

significant population of potential IHs[19]. Therefore the targeted susceptible DH population was defined as dogs and only the non-pet subpopulation (hunting dogs, dogs in sanctuaries/stray dogs and rural dogs) is considered for the risk-based surveillance activity due to its putative exposure to infective IHs.

- Surveillance and monitoring in the European Union and adjacent countries where findings of the parasite have been recorded

  There are no EU requirements for the monitoring or surveillance of *EM* in Member States where findings have been reported. Certain countries have been carrying out targeted surveillance to answer specific issues such as geographic expansion, effectiveness of control strategies and changes in pathogenicity. However, due to the considerable spatial and temporal heterogeneity in *EM* distribution within a country and across Europe, the results of local or regional surveys cannot be extrapolated to a whole country

  The detection of *Echinococcus spp.* in animals is notifiable in some Member States and occurrence may be reported at genus or species level. There is frequently no requirement for notification of human cases.

- Absence of infection and early detection of introduction

  A design prevalence of 1% to substantiate infection absence is unlikely to detect the introduction of infection within a short time. However, lower design prevalence may make surveys for early detection impracticable due to the large sample size required. Indeed, for a design prevalence of < 0.1%, at least 3,000 samples are required, provided there is 100% test sensitivity.

3.2.3.3. Assessment of the current situation in the European Union and adjacent countries regarding the programmes for the eradication of *EM* in wildlife host species

Long term control - but not elimination - of the parasite may be possible by means of baits in small areas where foxes are present. Data on other species are scarce. However, control by baiting requires more knowledge about how and where to control the parasite in a cost efficient way.

Increased fox hunting/trapping is not considered to be effective in controlling the parasite.

3.2.3.4. Description of the risk factors associated with human alveolar echinococcosis and the impact of *EM* infection in animals on public health

Humans are not part of the lifecycle but can become accidentally infected (dead-end host) by ingesting tapeworm eggs excreted by DHs.

[19] Information available from the International Union for Conservation of Nature and Natural Resources (http://www.iucn.org/)

The resulting infection in humans, alveolar echinococcosis (AE), typically presents as an infiltrative tumour-like growth in the liver, which at later stages may invade neighbouring organs. AE is considered one of the most severe human parasitoses in non-tropical regions. The true number of AE cases in Europe is unknown mainly because of lack of notification requirement at species level in several Member States and of underreporting due to poor knowledge of clinical symptoms and incorrect clinical management. There has been an increase in the number of reported AE cases in new areas and an increase in the incidence of AE in countries recognised as historically highly endemic which suggests a geographic spread and an increase of the disease in Europe. If early detection does not become more effective, European health systems might face costs in the order of billions of euros to care for the number of AE patients expected in the next two decades.

Dog ownership, cat ownership, living in a rural area, having a kitchen garden, occupation (farming), haymaking in meadows not adjacent to water, going to forests for vocational reasons, chewing grass and handling foxes were identified as potential risk factors in Europe. The available data suggest that dogs can be relevant as a risk factor for human infection although the dimension of the risk is influenced by the exposure of dogs to infected IHs, which have to be eaten by a dog to infect it, and by socio-cultural conditions determining the exposure of humans to faeces of infected dogs and materials contaminated with such faeces.

The presumably very long incubation period of AE makes the study of risk factors extremely difficult which makes the uncertainty on the risk factors considerably high.

3.2.3.5. Description of the efficacy of available *EM* drugs and the effectiveness of the current species-specific treatment protocols to protect domestic species against the parasite

Due to its favourable pharmacokinetic properties and activity against both immature and mature stages of *EM* in the intestine, praziquantel is the substance of choice for the treatment of *EM* in dogs via oral, intramuscular or subcutaneous administration.

The timing of treatment is crucial. Because the drug is only effective 24 hours after oral intake, dogs should be treated as close as possible to entry into the country where no findings of the parasite have been recorded in order to prevent reinfection. Results of model simulations indicate that the risk of introduction / transmission / establishment is the lowest when treating one day prior to crossing the border and increases when the treatment is administered more than 24 hours before crossing the borders. However the narrower the treatment window the more difficult it is for dog owners to plan the treatment, therefore a very narrow treatment window may decrease compliance.

3.2.3.6. Assessment of the laboratory techniques for the detection of *EM* in live and dead animals, in terms of sensitivity, specificity, predictive values and practicability

Although time-consuming, the sedimentation and counting technique (SCT) is a post mortem approach at necropsy considered as the reference standard for the detection of *EM*. It focuses on the identification of *EM* worms in the intestine using classical parasitological methods but it is not highly sensitive in non-endemic areas where animals are characterised by low worm burdens.

DNA-based tests for the detection of *EM* genome in faeces (*intra vitam* examination) or intestinal contents (*post mortem* examination) may be equally or more sensitive than SCT, particularly in samples with a low worm burden. Intrinsic limitations of DNA-based methodologies such as inhibitors, costs, small volume of sample to analyse, timing and sensitivity were recently overcome.

4. OUTCOMES OF THE CONSULTATION WITH MEMBER STATES' COMPETENT AUTHORITY

4.1. Consultation on EFSA's assessment reports

On the Commission's initiative EFSA presented its assessment of *EM* surveillance reports submitted by the four Member States concerned at the PAFF Committee, under the Animal Health and Welfare section.

EFSA presented its assessment of Member States' *EM* surveillance reports submitted in 2014 at the PAFF Committee meeting of 13-14 January 2015 and its assessment of Member States' EM surveillance reports submitted in 2015, including that of Norway, at the PAFF Committee meeting of 3 February 2016. The 2015[20] and 2016[21] EFSA presentations and the summary reports of the 2015 and 2016 meetings are available at DG SANTE website[22]. EFSA's assessment of Member States' *EM* surveillance reports submitted in 2013 has not been presented at a PAFF Committee meeting in 2014.

Member States' representatives at the PAFF Committee meeting held on 13-14 January 2015 did not raise any comments following the presentation of the assessment of Member States' 2014 *EM* surveillance reports by the EFSA's representative.

At the meeting of the PAFF Committee held on 3 February 2016 where the EFSA's representative presented the assessment of the Member States' 2015 *EM* surveillance reports the Danish representative expressed his satisfaction that the surveillance activities provided for in the Regulation were well implemented and reported by the

20 http://ec.europa.eu/food/animals/docs/reg-com_ahw_20150113_pres_echinococcus_multilocularis_efsa.pdf

21 https://prezi.com/oal-ql5oszti/efsa-about-ecchinococcus-multilocularis/

22 http://ec.europa.eu/food/animals/health/regulatory_committee/index_en.htm

four Member States. The Maltese representative explained that in 2015 the number of samples collected in the Maltese targeted susceptible DH population was not sufficient to reach the required confidence level of 0.95. The reported reason was the lack of collaboration of hunters in the collection of samples from hunting dogs.

4.2. Consultation on EFSA's scientific opinion on *EM* infection in animals

On the Commission's initiative EFSA presented the scientific opinion on *EM* infection in animals at the PAFF Committee meeting of 3 February 2016, under the Animal Health and Welfare section. The presentation is available at DG SANTE website[18].

Several Member States appreciated the presentation and asked for some clarification which was given. The Commission also clarified that this opinion together with the 2015 EFSA assessment report referred to in paragraph 4.1 will be a valuable basis for the preparation of the review of the Regulation, due in December 2016 in accordance with Article 9 thereof.

5. COMMISSION'S CONCLUSIONS

5.1. Commission's conclusions from EFSA reports

5.1.1. Commission's conclusions from EFSA's scientific and technical assistance in the analysis and critical assessment of surveillance programmes

The Regulation provides an adequate framework for the effective protection of Finland, Ireland, Malta and the United Kingdom against *EM* infection since none of them detected any positive samples during the surveillance activities implemented in 2013, 2014 and 2015.

5.1.2. Commission's conclusions from EFSA opinion on EM infection in animals

5.1.2.1. Geographical application of the preventive health measures

- The suitable wild DH population and the suitable IH population should exist to support the *EM* lifecycle. Therefore, even if no systematic assessment has been done anywhere on the quantitative contribution of dogs to the infection of IH population, dogs may in principle maintain *EM* lifecycle because red foxes are present. The application of the preventive health measures provided for in the Regulation on dogs entering Finland, Ireland and the United Kingdom is therefore scientifically justified and proportionate to the risk of spreading the infection through the movement of dogs.
- In areas where the dog is reported as the only DH present and no highly suitable IHs are present, the establishment of the *EM* cycle is considered close to impossible because the dog cannot maintain the lifecycle of *EM* in the absence of red foxes.

The application of the preventive health measures provided for in the Regulation on dogs entering countries where red foxes are absent may contribute to prevent the risk of human infection with the parasite through contact with contaminated faeces from dogs entering those countries without prior treatment.

However this risk does equally exist for dogs entering other Member States or dogs living in endemic areas and its control cannot be addressed within the existing powers conferred on the Commission by the co-legislators in the framework of Regulation (EU) No 576/2103 [and previously of Regulation (EC) No 998/2003].

The application of the preventive health measures on dogs entering Malta should therefore be discontinued since it is not scientifically justified nor does it address the risk of transmitting and establishing *EM* infection in Malta via dogs.

5.1.2.2. Surveillance activities

- Target population

The wild DH population is confirmed as the most suitable population for surveillance purposes. However, targeting the domestic DH population where no suitable wild DH population exist is not scientifically justified since domestic DHs alone are not able to maintain the *EM* lifecycle.

In Malta routine surveillance in dogs, and particularly in the autochthonous non-pet population where the infection is unlikely to occur, should therefore be discontinued. Targeting pet dogs returning to or introduced in Malta from endemic countries may result in the detection of positive samples but this will not bring any evidence of the possible establishment of the infection.

- Risk-based or representative sampling

A risk-based approach should only be applied if epidemiological risk factors including geographical risk factors are properly documented.

In order to better assess potential bias in the representative strategy more detailed information on the target wildlife population (such as density and geographical distribution, age structure and gender distribution) should be sought, when designing the surveillance programme, to allow the comparison with the characteristics of the sampled population.

- Target design prevalence

  The target design prevalence of not more than 1% provided for in Annex II to the Regulation and determining the sample size required appears to be sufficiently flexible for the assumed free Member States to both cope with the need to allow early detection of newly introduced *EM* infection and for substantiating absence of *EM* infection.

- One-island policy

  According to EFSA opinion applying a one-island policy in relation to *EM* surveillance in Northern Ireland and Ireland is certainly scientifically sensible and could be considered with a view of reducing the total resources currently used for sampling and testing.

  If a one-island policy were applied when identifying the epidemiologically relevant units, as suggested in EFSA opinion, a positive finding in Northern Ireland would affect the status of Ireland, *i.e.* the status of another Member State, while according to the Regulation a positive finding in Northern Ireland would affect Great Britain on "political grounds" and not Ireland even if there is a certain probability that *EM* is circulating in Ireland as well since there are no physical boundaries between Northern Ireland and Ireland to stop fox movements.

  Nevertheless, from a legal point of view, the one-island policy does not exist in Regulation (EU) No 576/2013. Introducing it in the delegated act adopted pursuant to Regulation (EU) No 576/2013 is therefore legally not possible and would contradict the set of rules that apply to the cross-border movement of dogs accompanying their owner for non-commercial purposes in accordance with Regulation (EU) No 576/2013 and by reference to that Regulation, for intra-Union trade or import purposes in accordance with Directive 92/65/EEC[23].

5.1.2.3. Preventive health measures

Movement of DHs with a pre-patent or patent infection (*i.e.* infected domestic and wildlife species involved in the *EM* lifecycle) is an important introduction pathway. According to EFSA, current knowledge suggests that the contribution of cats to the *EM* lifecycle is low. The application of the preventive health measures should therefore be restricted to dogs as provided for in the Regulation.

[23] 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).
http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01992L0065-20141229&qid=1457109673622&from=EN

The administration of praziquantel as close as possible to entry into the country where no findings of the parasite have been recorded is recommended in order to prevent reinfection. The treatment window provided for in the Regulation, *i.e*. 24h to 120h, is considered as a suitable compromise to encourage compliance.

5.1.2.4. Laboratory techniques for the detection of *EM*

The use of the SCT for the detection of EM parasite or DNA-based tests for the detection of *EM* genome have proved to be able to measure the actual infection status, to be able to be performed in faeces or intestinal contents and to be suitable for mass-screening. They should therefore remain as the reference methodologies used in the Member States' surveillance activities.

5.2. Commission's conclusions from consultation with Member States

Overall, Member States' representatives present at the PAFF Committee meetings held in 2015 and 2016 did not raise particular concerns with regard to the implementation of the Regulation and to EFSA's reports.

5.3. Commission's overall conclusion

The recent available scientific information published by EFSA shows that overall the Regulation provides an adequate framework for an effective protection of Finland, Ireland, Malta and the United Kingdom against *EM* infection. The surveillance activities aiming at detecting *EM* in DH species were well implemented and reported by the Member States for the past three years.

However, while the preventive health measures for the control of *EM* infection in dogs provided for in the Regulation are considered scientifically justified and proportionate to the risk of spreading the infection through the movement of dogs into Finland, Ireland and the United Kingdom, they would not address such risk in Malta where in the absence of reported suitable wild canid hosts, dogs cannot support the *EM* lifecycle.

In the light of EFSA's reports, reconsideration of certain aspects of the Regulation regarding the geographical application of the preventive health measures but also the surveillance activities to be implemented by Member States claiming freedom of *EM* in order to address potential bias in the applied strategy appear therefore to be appropriate to reassure other Member States and thus facilitating acceptance of these risk-mitigating measures.