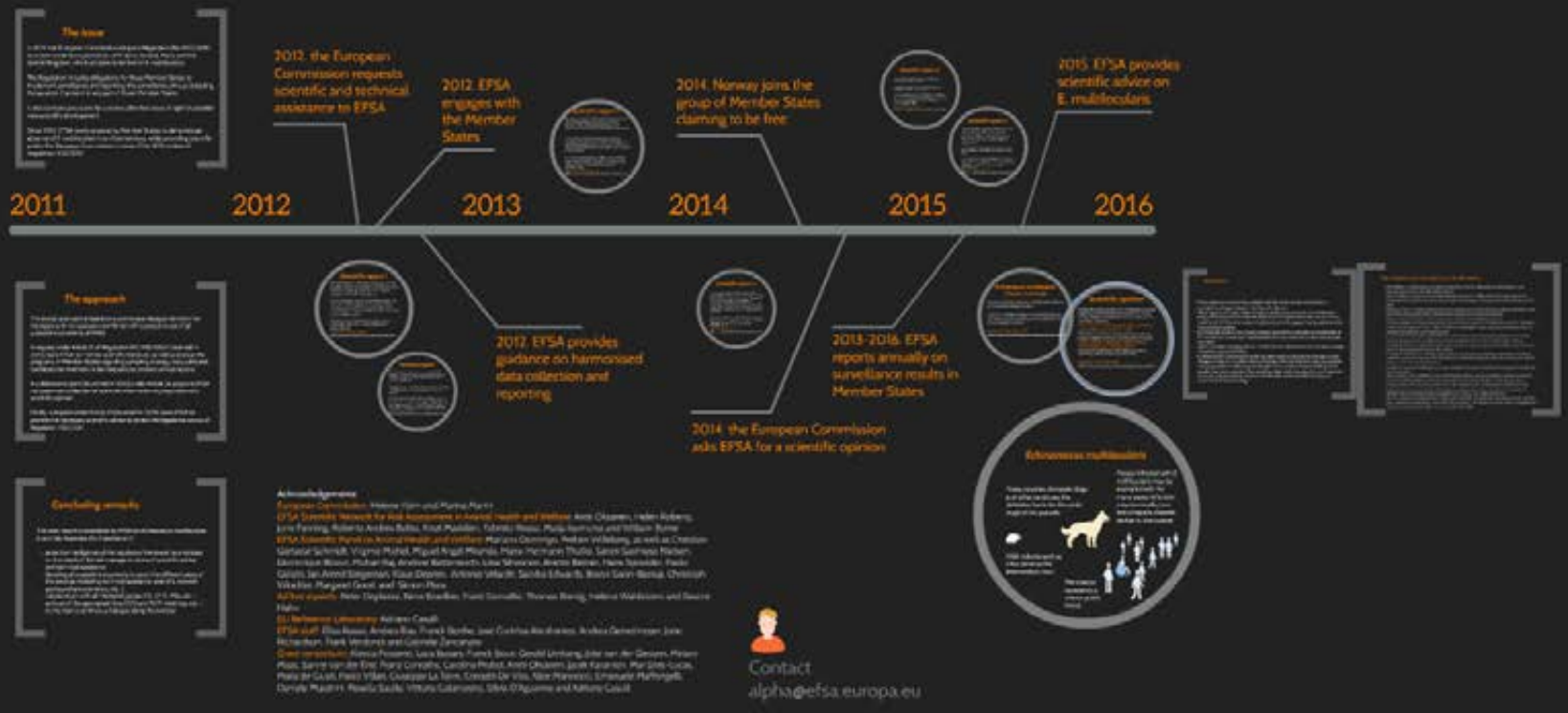
Echinococcus multilocularis in animals

EFSA delivers scientific advice to European risk managers



Echinococcus multilocularis

Foxes, coyotes, domestic dogs, and other canids are the definitive hosts for the adult stage of the parasite

People infected with *E. multilocularis* may be asymptomatic for many years; infection may eventually turn into a hepatic disorder similar to liver cancer

Wild rodents such as mice serve as the intermediate host

The disease represents a serious public threat

The issue

In 2011, the European Commission adopts a Regulation (No 1152/2011) to ensure continuous protection of Finland, Ireland, Malta and the United Kingdom, which all claim to be free of *E. multilocularis*

The Regulation includes obligations for these Member States to implement surveillance and reporting; the surveillance aims at detecting the parasite, if present in any part of those Member States

It also contains provisions for a review after five years, in light of possible new scientific development

Since 2012, EFSA works at assisting Member States to demonstrate absence of *E. multilocularis* from their territory, while providing scientific advice the European Commission in view of the 2016 review of Regulation 1152/2011

The approach

The overall approach is based on a continuous dialogue between risk managers and risk assessors combined with a proactive use of all available instruments of EFSA

A request under Article 31 of Regulation (EC) 178/2002 [received in 2012] tasks EFSA to monitor scientific literature, as well as analyse the programs in Member States regarding sampling strategy, data collected, and detection methods; it also requests to produce annual reports

A collaborative grant [launched in 2012] under Article 36 supports EFSA via systematic collection of scientific information in preparation of a scientific opinion

Finally, a request under Article 29 [received in 2014] tasks EFSA to provide the necessary scientific advice to review the legislative corpus of Regulation 1152/2011

2012. the European Commission requests scientific and technical assistance to EFSA

2012. EFSA engages with the Member States

2014. Norway joins the group of Member States claiming to be free

2012

2013

2014

2012. EFSA provides guidance on harmonised data collection and reporting

2014. the European Comm
asks EFSA for a scientific c

Scientific report 1

This report proposes a harmonised reporting system for surveillance systems in compliance with Reg 1152/2011 to facilitate the reporting by Member States as well as assessment of Member States reports

A tool for the description of the surveillance system has been specifically developed for this purpose. A data reporting framework (DCF) is proposed indicating all relevant data that must be reported to enable assessment of the surveillance results

Scientific and technical assistance on *Echinococcus multilocularis* infection in animals. EFSA Journal 2012;10(11):2973
Published in November 2012
http://www.efsa.europa.eu/en/efsajournal/pub/2973

Technical report

EFSA developed a tool to calculate the sample size needed to substantiate absence of a disease and/or to calculate the survey sensitivity (confidence) once the samples are collected

The report is applied to *Echinococcus* surveillance; however the RiBESS tool and the SSD can be used for other diseases

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*
Issued in November 2012
http://www.efsa.europa.eu/en/supporting/pub/366e

Scientific report 2

The report provides an analysis and critical assessment of the sampling strategy, the data collected, and the detection methods used in the surveillance for *E. multilocularis* carried out in Finland, Ireland, Malta and the UK

Under the assumption of unbiased representative sampling (Finland, Ireland and the UK) and unbiased risk based sampling (Malta) and considering the sensitivity of the tests applied, all four MS have fulfilled the requirement of the Regulation

Assessment of *Echinococcus multilocularis* surveillance reports submitted 2013 in the context of Commission Regulation (EU) No 1152/2011. EFSA Journal 2013;11(11):3465
Published in November 2013
http://www.efsa.europa.eu/en/efsajournal/pub/3465

Scientific report 3

Under the assumption of unbiased representative sampling (Finland, Ireland and the UK) and unbiased risk based sampling (Malta) and considering the sensitivity of the tests applied, all four MS have fulfilled the requirement of Regulation 1152/2011 to the effect that the surveillance activities should detect a prevalence of *E. multilocularis* of 1 % or less, with a confidence level of at least 0.95

Assessment of Echinococcus multilocularis surveillance reports submitted in 2014 in the context of Commission Regulation (EU) No 1152/2011. EFSA Journal 2014;12(10):3875
Published in October 2014
http://www.efsa.europa.eu/en/efsajournal/pub/3875

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2014. Norway joins the group of Member States claiming to be free

2015. EFSA provides scientific advice on E. multilocularis

2014

2015

2016

2012. EFSA provides guidance on harmonised data collection and reporting

2013-2016. EFSA reports annually on surveillance results in Member States

2014. the European Commission asks EFSA for a scientific opinion

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al Health and Welfare: Antti Oksanen, Helen Roberts,

Scientific report 4

The surveillance programme has not detected *E. multilocularis* in 2012 and 2013

Norway has fulfilled the requirement of Regulation 1152/2011 in 2012, but not in 2013

Assessment of *Echinococcus multilocularis* surveillance data 2012–2013 submitted by Norway in the context of Commission Regulation (EU) No 1152/2011. EFSA Journal 2015;13(2):4035
Published in February 2015
http://www.efsa.europa.eu/en/efsajournal/pub/4035

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Scientific report 5

The report provides an analysis and critical assessment of the sampling strategy, the data collected, the detection methods used and the results of the *Echinococcus multilocularis* surveillance carried out in Finland, Ireland, Malta, United Kingdom (UK) and Norway in 2014

It is concluded that Finland, Ireland, United Kingdom (UK) and Norway have fulfilled their obligations; Malta did not

Assessment of *Echinococcus multilocularis* surveillance reports submitted in 2015 in the context of Commission Regulation (EU) No 1152/2011. EFSA Journal 2015;13(11):4310
Published in November 2015
http://www.efsa.europa.eu/en/efsajournal/pub/4310

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Scientific opinion

Distribution and prevalence of *E. multilocularis*, role and importance of the different host species, risk factors and probability of introduction into areas where it has never been recorded

Assessment of monitoring and surveillance in the EU, and eradication programmes in wildlife

Risk factors for human alveolar ecchinococcosis and impact on public health of E. multilocularis in animals

Efficacy of deworming drugs and effectiveness of treatment protocols in domestic species

Assessment of laboratory techniques (sensitivity, specificity, predictive value, practicability)

Published in December 2015
http://www.efsa.europa.eu/en/efsajournal/pub/4373

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Methodologies

- A descriptive summary of the available scientific evidence and uncertainties is provided for all aspects dealt in the Scientific Opinion
- This is based on the systematic literature reviews carried out under the EFSA Grant Project GP/EFSA/AHAW/2012/01 (Echinococcus multilocularis infection in animals; Casulli et al., 2015) and on review of additional scientific papers (mainly published after the systematic review)
- A conceptual scenario-tree model has been generated to estimate the probabilities of EM introduction, transmission and establishment via movement of domestic animals and foxes
- Some examples regarding absence of infection assessment have been produced using a Bayesian approach (TOR2a)
- A deterministic mathematical model has been used to calculate the average number of eggs excreted in a country where no findings of the parasite have been recorded by a dog exposed in an endemic area and taken into a country where no findings of the parasite have been recorded. This model has been used to analyze different treatment protocols and changing the treatment timing and considering different types of movements of domestic dogs.

Main conclusions and recommendations from the 2015 Opinion

- Since 1980s *E. multilocularis* has been expanding in the EU, although the distribution is not homogeneous across the affected territories
- Red fox (*Vulpes vulpes*) is the principal definitive host of *E. multilocularis* in Europe; there is no evidence that any other carnivore can maintain the lifecycle of the parasite in the absence of red foxes
- Because of their variable importance for the maintenance of the lifecycle, rodents and other small mammals are not particularly suitable target species for surveillance purpose
- Movement of infected definitive hosts is an important introduction pathway
- The knowledge on the potential role of environmental factors for the persistence of the lifecycle is scarce; hence studies on the matter should be encouraged in order to better understand the link between introduction and establishment
- In areas where no suitable autochthonous wild canid hosts and no highly suitable intermediate hosts are present, such as Malta for example, establishment of the *E. multilocularis* cycle is considered close to impossible. Such countries do not need to carry out surveillance on domestic dogs to substantiate absence of the disease
- It might be relevant to reconsider some aspects of the current legislation regarding surveillance activities, such as for example the identification of epidemiologically relevant units that should be independent from political borders
- Studies to improve knowledge on epidemiological risk factors should be encouraged to enable risk-based sampling
- The parasite is not notifiable in non-free Member States, and its occurrence may be reported at genus level. *Echinococcus* notifications should however always be done at the species level
- Praziquantel is the substance of choice for the treatment of *E. multilocularis* in definitive hosts. However, the treatment window should be reconsidered to reduce the risk of re-infection. A general rule is to treat as close as possible to entry into a non-infected country
- There is a lack of standardization of diagnostic methods. The diagnostic sensitivity of the relevant tests should be established, in line with OIE standards. Until better documentation is available, the diagnostic sensitivity should be set conservatively to 78%

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Concluding remarks

The work recently completed by EFSA on *Echinococcus multilocularis* in animals illustrates the importance of:

- proactive intelligence of the regulatory framework to anticipate on the needs of the risk manager in terms of scientific advice and technical assistance
- blending of available instruments to cover the different steps of the exercise (including technical assistance, scientific network, grants and procurements, etc...)
- collaboration with all interested parties (EC, EFTA, MSs, etc...) and use of the appropriate fora (CVO and PAFF meetings, etc...) to maintain a continuous dialogue along the exercise

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