SCIENTIFIC REPORT

efsa JOURNAL

Annual assessment of *Echinococcus multilocularis* surveillance reports submitted in 2024 in the context of commission delegated regulation (EU) 2018/772

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Abstract

This report comprises the 14th assessment of the *Echinococcus multilocularis* surveillance scientific reports, provided by Finland, Ireland, United Kingdom (Northern Ireland) and Norway on their respective surveillance programmes. Every year since 2012, EFSA presents the assessment to the European Commission in which the sampling strategy, data collection and detection methods used by these countries are evaluated. More specifically, the surveillance programmes of these four countries are evaluated by checking the information submitted by each of them and verifying that the technical requirements are fulfilled as laid down in 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. The information is divided into four different categories for assessment: the type and sensitivity of the detection method, the selection of the target population, the sampling strategy and the methodology. For each category, the main aspects that need to be considered in order to accomplish the technical requirements of the legislation are checked against compliance of several criteria. The countries participating in this surveillance (Finland, Ireland, the United Kingdom (Northern Ireland) and Norway) succeeded in the fulfilment of the technical legal requirements foreseen in Commission Delegated Regulation (EU) 2018/772 concerning these four different categories. None of the four countries recorded positive samples in the 12-month reporting period.

KEYWORDS

absence of infection, *Echinococcus multilocularis*, freedom from disease, surveillance

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SUMMARY

Following a request from the European Commission and, indirectly, from the European Free Trade Association (EFTA) Surveillance Authority, the Biological Hazards & Animal Health and Welfare Unit (BIOHAW) was asked – in the context of Article 31 of Regulation (EC) No 178/2002 – to annually evaluate the surveillance programmes on *Echinococcus multilocularis* infection in animals carried out by the following countries: Finland, Ireland, Malta and the United Kingdom (Northern Ireland). The whole territory of Norway was added in 2019 after the Decision of the EEA Joint Committee No 183/2019.

The Annex of Commission Implementing Regulation (EU) 2018/878 describes the involved countries, and in order to be included in this Annex, Member States must comply with the rules laid down in Article 2 of Commission Delegated Regulation (EU) 2018/772 on 'rules for categorisation of Member States in view of their eligibility for preventive health measures for the control of *Echinococcus multilocularis* infection in dogs entering their territory'.

a. Finland, Ireland, the United Kingdom (Northern Ireland) and Norway fall under the category described in paragraph 3, i.e. they are in the position to demonstrate that the occurrence of the infection with this parasite has not been recorded in wild definitive host animals. Article 4(2) provides details on the conditions to be fulfilled in order to remain eligible for preventive health measures.
b. Malta falls under the category described in paragraph 2, i.e. it is in the position of demonstrating that the infection with *E. multilocularis* parasite has not been established because of the absence of wild red foxes in the whole of its territory. For that reason, the territory of Malta is exempted from a surveillance programme on the parasite and will not be included in the assessment.

Therefore, in this report, EFSA assesses the pathogen-specific surveillance programmes implemented by the Finland, Ireland, the United Kingdom (Northern Ireland) and Norway. From this point onward, these four countries will be referred to as Reporting Countries (RC). In order to facilitate the assessment, the information given by the different countries was divided into four different categories corresponding to the critical points that are addressed in the legislation in the requirements for the pathogen-specific surveillance programme provided for in point (c) of Article 4(2): (i) the type and sensitivity of the detection method, (ii) the selection of the target population, (iii) the sampling strategy and (iv) the methodology.

The Reporting Countries used appropriate techniques for the detection of *E. multilocularis* in intestinal contents or faeces, performed a 12-month surveillance period of data collection and designed an appropriate sampling strategy for the detection of the parasite, if present in any part of the country, at the design prevalence of less than 1% (0.01), with a 95% confidence level.

All the countries selected adequate wild definitive hosts in order to perform the surveillance. None of the Reporting Countries recorded positive samples in the 12-month surveillance period.

1 | INTRODUCTION

1.1 | Impact on human population

Overall, at any time, more than 1 million people are affected by one of the four human echinococcosis diseases: alveolar (caused by *E. multilocularis*), cystic (caused by *Echinococcus granulosus* sensu lato), neotropical (caused by *Echinococcus vogeli*, *Echinococcus oligarthrus*). The WHO assists countries to develop and implement pilot projects leading to the validation of effective cystic echinococcosis control strategies.[1]

Human alveolar echinococcosis (AE), caused by the larval stage of the fox tapeworm *E. multilocularis*, is a serious parasitic zoonosis (EFSA AHAW Panel, 2015; EFSA and ECDC, 2017; Torgerson et al., 2010). Alveolar echinococcosis is confined to the northern hemisphere, in particular to regions of Asia (around 95% of the burden), Europe (< 5%) and North America (< 0.05%). Table 1 reports the number of cases and notification rates in the European Union (EU)/EFTA by country and year. *E. multilocularis* is considered an emerging parasite in Europe. In fact, AE has been recently detected in Croatia, Italy and Serbia; thus, differential diagnosis and therapy of AE is a new challenge in clinical practice in these countries (Balen Topić et al., 2023; Dezsényi et al., 2019; Dušek et al., 2020; Lalošević et al., 2023; Tamarozzi et al., 2024).

TABLE 1 Reported human cases of cystic and alveolar echinococcosis and notification rates per 100,000 population in the EU/EFTA, by country and year, 2018–2022 (EFSA and ECDC, 2023).

Country	2022 National coverage[a]	Data format[a]	2022 Confirmed cases and rate Cases	Rate	2021 Confirmed cases and rate Cases	Rate	2020 Confirmed cases and rate Cases	Rate	2019 Confirmed cases and rate Cases	Rate	2018 Confirmed cases and rate Cases	Rate
Austria	Y	C	54	0.60	42	0.47	34	0.38	36	0.41	46	0.52
Belgium	Y	C	23	0.20	17	0.15	19	0.16	22	0.19	15	0.13
Bulgaria	Y	A	89	1.3	89	1.3	95	1.4	193	2.8	206	2.9
Croatia	Y	C	5	0.13	3	0.07	3	0.07	3	0.07	4	0.10
Cyprus	Y	C	0	0	0	0	1	0.11	0	0	0	0
Czechia	Y	C	10	0.10	1	0.01	4	0.04	1	0.01	4	0.04
Denmark[b]	–	–	–	–	–	–	–	–	–	–	–	–
Estonia	Y	C	1	0.08	4	0.30	1	0.08	2	0.15	0	0
Finland[c]	Y	C	2	0.04	6	0.11	4	0.07	8	0.14	1	0.02
France	Y	C	79	0.12	75	0.11	55	0.08	55	0.08	62	0.09
Germany	Y	C	163	0.20	160	0.19	171	0.21	150	0.18	176	0.21
Greece	Y	C	5	0.05	4	0.04	7	0.07	7	0.07	11	0.10
Hungary	Y	C	9	0.09	7	0.07	4	0.04	10	0.10	9	0.09
Ireland[c]	Y	C	1	0.02	1	0.02	0	0	0	0	2	0.04
Italy[b]	–	–	–	–	–	–	–	–	–	–	–	–
Latvia	Y	C	4	0.21	6	0.32	5	0.26	6	0.31	10	0.52
Lithuania	Y	C	74	2.6	20	0.72	37	1.3	81	2.9	50	1.8
Luxembourg	Y	C	1	0.15	1	0.16	3	0.48	1	0.16	0	0
Malta[c]	Y	C	0	0	0	0	0	0	0	0	0	0
Netherlands	Y	A	45	0.26	53	0.30	48	0.28	48	0.28	42	0.24
Poland	Y	C	46	0.12	26	0.07	18	0.05	70	0.18	51	0.13
Portugal	Y	C	2	0.02	2	0.02	1	0.01	5	0.05	9	0.09
Romania	Y	C	4	0.02	1	0.01	0	0	1	0.01	4	0.02
Slovakia	Y	C	6	0.11	2	0.04	3	0.05	11	0.20	10	0.18
Slovenia	Y	C	5	0.24	11	0.52	3	0.14	6	0.29	6	0.29
Spain[d]	Y	C	72	0.15	33	–	8	–	34	0.07	68	0.15
Sweden	Y	C	22	0.21	25	0.24	23	0.22	26	0.25	29	0.29
EU-27 total			**722**	**0.19**	**589**	**0.17**	**547**	**0.16**	**776**	**0.20**	**815**	**0.21**
United Kingdom[c,e]	Y	C	–	–	–	–	–	–	3	0	0	0

(Continues)

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[1] https://www.who.int/news-room/fact-sheets/detail/echinococcosis.

TABLE 1   (Continued)

Country	2022 National coverage[a]	2022 Data format[a]	2022 Confirmed cases and rate Cases	2022 Confirmed cases and rate Rate	2021 Confirmed cases and rate Cases	2021 Confirmed cases and rate Rate	2020 Confirmed cases and rate Cases	2020 Confirmed cases and rate Rate	2019 Confirmed cases and rate Cases	2019 Confirmed cases and rate Rate	2018 Confirmed cases and rate Cases	2018 Confirmed cases and rate Rate
EU total			**722**	**0.19**	**589**	**0.17**	**547**	**0.16**	**779**	**0.17**	**815**	**0.18**
Iceland	Y	C	0	0	0	0	0	0	0	0	0	0
Norway[c]	Y	C	9	0.17	11	0.20	6	0.11	7	0.13	7	0.13
Liechtenstein[b]	–	–	–	–	–	–	–	–	–	–	–	–
Switzerland[b]	–	–	–	–	–	–						

Abbreviation: –, data not reported.

[a]Y, yes; N, no; A, aggregated data; C, case-based data.

[b]No surveillance system.

[c]Finland, Ireland, Malta, the United Kingdom and mainland Norway have been declared free of *E. multilocularis*.

[d]Data not complete for 2020–2021, rate not estimated.

[e]Cases reported by the United Kingdom for the period 2017–2019 were also considered for this estimation (EU-28). When the United Kingdom data were collected for the period 2017–2019, the United Kingdom was an EU MS, but it became a third country on 1 February 2020.

Affected humans show clinical signs that include fatigue, loss of weight, abdominal pain, general malaise and signs of hepatitis or hepatomegaly. In untreated patients, the disease can develop to a severe form associated with liver failure, splenomegaly, portal hypertension and acidosis which can be fatal: before the advent of medical benzimidazoles treatment, the fatality rate exceeded 90% of AE cases within 10–15 years from diagnosis (Wilson et al., 1992). Even treated patients can experience a reduction in their quality of life (Mihmanli et al., 2016; WHO, 2017). Indeed, AE is thought to be responsible for about 666,434 disability-adjusted life-years (DALYs) globally per year (Torgerson et al., 2010).

1.2 | Lifecycle of *Echinococcus* spp.

The transmission cycle of *E. multilocularis* occurs when the adult worm (sexual stage) of the cestode residing in the small intestine of the definitive hosts (canids) release viable eggs into the environment via faeces (EFSA AHAW Panel, 2015; Peregrine et al., 2012). The infective eggs are ingested by an intermediate host (rodents) and the oncosphere migrates inside them until reaching target organs such as the liver (CDC, online; Peregrine et al., 2012). In the liver, the oncosphere develops into larval vesicles (metacestode asexual stage) which resembles a malignancy in appearance and behaviour, because it proliferates indefinitely by exogenous budding and invades the surrounding tissues. In rodents, parasitic vesicles contain numerous protoscoleces (infective stages), while in humans, protoscoleces are rarely observed (Moro & Schantz, 2009). The cycle continues when the definitive host consumes an infected intermediate host (Torgerson et al., 2010). Humans may be infected through the ingestion of viable eggs of the parasite by close contact with the definitive host, hand-to-mouth transmission or ingestion of food or water (Torgerson et al., 2010). There is an increasing concern on hand-to-mouth transmission of *Echinococcus* spp. eggs (Tamarozzi et al., 2020).

Although several species can be infected by *E. multilocularis* in nature, only a few species (fox-*Arvicolinae*) maintain the cycle in Europe. A scientific opinion on *E. multilocularis* performed by EFSA (2015), revised the potential hosts (definitive and intermediate) of the parasite for this continent (Table 2; See EFSA AHAW Panel (2015) for more detailed information).

TABLE 2   Potential definitive and intermediate hosts of *E. multilocularis* in Europe (EFSA AHAW Panel, 2015).

Definitive hosts	
Red fox (*Vulpes vulpes*)	Considered the main DH
Arctic fox (*Vulpes lagopus*)	In Europe, only relevant in Svalbard (Norway)[a]
Raccoon dog (*Nyctereutes procyonoides*), Wolf (*Canis lupus*), Golden jackal (*Canis aureus*)	In the presence of the red fox, they can act as DHs. There is no evidence supporting their ability to maintain the lifecycle in absence of the red fox
Domestic dog and wild cat (*Felis s. silvestris*)	Overall, prevalence of dogs with the parasite is low. However, in experimental surveys, they become infected easily. On the contrary, cats rarely get infected experimentally, but their natural infection has been reported on numerous occasions. For both species, further information is needed
Intermediate hosts	
Common vole (*Microtus arvalis*), field vole (*Microtus agrestis*), common pine vole (*Microtus subterraneus*), sibling vole (*Microtus levis*), bank voles (*Myodes* spp.), water voles (*Arvicola* spp.), snow vole (*Chionomys nivalis*), lemming (*Lemmus lemmus*)	Various species of voles are confirmed as suitable hosts. However, factors such as their population densities and predation rates may influence in their role in the life cycle

TABLE 2 (Continued)

Muridae (*Apodemus* spp., *Mus* spp., *Rattus* spp.), brown hare (*Lepus europaeus*), shrews (*Sorex* sp.)	Although some murid rodents, hares and shrews are susceptible, natural infections occur only sporadically
Muskrat (*Ondatra zibethicus*), beaver (*Castor* spp.), nutria (*Myocastor coypu*), Alpine marmot (*Marmota marmota*)	Large rodents are susceptible hosts. Their role seems to be related to the dispersion of the parasite; e.g. through translocations (beaver)
Suids, horses and domestic dogs	Only accidental or refractory intermediate hosts

[a]Since 2015, the Arctic fox has been reintroduced and now can be found in Fennoscandia.

1.3 | Presence in Europe

Until the 1980s, only four countries (France, Germany, Switzerland and Austria) were known to be endemic for the disease (Eckert & Deplazes, 1999). Since then, EM infections in animals have been increasingly reported in countries previously thought to be free (Casulli et al., 2015; Davidson et al., 2012; Oksanen et al., 2016).

In total, 25 MS and two non-MS provided 2022 monitoring data on *Echinococcus* in animals. Thirteen MS, the United Kingdom (Northern Ireland) and two non-MS reported data on, respectively, 6710 and 507 foxes that were examined for *E. multilocularis*. Eight MS and one non-MS reported positive findings with an overall proportion of test-positives of 11.6%. Furthermore, recent studies suggest that other species may play an important role in the epidemiology of the disease. For example, *E. multilocularis* infections are present in golden jackal populations in the south-western part of Hungary, with a prevalence of 15.6% and mean intensity of 664 worms (Balog et al., 2021).

With regard to human echinococcosis, 722 confirmed cases were reported in the EU in 2022. The EU notification rate was 0.19 cases per 100,000 population (Table 3).

TABLE 3 Summary of echinococcosis in humans, of *E. multilocularis* and of *E. granulosus s.l.* in most important definitive and intermediate animal hosts in the EU, 2018–2022 (EFSA and ECDC, 2023).

	2022[a]	2021[a]	2020	2019[b]	2018[b]	Data source
Humans						
Total number of confirmed cases	722	589	547	779	815	ECDC
Total number of confirmed cases/100,000 population (notification rates)	0.19	0.17	0.16	0.17	0.18	ECDC
Number of reporting MSs	25	25	25	26	26	ECDC
Infection acquired in the EU	235	127	63	176	149	ECDC
Infection acquired outside the EU	98	83	77	96	83	ECDC
Unknown travel status or unknown country of infection	389	379	407	507	583	ECDC
Animals						
Echinococcus multilocularis in foxes						
Number of animals tested	6710	6318	5506	6326	6566	EFSA
% positive animals	12.5	17.0	16.1	13.7	18.4	EFSA
Number of reporting MSs	14	14	10	13	13	EFSA
Echinococcus spp. in dogs Number						
Number of animals tested	2502	2942	2515	2113	2605	EFSA
% positive animals	0.08	0.07	0.08	0.24	0.08	EFSA
Number of reporting MSs	7	5	5	6	6	EFSA
Echinococcus granulosus s.l. in cattle (bovine animals)						
Number of animals tested	7,185,526	7,065,934	7,035,066	10,956,688	9,920,327	EFSA
% positive animals	0.32	0.21	0.21	0.17	0.23	EFSA
Number of reporting MSs	16	16	15	16	17	EFSA
Echinococcus granulosus s.l. in sheep and goats						
Number of animals tested	12,337,176	10,806,419	11,089,043	36,890,847	38,870,491	EFSA
% positive animals	0.81	0.38	0.96	0.38	0.37	EFSA
Number of reporting MSs	13	14	12	15	15	EFSA

[a]For the 2021–2022 period, data on animal samples from the United Kingdom (Northern Ireland) were taken into account. In accordance with the agreement on the withdrawal of the United Kingdom from the EU, and in particular with the Protocol on Ireland/Northern Ireland, the EU requirements on data sampling are also applicable to Northern Ireland.

[b]Data from the United Kingdom were taken into account for 2018–2019 since the United Kingdom was still an EU MS. However, on 1 February 2020, it became a third country.

The prevalence of the parasite is not homogeneous and may vary depending on multiple elements such as for example microclimatic conditions, geographical location, host population dynamics and number of intermediate hosts (Casulli et al., 2015; EFSA AHAW Panel, 2015). A systematic review of the geographical distribution of *E. multilocularis* in definitive and intermediate hosts in the EU and adjacent countries found differences between countries (Oksanen et al., 2016; Table 4). The prevalence has been reported to range from 0% to more than 50% (EFSA AHAW Panel, 2015).

TABLE 4 Table based on suggested prevalence classes (Oksanen et al., 2016) of countries in which *E. multilocularis* has been reported in foxes (see also ECDC, 2016; EFSA AHAW Panel, 2015; Lalošević et al., 2016).

Countries	Prevalence in foxes
Finland, Ireland, Malta, United Kingdom, Norway[a]	0
Denmark, Slovenia and Sweden	≤ 1%
Austria, Belarus, Belgium, Croatia, Hungary, Italy, the Netherlands, Romania and the Ukraine	> 1% to < 10%
Czech Republic, Estonia, France, Germany, Latvia, Lithuania, Luxembourg, Poland, Serbia, Slovakia, Liechtenstein and Switzerland	>10%

[a]Excluding Svalbard.

1.4 | Regulatory framework and surveillance programmes

The European Union adopted Commission Delegated Regulation (EU) 2018/772 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. Article 2 lays down the pathways for a Member State to become eligible for the implementation of preventive health measures for the prevention of introduction of *E. multilocularis* through dogs in Member states, or parts thereof. The concerned Member State may (i) demonstrate that the infection with the *E. multilocularis* parasite has not been established because of the absence of wild red foxes in the whole of its territory; (ii) demonstrate that wild definitive host animals likely to harbour the *E. 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 during the ongoing surveillance activities or (iii) is implementing a compulsory eradication programme.

On the one hand, this Regulation gives to those Member States (or parts thereof) the right to apply preventive health measures (see Article 6) to dogs intended for non-commercial movements prior to their introduction. It should be noted that the same preventive health measures are to be implemented for the import and commercial trade of dogs. On the other hand, this Regulation entails certain obligations for those Member States if they wish to remain eligible for preventive health measures (see Art.4), including the implementation of pathogen-specific surveillance programmes, in accordance with Annex I, to provide evidence for the absence of *E. multilocularis* infection. The requirements for the pathogen-specific surveillance programme are reported and summarised below:

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 confidence level of at least 95%.
2. The pathogen-specific surveillance programme shall describe the target wild definitive host population, including density, age structure, geographical and gender distribution, taking into account the relative risk of infection with the *Echinococcus multilocularis* parasite in different species and subpopulation 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.

The outcomes of the pathogen-specific surveillance programme of each Reporting Country need to be annually submitted to the Commission by the 31st of May.

At the moment, only four Member States (Finland, Ireland, Malta and the United Kingdom (Northern Ireland)) are listed in the Annex to Commission Implementing Regulation (EU) 2018/878 (as amended by the Commission Implementing Regulation (EU) 2020/2017 of 9 December 2020) as complying with the rules for categorisation laid down either in Article 2(2) or (3) of Commission Delegated Regulation (EU) 2018/772. The Decision of the EEA Joint Committee No 183/2019 of 10 July 2019 also added the whole territory of Norway to the list of countries mentioned in the Annex to Commission Delegated

Regulation (EU) 2018/878 (as amended by the Commission Implementing Regulation (EU) 2020/2017 of 9 December 2020) as complying with the rules for categorisation laid down in Article 2(3) of Commission Delegated Regulation (EU) 2018/772.

This report follows previous annual reports[2] presented by EFSA to the European Commission and aims to analyse and assess the sampling strategy, data collection and detection methods used by these four countries in the context of Commission Delegated Regulation (EU) 2018/772 in their respective *E. multilocularis* (pathogen-specific) surveillance programmes and verify that the requirements laid down in this regulation are being complied with.

1.5 | Background and Terms of Reference as provided by the European Commission and the EFTA surveillance authority

The Commission adopted Commission Regulation (EU) No 1152/2011 of 14 July 2011, as regards preventive health measures for the control of *Echinococcus multilocularis* infection in dogs. This was in order to ensure continuous protection of Finland, Ireland, Malta and the United Kingdom that claim to have remained free of the parasite *E. multilocularis* as a result of applying national rules until 31 December 2011. The Decision of the EEA Joint Committee No 103/2012 of 15 June 2012 added the whole territory of Norway to the list of countries complying with the conditions of Article 3 of the Regulation. For the purposes of Norway's obligations under the EEA Agreement, including those under Regulation (EU) No 1152/2011, the territory of Norway does not include Svalbard, cf. Protocol 40 to the EEA Agreement.

This Regulation includes certain obligations for these countries in order 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, the detection techniques and the reporting.

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EFSA is asked, in the context of Article 31 of Regulation (EC) No 178/2002, to provide the following scientific and technical assistance to the Commission:

1. Regular follow-up of the literature regarding *E. multilocularis* infection in animals in the European Union and adjacent countries, including its geographical distribution and prevalence.
2. Analysis and critical assessment, in the context of Regulation (EU) No 1152/2011, of (i) the sampling strategy considered for the programmes of the countries concerned; (ii) the data collected in the framework of these programmes; (iii) the detection methods used.

1.6 | Interpretation of the Terms of Reference

This report addresses ToR 2 of the mandates M-2012-0200 and M-2014-0287 submitted to EFSA by the European Commission and the EFTA Surveillance Authority, respectively, and applies the principles and procedures established in the EFSA reports 'Scientific and technical assistance on *E. multilocularis* infection in animals' (EFSA, 2012a) and '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*' (EFSA, 2012b).

Commission Delegated Regulation (EU) 2018/772, repealing Regulation (EU) No 1152/2011, gives a description of the requirements for the surveillance programme (Annex I). The methodology adopted by EFSA for the previous assessments does not require changes to fit the new requirements which remain the same in their substantial traits.

1.7 | Additional information

1.7.1 | Malta

Based on the 'rules for categorisation of Member States in view of their eligibility for preventive health measure' (Art.2), Malta falls under the category described in paragraph 2 of the same article, i.e. it is in the position of demonstrating that an infection with the *E. multilocularis* parasite has not been established because of the absence of wild red foxes in the whole of its territory. Article 4 provides details on the conditions to be fulfilled in order to remain eligible for preventive health measures. For Member States like Malta, in the absence of definitive host, the conditions to be met are:

a. Having a national observation programme in place to detect the presence of wild red foxes.
b. Immediate notification to the Commission and the other Member States of the detection of the presence of wild red foxes during each 12-month observation period.

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[2]www.efsa.europa.eu/en/topics/topic/animal-health#activities-on-specific-animal-diseases.

c. Report to the Commission on the results of the national programme referred to in point (a) by 31 May following the end of each 12-month observation period.

The evaluation of the observation programme of Malta and its results are out of the remit of this assessment.

1.7.2 | The United Kingdom (Northern Ireland)

In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Windsor Framework in conjunction with Annex 2 to that Framework, for the purposes of this scientific report, references to Member States include the United Kingdom in respect of Northern Ireland.

2 | DATA AND METHODOLOGIES

To address ToR 2, EFSA developed a scientific and a technical report in 2012 (EFSA, 2012a, 2012b). The principles and procedures that were established there have been applied in the assessment of each of the subsequent annual national surveillance reports submitted to the Commission, including this report.

As a **first step**, the quality of the report on the surveillance activities of 2023 of the Reporting Countries was assessed by checking the description of the surveillance system for completeness against the relevant elements that need to be addressed in the context of Commission Delegated Regulation (EU) 2018/772.

In order to facilitate the assessment, we divided the information into four different categories (see Table 5) corresponding to the critical points of the three paragraphs addressed in the legislation in the requirements for the pathogen-specific surveillance programme (Annex I).

TABLE 5 Assessment categories and their equivalence in the Commission Delegated Regulation (EU) 2018/772 (Annex I).

Information category	Main points considered in the assessment	Delegated regulation (EU) 2018/772
1	**The type and sensitivity** of the detection method was evaluated to ensure the fulfilment of the technical legal requirements regarding appropriate techniques for the detection of *E. multilocularis* in intestinal contents (sedimentation and counting technique (SCT) – or a technique of equivalent sensitivity and specificity) or intestinal contents/faeces (detection of species-specific DNA from tissue or eggs of the *E. multilocularis* parasite by polymerase chain reaction (PCR), or a technique of equivalent sensitivity and specificity)	Annex I – Point 3
2	The selection of the target population was evaluated to ensure the fulfilment of the technical legal requirements regarding the collection of samples from wild definitive hosts or domestic definitive hosts in the absence of the first	Annex I – Point 2
3	**The sampling strategy** was evaluated to ensure the fulfilment of the technical legal requirements regarding appropriate sampling for detection of the *E. multilocularis* parasite, if present in any part of the Member State, at the design prevalence of less than 1% (0.01)	Annex I – Point 1
	The sampling strategy was also evaluated to ensure the fulfilment of the technical legal requirements regarding the 12-month surveillance period of data collection	Annex I – Point 3
4	**The methodology** was evaluated to ensure the fulfilment of the technical legal requirements regarding a confidence level of at least 0.95 against a design prevalence of 1% (0.01)	Annex I – Point 1, 2, 3

For each of the four evaluation parts, the most relevant elements were extracted from the reports submitted by the RC and checked against the criteria described below (Table 6).

TABLE 6 Relevant elements checked for compliance of the technical requirements of Annex I of Commission Delegated Regulation (EU) 2018/772.

Points addressed in the Annex I	Element	Description of element
Type and sensitivity of the detection method	**Type of test**	The diagnostic test used for the detection of EM must be defined. Modifications of the original method should be indicated
	Test sensitivity	The sensitivity and specificity of the test used in the surveillance system must be reported. This would ideally be estimates from each participating laboratory reported as a point estimate (average) of the values across the country with minimum and maximum values or a probability distribution. Alternatively, a value of 0.78, as recommended by EFSA (2015), shall be used

TABLE 6 (Continued)

Points addressed in the Annex I	Element	Description of element
Selection of the target population	Definition of susceptible host population targeted by the system	The susceptible wild definitive host population(s) (red foxes, raccoon dogs) targeted by the surveillance system should be described and the choice justified. If domestic host species (dogs or cats) are sampled, evidence for the absence of wild definitive hosts and for these domestic animals having had access to outdoors should be provided
	Size of susceptible host population targeted by the system	The size of the targeted (wildlife) population should be reported, together with the evidence for this. Historical population data should be updated since these may not reflect current populations
Sampling strategy	Epidemiological unit	It should be clearly defined if individual animals or individual faecal samples collected from the environment constitute the epidemiological unit. If individual faecal samples are collected from the environment, the method applied to establish the species from which the faeces originated has to be reported
	Sample size calculation	The applied survey design should be fully documented, including considerations regarding potential biases inherent in the survey design. The method and the formula used to calculate the sample size should be fully documented.
	Implementation of the sampling activity	The sampling methods used should be fully documented including the related assumptions and uncertainties, and a justification for choosing the approach should be provided. Timeframe of the surveillance data and geographical clustering of the infection must be reported. The sample collection period must comprise the whole year and the spatial distribution of the sampling must be representative
Methodology	Design prevalence (DP)	DP is specified in Annex I of Regulation (EU) No 2018/772 and must be 1% (0.01) or lower
	Geographic epidemiological unit	The geographic epidemiological unit(s) identified as target for the surveillance activity has to be clearly indicated and supported by justification
	Methodology for calculation of area sensitivity	For the calculation of the area sensitivity, the diagnostic sensitivity should be set conservatively to the lowest value, excluding the lowest 20th percentile, from the ones reported in the scientific literature and related to the diagnostic tests implemented by the countries listed in Annex I of the Commission Delegated Regulation (EU) No 2018/772. In this case, is 78% (EFSA AHAW Panel, 2015)

A summary of the assessment of the relative elements of the different countries is given at the end of the document (see Appendix A) As a **second step**, the raw data on individual samples submitted by the five countries via the EFSA Data Collection Framework (DCF) were analysed. For the purpose, the software R (R core Team, 2022) was used to compute descriptive statistics. Table 7 lists and describes all the parameters that were extracted from the data submitted.

TABLE 7 List of the parameters extracted from the raw data submitted by the Member States via the data collection framework.

	Parameter	Description
1	Theoretical sampling period	The 12-month reporting period. It may go from January to December, but this is not a restriction: the reporting period can also include 12 contiguous months over 2 years
2	Actual sampling period	Range. Date of the first sampling date and date of the last sampling within the theoretical sampling period
3	Summary dates	Descriptive statistics of the sampling period
4	Sampling period	Total number of days sampled within the actual sampling period
5	Number of samples	Total number of samples collected during the theoretical sampling period
6	Number of test results	Total number of test results. If the number of test results is equal to the number of samples, none of the latter required further investigations (i.e. were negative at the first test)
7	Laboratory test completion	Comparison between the year when the samples are collected and the year when the test was completed
8	Sensitivity	Sensitivity of the diagnostic test
9	Host	Target population size (N); additional information on the host species
10	Animal sample	Type of sample collected
11	Sampling Strategy and Design	As reported (e.g. representative sample, risk-based)
12	Sampling point	Activity adopted for the sample collection (e.g. hunting, veterinary activity, …)

3 | INFORMATION AS SUBMITTED IN THE REPORT BY THE REPORTING COUNTRIES

3.1 | Diagnostic test

3.1.1 | Finland

The Finnish Food Authority used a PCR method (PCR 12S rRNA) for the detection of *E. multilocularis* eggs or other tissue in rectal content. The PCR method was described by Isaksson et al. (2014), with a modification in the magnetic beads washing step (manual instead of automatic). As a positive control in DNA isolation, own spiked specimens have been used: 10 inactivated (−80°C) *E. multilocularis* eggs/3 mL of intestinal content. Negative control is water sample in PCR. In routine analyses, a positive control was always analysed parallel to actual samples. If a positive control was found negative, the analysis of the whole batch of samples was repeated. In 2023, 26 out of 28 positive spiked samples (93%) were found positive. The Finnish Food Authority successfully passed the EURLP proficiency tests on the detection of *Echinococcus* spp. worms in the intestinal mucosa and on the molecular identification of *Echinococcus* spp. in 2023.

3.1.2 | Ireland

Rectal contents from red foxes were examined according to the method of Trachsel et al. (2007) referred to as PCR Cest1-Cest2 NAD1. The DNA nucleotide sequences of primers were Cest1 = TGCTGATTTGTTAAAGTTAGTGATC and Cest2 = CATAA ATCAATGGAAACAACAACAAG. The positive control that was used was an extract of DNA from adult *E. multilocularis* worms which was supplied by the EU Reference Laboratory for Parasites (EURLP). The negative control used was sterile saline solution. The test sensitivity estimate of 0.78 was based on the most recent advice arising from scientific opinion by EFSA (EFSA AHAW Panel, 2015). In addition, the Irish National Reference Laboratory for Parasites is amenable to participating in any study in order to re-evaluate the test sensitivity estimate, provided a sufficient number of *E. multilocularis* positive samples are supplied by the EURLP or a similar laboratory.

3.1.3 | United Kingdom (Northern Ireland)

In Northern Ireland (NI), a Sedimentation and Counting Technique (SCT) test was used to detect *E. multilocularis* from individual intestinal content (Eckert, 2003). The analyses were performed at the Agri-Food and Biosciences Institute (AFBI) which is the official laboratory for the Department of Agriculture, Environment and Rural Affairs (DAERA). The counting method sensitivity varies between laboratories. EFSA's suggestion to consider an Se of 78% was used (EFSA, 2015). In Northern Ireland, AFBI participates in annual proficiency testing with the last one being successfully completed in March 2024.

3.1.4 | Norway

In the Norwegian *E. multilocularis* surveillance programme, a DNA-fishing technique was used, referred to as PCR 12S rRNA, which involves magnetic capture mtDNA extraction from samples applying specific DNA hybridisation (Isaksson et al., 2014) with a modification in the magnetic beads washing step (manual instead of automatic), followed by real-time PCR (CO1rtPCR) (Øines et al., 2014). The DNA samples are analysed in duplicates in the real-time PCR to increase sensitivity, and to reduce the risk of errors introduced by the operator. The results from samples with very low target DNA have shown some false negative, which are minimised by running detection in duplicates (Øines et al., 2014). The used primers in this method were 'EMrtCO1F'(50-TGGTATAAAGGTGTTTACTTGG-30), 'EMrtCO1Rew'(50-ACGTAAACAACACTATAAAAGA-30) and 'Zen probe'50-56-FAM/TCTAGTGTA/Zen/AATAAGAGTGATCCTATTTTGTGGTGGGT/3IABkFq/−30). The samples which identified positive are verified by PCR/sequencing confirmation of NAD1 (Trachsel et al., 2007) and an independent real-time PCR (Taq PCR/12S rDNA real-time by Isaksson et al., 2014).

The sensitivity value published by Øines et al. (2014) is Se ≥ 0.63, with a specificity value (Sp) of 1.00, although our own examination of spiked samples (Table 8) suggests the real Se value may be higher. Prior to analysing surveillance samples, we annually test new reagents by spiking faeces or water with known quantities of *E. multilocularis* eggs or whole worms. Our data from 2015 to 2023 reveal an overall sensitivity of 0.82, which correlates positively with the amount of DNA in the samples. Specifically, samples containing ≥ 10 eggs or one whole worm exhibit a sensitivity of 0.91, while those with ≥ 5 eggs or one whole worm show a sensitivity of 0.89. Regarding specificity, negative controls (using MQ water) were included for all reactions, none of which tested positive by RT-PCR. Additionally, positive controls comprised eggs/DNA extracted from whole worms (provided by the EURL), while MilliQ water served as the negative control. Extraction blank controls (EBC) were also incorporated with every batch of samples run. Norway participates in the EURLP's annual proficiency test (PT) for national reference laboratories. The results of the *Echinococcus* spp. PT from EURLP 2024: PT-05: Detection of *Echinococcus* spp. worms in the intestinal mucosa were positive.

TABLE 8 Table reporting the results from testing spiked samples (2015–2023 data).

Year	1 egg			5 eggs			10 eggs			50 eggs			One whole worm		
	Number of samples tested	Number of positive samples	Se*	Number of samples tested	Number of positive samples	Se*	Number of samples tested	Number of positive samples	Se*	Number of samples tested	Number of positive samples	Se*	Number of samples tested	Number of positive samples	Se*
2015	4	2	0.50				4	4	1.00	2	2	1.00			
2016	10	10	1.00				10	10	1.00				2	2	1.00
2017	8	2	0.25				8	6	0.75				8	6	0.75
2018	2	0	0.00				2	2	1.00				10	10	1.00
2019	6	1	0.17	6	4	0.67	4	3	0.75				7	7	1.00
2020	8	1	0.13	6	3	0.50	8	5	0.63				8	6	0.75
2021	16	14	0.88	16	14	0.88	16	14	0.88				16	16	1.00
2022				8	8	1.00	20	19	0.95				8	8	1.00
2023				6	5	0.83	15	14	0.93				6	6	1.00
Overall	54	30	0.56	42	34	0.81	87	77	0.89	2	2	1.00	65	61	0.94

*Sensitivity.

3.2 | Target population (size & distribution & age structure)

3.2.1 | Finland

For the whole country of Finland, the entire wild small canid population(s) of the country was defined as the geographical epidemiological unit (even though the population is a continuum of the north-western taiga population). The epidemiological and sampling unit was defined as the individual animal (red fox or raccoon dog). The targeted host species were the raccoon dog and red fox. The justifications reported for choosing these target species were the facts that the red fox is the primary host of *E. multilocularis* in Europe (Deplazes, 2006), and that raccoon dogs have been shown to be good definitive hosts for *E. multilocularis* (Kapel et al., 2006). Population size estimates are based on hunting bag statistics provided by the Natural Resources Institute Finland LUKE.[3] Kauhala (2007) estimated that annual hunting bag is ca. 50% of the autumn population of the raccoon dog and ca. 40% of the autumn population of the red fox. The average annual hunting bag in the 5-year period 2018–2022 (latest available data) was 144,520 raccoon dogs and 42,320 red foxes. Therefore, FI estimated the population sizes of the raccoon dog and the red fox to be $2 \times 144{,}520 = 289{,}040$ individuals and $2.5 \times 42{,}340 = 105{,}800$ individuals, respectively. The estimated size of the susceptible population is therefore 394,840.

Snow track counts for the fox and game bag for the raccoon dog are used as proxies for population density in the maps in Figure 1. Most of the hunting bag of the raccoon dog has come from southern part of Finland in 2018–2022 (Figure 1). In recent years, the fox bag has decreased markedly in the northernmost Lapland but in other parts of the country, the fox bag has fluctuated. According to annual snow track counts (systematic method for the monitoring of small game populations) by LUKE, the Finnish fox population has decreased over 50% during the past three decades. The red fox is most abundant in the south-western part of the country (Figure 1). For monitoring of the raccoon dog population, snow track counting is not a feasible method because the species hibernates in winter. No information on age or gender structure of the target population was available.
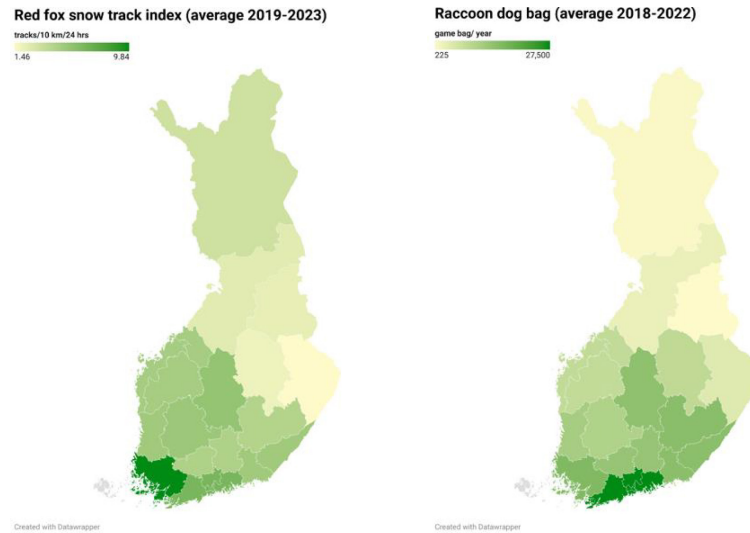
FIGURE 1   Finland – Fox abundance (left) by snow track counts and raccoon dog abundance (right) by average annual game bag (data by the Natural Resources Institute Finland, LUKE).[3]

Source: © Finnish Food Authority.

Disclaimer: The designations employed and the presentation of material on this map do not imply the expression of any opinion whatsoever on the part of the European Food Safety Authority concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.

3.2.2 | Ireland

The epidemiological unit used was the same geographical area as that of the EU member state Ireland. The rationale for selecting this area as the epidemiological unit was in order to comply with the conditions of Regulation 2018/772 for member states as listed in Annex 1. The animal level epidemiological unit was the individual animal (i.e. the red fox). In accordance with the requirements for pathogen-specific surveillance for *E. multilocularis* outlined in Commission Delegated Regulation (EU) 2018/772, the most suitable host species to survey is a wildlife definitive host species. In Ireland, because of the occurrence of red foxes throughout the country and no known occurrence of raccoon dogs (Hayden & Harrington, 2000; Marnell et al., 2009), the former was selected as the wildlife definitive host species to survey for the presence of *E. multilocularis*. The red fox population has been estimated to be between 150,000 and 200,000 (Hayden & Harrington, 2000; Marnell et al., 2009). The red fox is a seasonal breeder, whereby cubs are born in the spring and are almost fully grown by 7 months of age (Hayden & Harrington, 2000). Therefore, the age structure of the population between young and adult foxes varies depending on the time of year. There is little published scientific evidence of the gender structure of the Irish red fox population. Further information about the distribution of the red fox population within Ireland has been produced in a report by Dr Tomás Murray from the National Biodiversity Data Centre in 2015 (Figure 2).
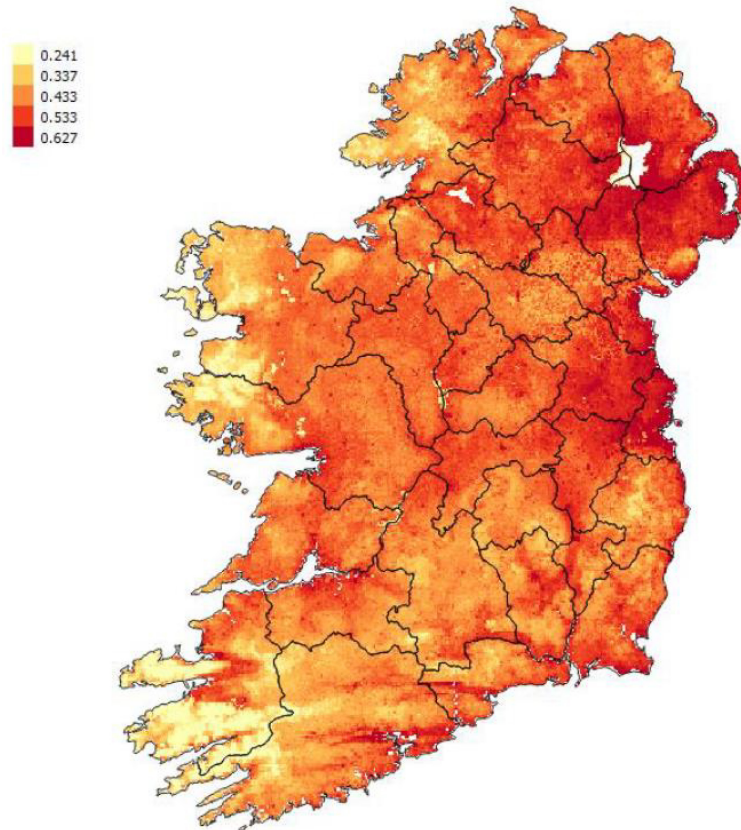
FIGURE 2 Probability of presence per 1 km^2 from the final Maxent species distribution model on the island of Ireland (Phillips et al., 2006) for red fox.
Source: data up to 2015 provided by Dr Tomás Murray, from National Biodiversity Data Centre (Ireland). © Dr Tomás Murray, Biodiversity Ireland.
Disclaimer: The designations employed and the presentation of material on this map do not imply the expression of any opinion whatsoever on the part of the European Food Safety Authority concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.

3.2.3 | The United Kingdom (Northern Ireland)

The red fox is the only wild definitive host for *E. multilocularis* in Northern Ireland. No other wild definitive host is present. Northern Ireland is part of an island with no access for other wild carnivores from other parts of Europe. For Northern Ireland, the fox population size (adults) has been estimated at 14,000 by wildlife experts (Declan O'Mahony (AFBI); pers. comm.) which is equivalent of 1 fox per km^2 and accounts for the large area of rural land in contrast to the urban land use. This probability of presence per 1 km^2 originates from the final Maxent species distribution model (Phillips et al., 2006) for red fox. The input data go up to 2015 and were provided by Dr Tomás Murray, from National Biodiversity Data Centre (Ireland) (Conserve Ireland, 2009). The rapid spread of sarcoptic mange in the red fox population and the population genetic structure according to microsatellite analysis (Atterby et al., 2015) demonstrate that there is considerable mixing of the red fox population within GB and within the island of Ireland, despite the variation in abundance. More in detail, there is a single land border with another EU Member State, which is the Republic of Ireland. This border is porous for wildlife; however, Ireland also has official disease-free status for *E. multilocularis*. The fox is found throughout Ireland, although the density of fox populations is highly variable. They are most abundant in areas that offer a wide variety of food and cover. In contrast areas of uniform land, such as moorland or open plains, generally carry much lower densities. At high population densities, foxes generally have small home ranges and disperse over short distances. Some foxes become resident in an area and form stable home ranges, while others are nomadic and appear to wander from one place to another. Two crucial factors determining the size of a fox territory are the availability of food and the cost of defending the territory. Regarding the structure of the population, some considerations can be done: breeding season begins in January and the red fox may have up to five cubs in a litter. The cubs stay with the mother for ~7 months. Max age is 10–11 years but 3 years is the average. Survival rate depends on availability of food and mortality due to road traffic accidents.

3.2.4 | Norway

The red fox is the target species. There are no scientific studies describing the Norwegian red fox population size. However, around 21,500 red foxes are hunted annually in Norway. Average number in the period 2019–2023 was 21,500, with a 6, 8% drop in hunted numbers in 2022–2023 compared to the 2021–2022 period (Statistics Norway). In the absence of more

accurate alternatives, we used an estimate for the population of Norwegian red foxes of 151,000 for calculations of desired sampling size. This population estimate was provided by professor emeritus Olav Hjeljord at the Norwegian University of Life Sciences and was partly based on the spatial distribution of preferred fox habitat and hunting statistics. The red fox is geographically distributed all over mainland Norway (Figure 3). The population density during spring is (roughly estimated) varying from 1 red fox/10 km^2 in mountain areas to 3 red foxes/10 km^2 in forest/marsh lands and to 10 red foxes/10 km^2 in urban/agricultural areas such as parts of eastern Norway (personal communication Prof. emeritus Olav Hjeljord, 2020). As for many other predator species in Scandinavia, the reproduction and survival rate of red fox pups fluctuates by following the fluctuations in the small rodent populations. Both the number of litters and the litter size vary significantly with the prevalence and thus accessibility of small rodents. The latter fluctuates greatly in 3–5 years cycles, usually with high populations of rodents every fourth year often designated as a 'rodent year'. In such years, rodents dominate the red fox diet, thus more and bigger litters are born. However, the peaks in rodent populations does not necessarily occur in the same year in different parts of Norway, making it even more of a challenge to estimate the red fox population accurately any given year. In years with shortage of food, the mortality among the pups is presumably high (Scandfox[4]).

FIGURE 3 Map showing observations of red fox in Norway. Online service where citizens can logon and register their observations of fauna and flora in Norway.
Source: © Norwegian Biodiversity Information Centre.[5]
Disclaimer: The designations employed and the presentation of material on this map do not imply the expression of any opinion whatsoever on the part of the European Food Safety Authority concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.

Indeed, Norway harbours much smaller populations of other potential definitive hosts for *E. multilocularis*. Notably, there are wolves and arctic foxes, with occasional reports also mentioning raccoon dogs.

The arctic fox is a critically endangered species in Mainland Norway and is closely monitored. A re-established programme to increase the number of arctic foxes in mainland Norway is currently ongoing. The mainland population over the period 2021–2023 was estimated to be between 277 and 336 adult foxes (Ulvund et al., 2023), which is a growth compared with the period 2020–2022. In 2023, a sample from an arctic fox, submitted for necropsy at the Norwegian Veterinary Institute (NVI), was examined by the same methodology as for the *E. multilocularis* surveillance programme, yielding a negative result.

A small and tightly regulated population of wild wolves inhabits Norway (*Canis lupus lupus*). During the winter of 2022–2023, there were 43–44 wolves recorded in Norwegian territories and an additional 46–48 wolves residing in territories spanning both Norway and Sweden (according to Rovdata[6]). On top of the 512 red foxes tested between 2022 and 2023 as

[4]https://www.scandfox.no/Fakta-om-r%C3%B8dreven.
[5]https://artsdatabanken.no/Pages/180936.
[6]https://rovdata.no/ulv/bestandsstatus.aspx.

part of our official surveillance programme, 12 samples of wolves were submitted for forensic post-mortem examination and they were also included in the surveillance examination for *E. multilocularis*; all results returned negative.

3.3 | Sample size (sampling strategy & distribution)

3.3.1 | Finland

The sample size was calculated by Finland using an overall sensitivity of the diagnostic approach of 0.78 and the design prevalence (DP) of 1% prescribed in Regulation (EU) No 2018/772 using the RiBESS tool. As size for the target population, a fixed value of 394,840 was used. The RiBESS tool returned a sample size equal to 383 to achieve the required confidence. The samples were collected by hunters on a voluntary basis. Hunters were informed of the sample collection by press releases in the Finnish Food Authority website[7] and e-mails and personal contacts to the Finnish Wildlife Agency[8] which in turn informed local hunting associations. To motivate hunters, they received by post a written report of the results of the health status of the animals they sent in. Rewards of animal samples (15 €/animal) were available for samples sent in from South Finland (area of dense fox and raccoon dog populations).

A total of 347 and 200 samples were collected from raccoon dogs and foxes, respectively (*N* = 547). Large proportion of the samples originates from Southeast Finland as this is the region where active monitoring of rabies control programme has taken place since 1990 (Pohjois-Karjala, Etelä-Karjala, Etelä-Savo, Kymenlaakso). The same area can be considered having an elevated risk of introduction of *E. multilocularis* due to geographical closeness of infected areas in the south. Also, Southeast Finland has a high density of raccoon dogs in Finland (Kauhala, 2007), but in general, the population densities for both species are highest in the southern part of the country. Hunters in the south-western part of the country (Helsinki-Uusimaa, Varsinais-Suomi, Satakunta, Pirkanmaa, Kanta-Häme, Päijät-Häme) have also submitted samples following a request from the Finnish Food Authority. Active hunting campaign to reduce the red fox population in the fjeld region of northern Lapland is another constant source of samples. The raccoon dog is continuously spreading northwards, and nowadays, a few hundred individuals are hunted yearly even in southern Lapland.

Gender ratio of sampled animals was unbalanced in foxes (female: male 1:1.30) but not in raccoon dogs (1:1.02). Of the animals that could be classified by age (*N* = 493), 61% were juveniles. The proportion of juveniles was 66% in raccoon dogs and 50% in foxes. A major sampling area was the bait vaccination zone for rabies control in south-eastern Finland (Pohjois-Karjala, Etelä-Karjala, Etelä-Savo, Kymenlaakso, 64% of the samples). Six south-western regions which were specifically encouraged by FFA to send samples provided 16% of samples. Proportion of samples from Lappi (Lapland) where active red fox population reduction to protect the arctic fox is ongoing increased slightly compared to previous year (14% of all samples) (Figures 4 and 6).

Samples were collected throughout 2023 (Figure 5). Sampling is mostly done in the cold season. Nearly all the foxes from Lapland were hunted in January–March. In May, June and July, the sample sizes decreased since the fox is protected, and consequently, hunting is only focused on diseased or injured individuals. The raccoon dog is classified in the Finnish law as an alien invasive species with no protection seasons but hunting and sampling still happens mostly in the cold season.

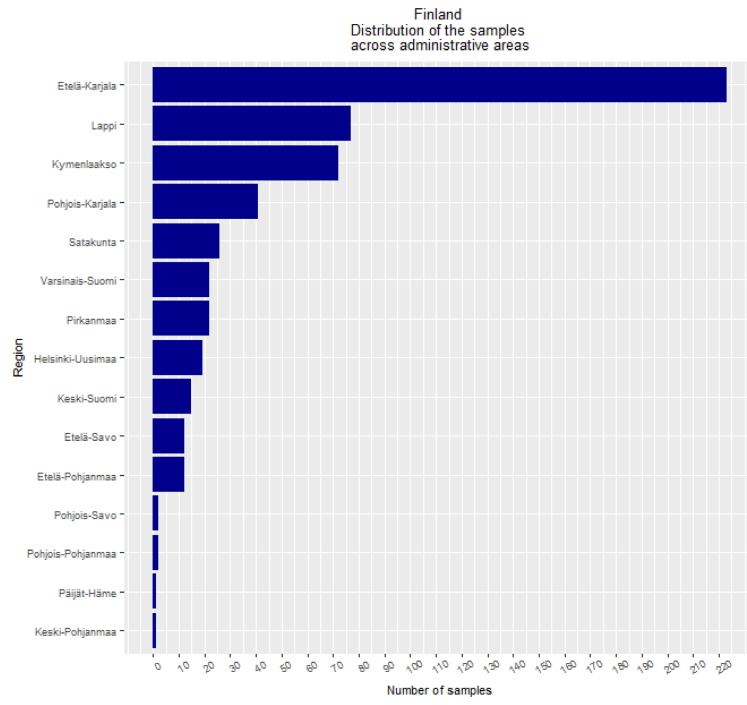All 547 samples were negative by PCR. Thus, no sample was found positive for *E. multilocularis*.

FIGURE 4   Finland – Distribution of samples across administrative areas.

FIGURE 5   Finland – Temporal distribution of samples.

No. of Samples per NUTS3 region

223
191.29
159.57
127.86
96.14
64.43
32.71
1
No Samples

Sampling intensity (Samples per 1,000 km^2)

33
28.29
23.57
18.86
14.14
9.43
4.71
0
No Samples

FIGURE 6 Finland – Sampling activity and intensity by NUTS 3 region.

3.3.2 | Ireland

The survey was designed to detect *E. multilocularis*, if present, in red foxes in Ireland by taking a representative sample of the red fox population based on a design prevalence of 1%, a target survey sensitivity of 0.95, a fox population size of 150,000 and test sensitivity of 0.78. The animal samples were obtained from foxes which were culled (by shooting) for pest and predator control reasons and foxes that were inadvertently captured in traps set for other wildlife as part of wildlife disease control measures. Each of the 16 Regional Veterinary Offices in Ireland was requested to obtain a specific number of foxes, based on their respective area size and the fox population density to reflect the number calculated in the 'Red fox (*Vulpes vulpes*) Species Distribution Model' for each area. Samples were collected through the work of the 16 Regional Veterinary Office personnel and from all eight NUTS 3 regions (Figure 7). In total, a collection of 384 samples was reported by Ireland. The sampling intensity was undertaken to reflect the distribution throughout Ireland and further adjusted to reflect the geographical variation in the density of the fox population distribution (Figures 2 and 9). Samples were obtained during 9 months of the year (Figure 8). A greater number of samples were collected from culling during October and November, in order to avoid the culling of adult female foxes during the nursing period. Collection of samples predominantly during the winter months should not adversely affect the sensitivity of the survey, based on a study from an endemic urban area in Switzerland, which found a greater prevalence of *E. multilocularis* in foxes in winter months (Hofer et al., 2000).

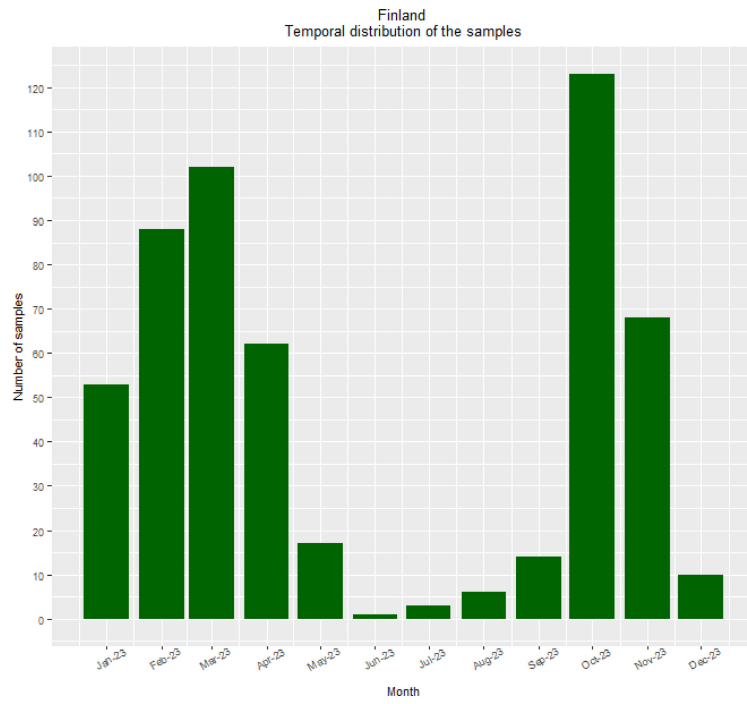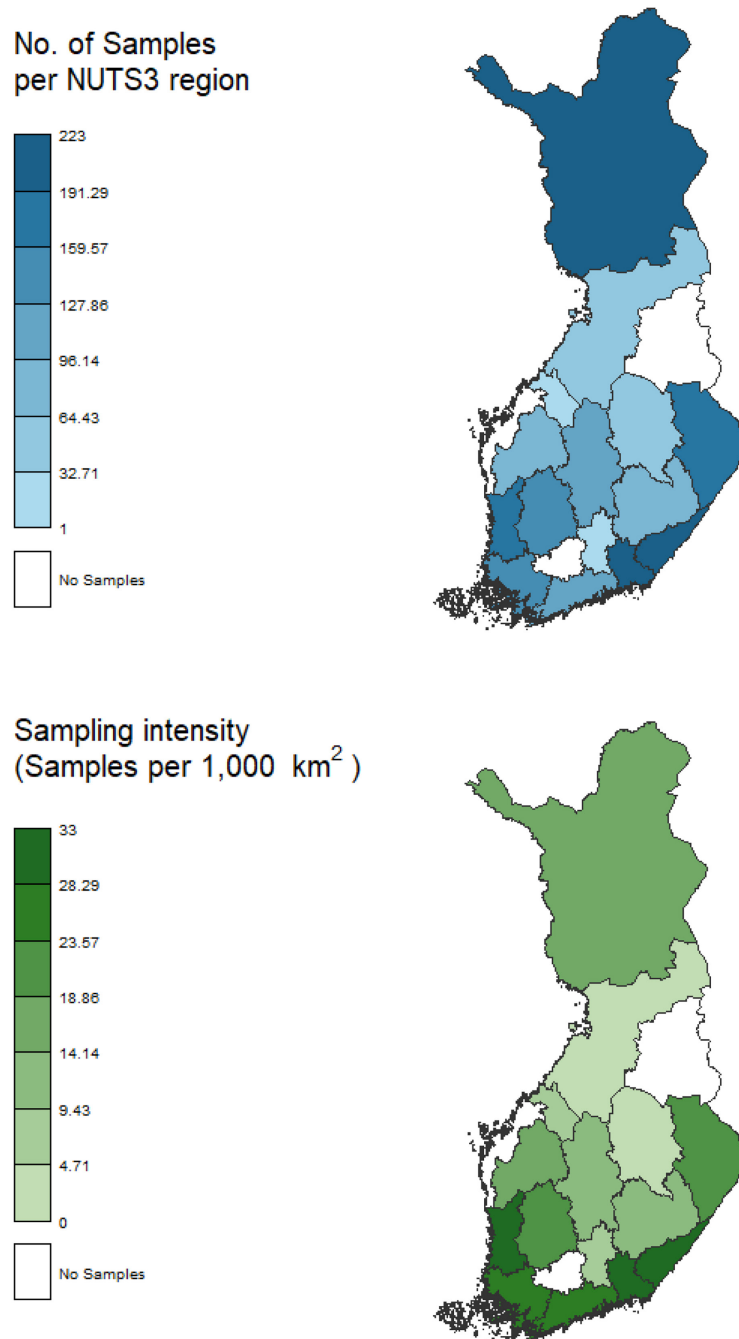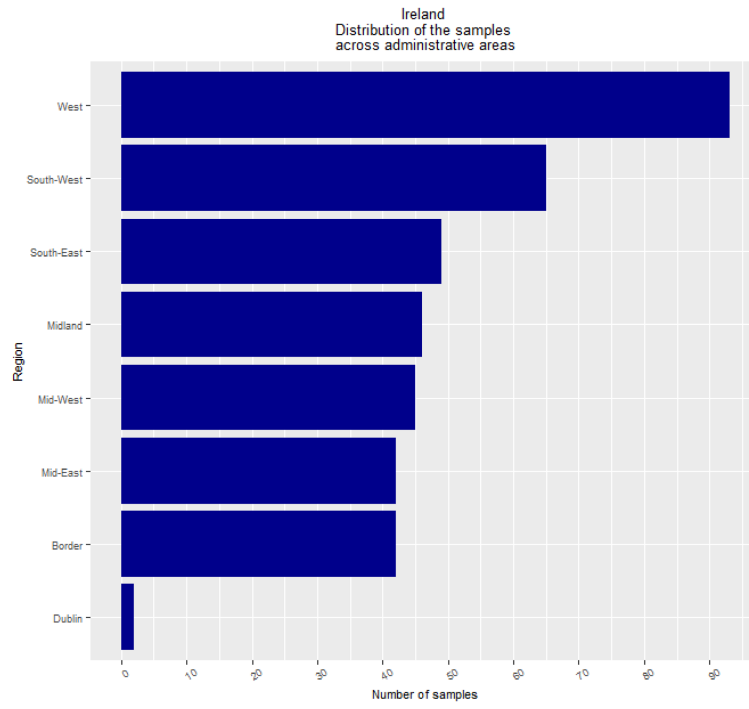**FIGURE 7**   Ireland – Distribution of samples across administrative areas.
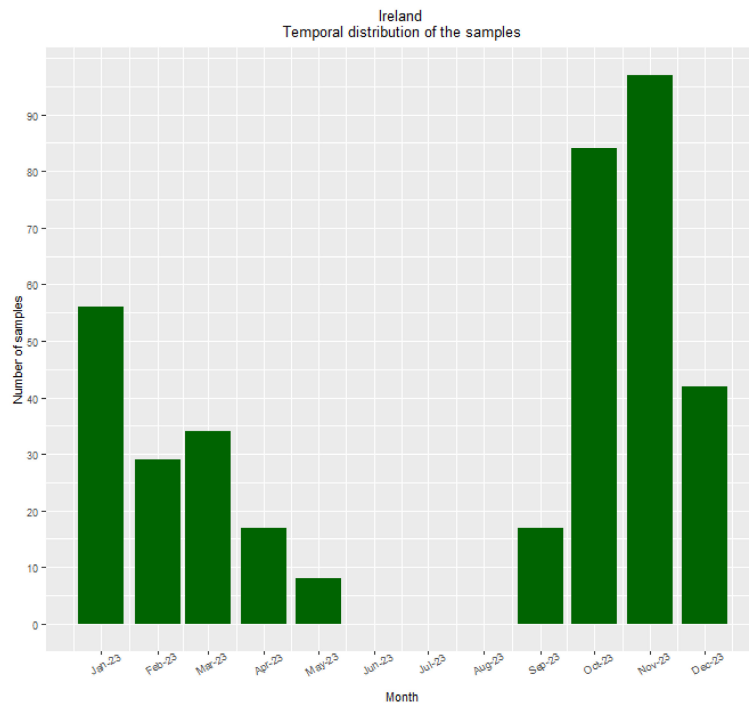

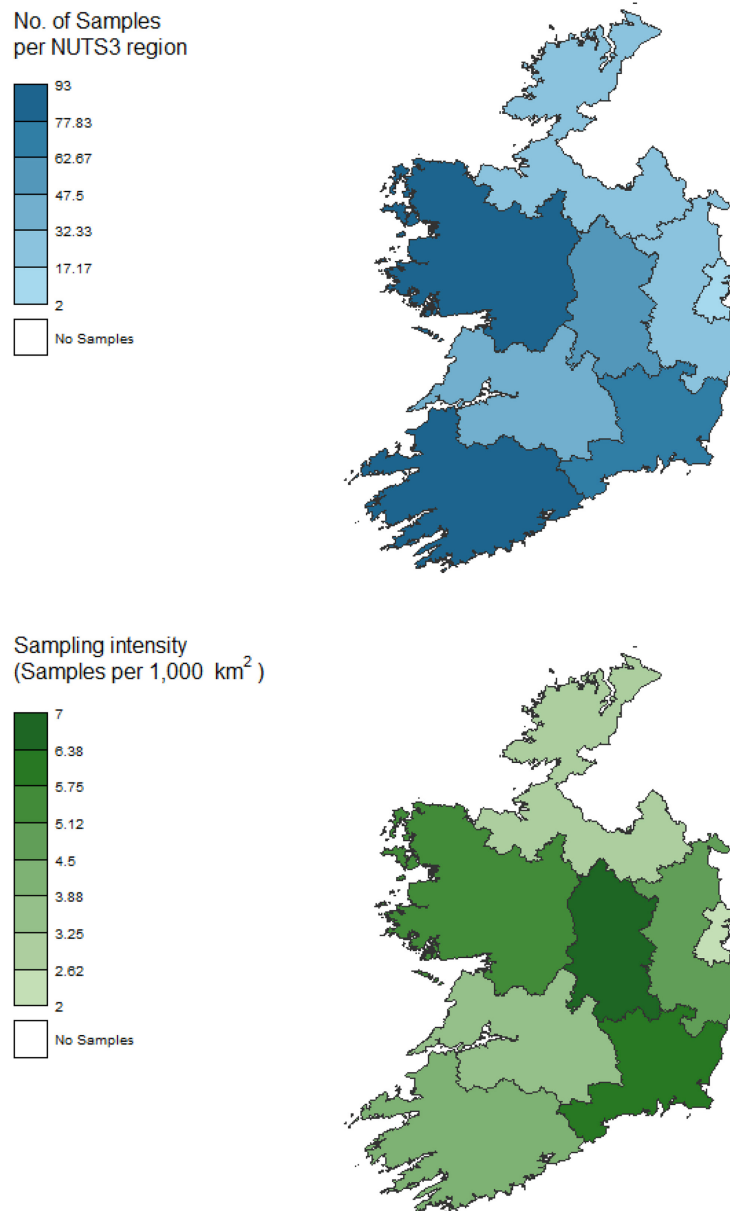**FIGURE 8**   Ireland – Temporal distribution of samples.

FIGURE 9 Ireland – Sampling activity and intensity by NUTS 3 region.

3.3.3 | United Kingdom (Northern Ireland)

The epidemiological unit was the individual animal. As animal carcasses rather than fox intestinal content were collected, the results could be reported at the individual fox level. The sample size was calculated using the EFSA RiBESS tool (assuming a test sensitivity of 0.78) which returned a value of 379 samples to be tested, over a population of 14,000 individuals, to achieve the target 95% confidence set by the Regulation. Random sampling – not risk-based is carried out. Wild animal carcasses were collected from hunting and road kills. This type of passive surveillance, relying purely on the hunting activity and the occasional road kills, entails a fluctuation on the number of samples and tests. Road kills were only occasionally suitable for testing; therefore, the number was low. Reports were made at NUTS 3 level (the lowest level of NUTS: districts in Northern Ireland). The NUTS boundaries are only rarely amended, and therefore, comparisons could be made from 1 year to the next in terms of distribution. In NI, 379 samples were collected and tested. The sampling activity was implemented in all regions (see Figures 10 and 12). Sampling was carried out at certain times of the year, mainly during the autumn and winter seasons (see Figure 11).

United Kingdom (Northern Ireland)
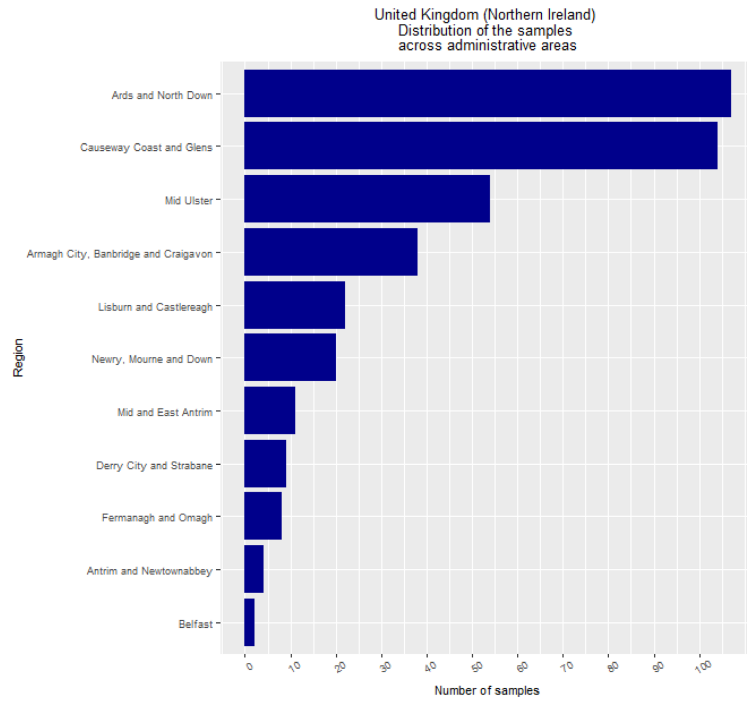Distribution of the samples
across administrative areas

FIGURE 10 Northern Ireland – Distribution of samples across administrative areas.

United Kingdom (Northern Ireland)
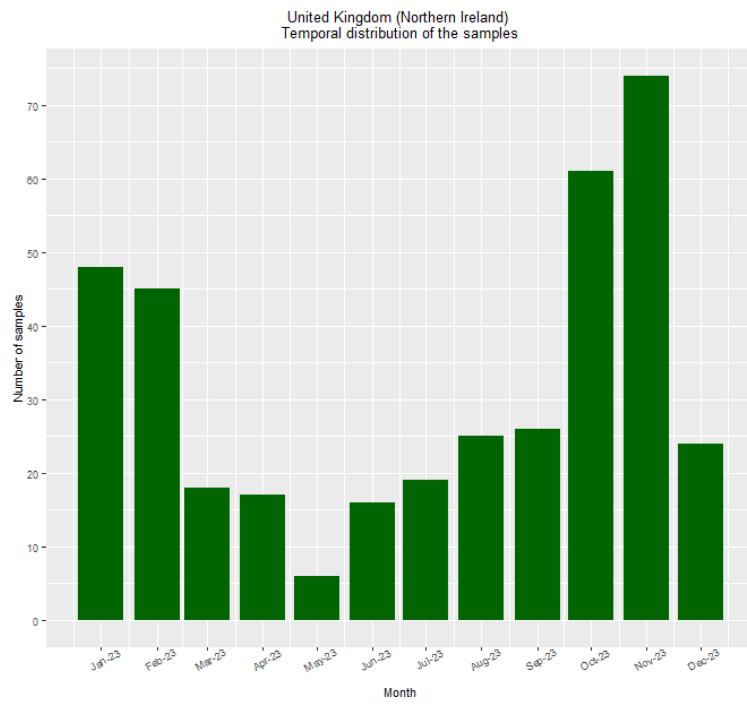Temporal distribution of the samples

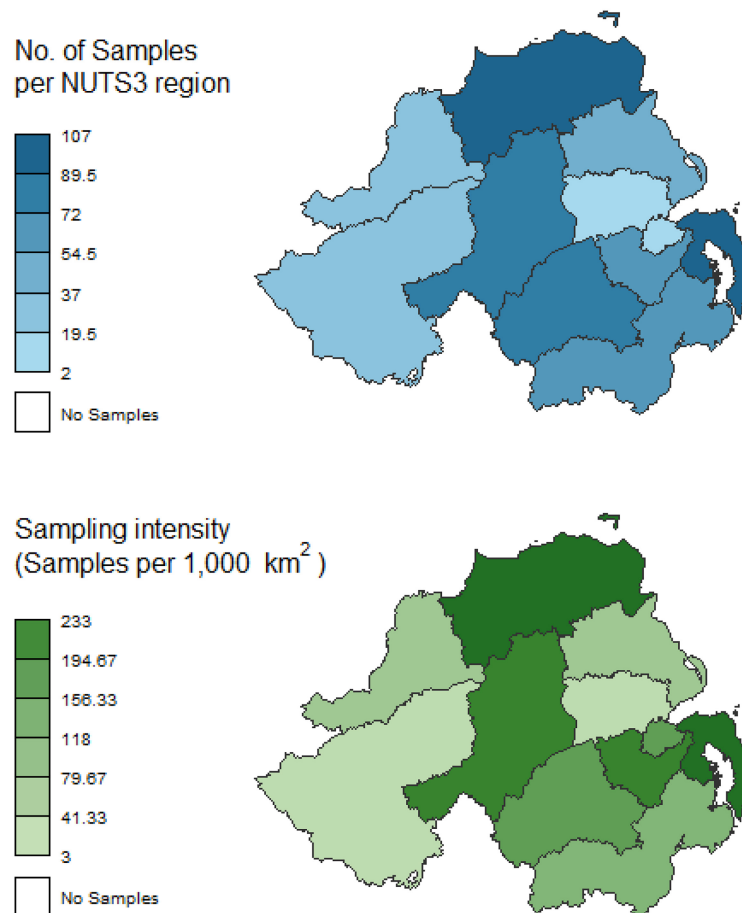**FIGURE 11** Northern Ireland – Temporal distribution of samples.

FIGURE 12   Northern Ireland – Sampling activity and intensity by NUTS 3 region.

3.3.4 | Norway

The determination of the required sample size essential to establish the absence of the parasite from the target population with a confidence level of 95% was conducted using the RiBESS tool.[9] The calculation utilised the sensitivity value of the method as published by Øines et al. (2014), with Se ≥ 0.63, alongside a specificity value of Sp = 1.00, along with an estimated population size of 151,000. The objective was to obtain approximately 474 samples from red foxes in 2023, with the epidemiological unit being the red fox. If the targeted population exceeds 70,000, the same sample size of 474 samples would be required, assuming Sp = 1.00 and Se = 0.63, as determined using the RiBESS tool. In Sweden, the neighbouring country of Norway, the first reported case of *E. multilocularis* was documented in late 2011. This case was identified in a red fox from the southern region of the country. Since then there have been several studies on different aspects related to *E. multilocularis* as well as surveillance studies in Sweden. These studies have shown that *E. multilocularis* is still present in red fox in Sweden albeit with a low overall prevalence. The parasite has been identified in intermediate hosts such as field voles (*Microtus agrestis*) and water voles (*Arvicola amphibius*) trapped in areas where the parasite has been identified in foxes (National Veterinary Institute (SVA), 2022). The presence of *E. multilocularis* in southern parts of Sweden may entail an increased risk of introduction of the parasite to Norway via migrating foxes. However, habitat use and extent of migration of red foxes from Sweden are not known. Therefore, it is complicated to assess the potential threat from migrating foxes from Sweden. Additionally, increasing prevalence of *E. multilocularis* has been observed in other nearby regions such as the Baltics and Denmark. We therefore consider the risk of introduction to be relatively high. Although the parasite is now approaching via migrating wildlife in neighbouring countries, lack of compliance with the anthelmintic treatment requirements for pets entering Norway is also a cause for concern. Therefore, we have opted to maintain the simple random sampling of red foxes, which is conducted by recruiting foxhunters for the sampling process. For recruitment of foxhunters, we have used an online registration at the NVI's Web pages to register as a (potential) hunter for the following years sampling. This registration is usually open for 3–4 weeks in November/December. The hunters enter their identification and demographic details via the webpage of the NVI.[10] This registration is announced on NVI's official web page and the Facebook profile page. Former participants in the surveillance programme are reminded to register again but new

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[9]https://shiny-efsa.openanalytics.eu/app/ribess.

[10]https://www.vetinst.no/nyheter/registrering-som-provetaker-av-rodrev-2024.

participants are also recruited. The selection of the participating foxhunters aims on balanced geospatial distribution and takes into consideration the quality of their previously submitted samples. Sample containers and detailed instructions for sampling were disseminated to the hunters who participate in the programme. The foxes were mainly killed with firearms (shotgun or rifle), but occasionally caught in traps or road killed. To secure that the samples originated from individual animals, the hunters also had to submit the tongue from each fox. The samples together with information concerning origin of the fox, date of the hunt, sex (male or female) and estimated age of the animal (juvenile or adult) were submitted to the laboratory in prepaid envelopes. In addition to samples from red foxes, samples from wolves killed legally or illegally during 2023 were tested for *E. multilocularis*. For safety reasons, all samples were frozen at −80°C for at least 3 days before analysis. All counties in Norway were represented in the sampling regimen. Five hundred and twelve samples were collected from red foxes in 2023 and all were negative in PCR.

The spatial distribution of samples is somewhat uneven (Figures 13 and 15), but all counties were represented. The topography of Norway (large areas with mountains) entails scattered settlements, and hunters do the fox sampling voluntarily in the proximity of their homes. When compared with the fox hunting statistics for 2022–2023 (Statistics Norway[11]), the counties Viken and Innlandet reported the highest numbers of hunted foxes. As visualised in Figure 15 sampling activity and sampling intensity differs between different parts of Norway. The areas with highest activity and density of sampling corresponds quite well with urban/agricultural areas where the population density of foxes is highest. The temporal distribution of samples is also somewhat uneven (See Figure 14). This is most likely due to preferred hunting conditions during winter (January–March) and banned hunting between 15 April and 15 July (and between 24th and 31st December). In September and October, it is also hunting season for wild cervids such as moose and red deer (and in which many Norwegian hunters participate), which might be an explanation for the low numbers of red fox samples from these months.
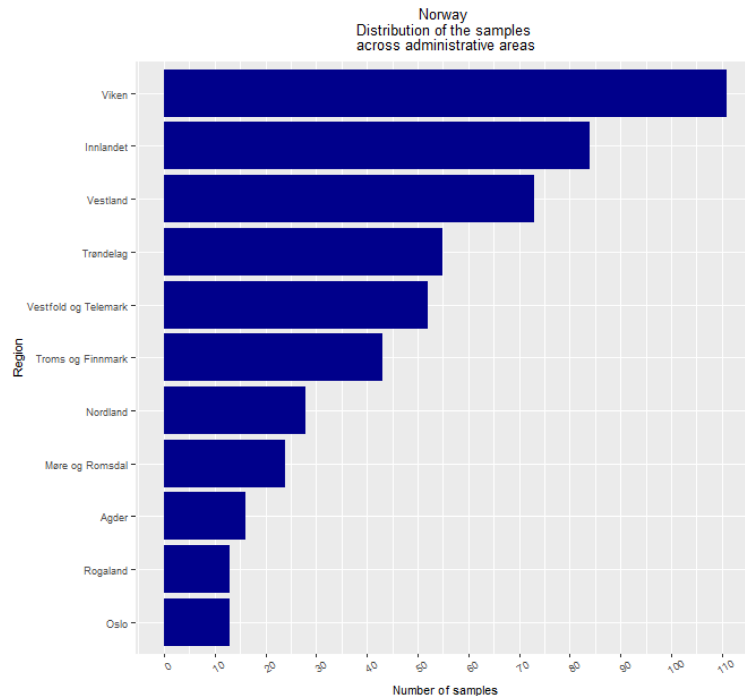
FIGURE 13　Norway – Distribution of samples across administrative areas.

[11]https://www.ssb.no/jord-skog-jakt-og-fiskeri/jakt/statistikk/smavilt-og-radyrjakt.
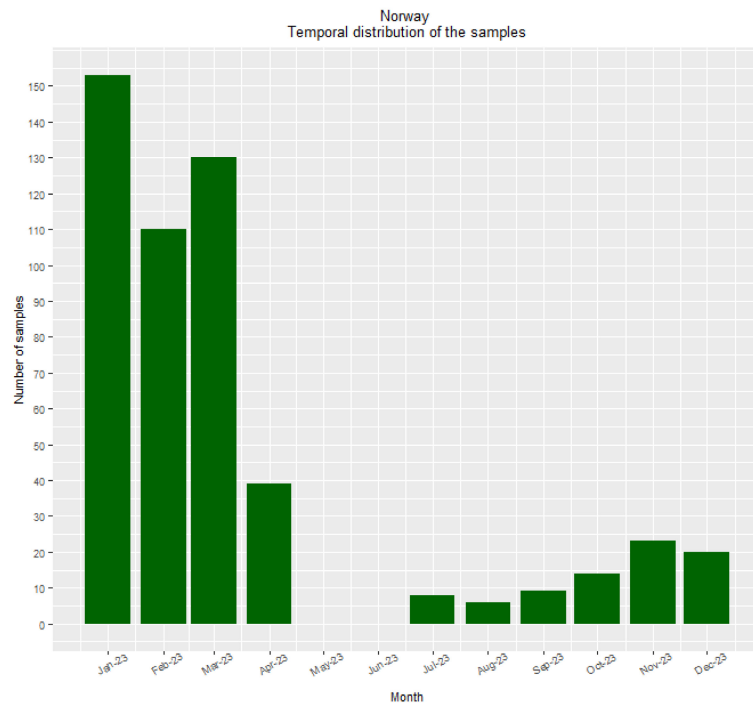
FIGURE 14 Norway – Temporal distribution of samples.

No. of Samples per NUTS3 region

111
98.75
86.5
74.25
62
49.75
37.5
25.25
13
No Samples

Sampling intensity (Samples per 1,000 km^2)

29
25.5
22
18.5
15
11.5
8
4.5
1
No Samples
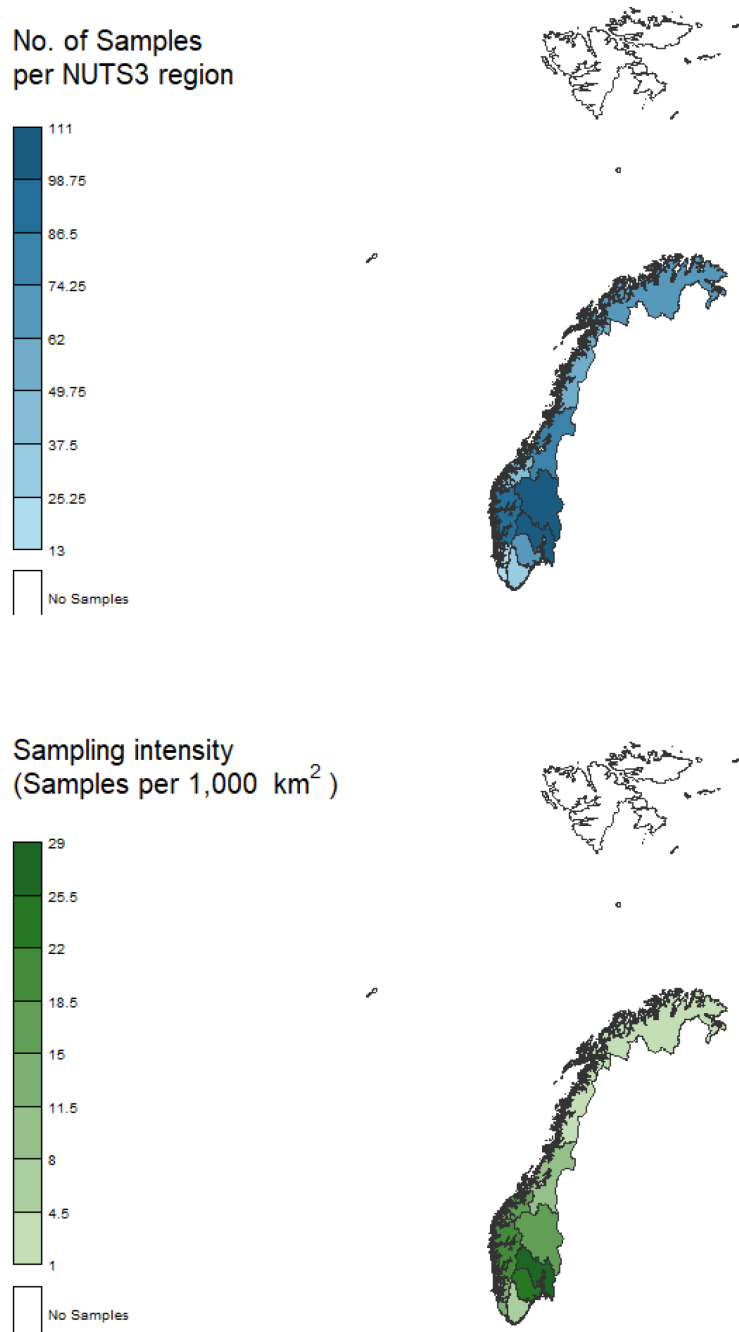
FIGURE 15   Norway – Sampling activity and intensity by NUTS 3 region.

4 | EFSA COMMENTS AND CONSIDERATIONS

4.1 | Finland

4.1.1 | Type and sensitivity of the detection method

Type of the detection method

The diagnostic test used by Finland for the detection of *E. multilocularis* consists of a PCR method (PCR targeting 12S rRNA gene) described by Isaksson et al. (2014). The technique has been well described. A slight modification of the technique has been realised and it has been indicated in the report.

Test sensitivity

The test sensitivity used for the estimation of the sample size was 0.78, as suggested by EFSA (EFSA, 2015). However, an overall system sensitivity of 0.89 (0.86–0.92) has been estimated based on internal validations performed by Evira/Finnish

Food Authority (EFSA, 2019). The additional positive (spiked) samples tested in 2023 help in narrowing the uncertainty around the sensitivity of the test in use (Table 9).

TABLE 9 Results of the internal validation round of tests performed by Finland over time.

Year	Spiked[a] samples (n, positive controls)	Samples testing positive (s)	Estimated sensitivity for each trial (exact binomial test)	Bayesian cumulative[b]
2014	131	102	0.78 (0.70–0.85)	0.78 (0.7–0.84)
2015	38	32	0.84 (0.69–0.94)	0.79 (0.73–0.85)
2016	32	31	0.97 (0.84–1)	0.82 (0.76–0.87)
2017	76	72	0.95 (0.87–0.99)	0.85 (0.81–0.89)
2018	31	31	1 (0.89–1)	0.87 (0.83–0.90)
2019	24	24	1 (0.86–1)	0.88 (0.84–0.91)
2020[c]	–	–	–	–
2021	23	21	0.91 (0.72–0.99)	0.88 (0.85–0.91)
2022	24	24	1 (0.86–1)	0.89 (0.85–0.92)
2023	28	26	0.93 (0.76–0.99)	0.89 (0.86–0.92)
Total	**407**	**363**	**0.89 (0.86–0.92)**	

[a]10 eggs in each spiked sample.

[b]Estimated based on the distribution $Beta\left(\sum_{i=1}^{y} s_i + 1,\ \sum_{i=1}^{y} n_i - \sum_{i=1}^{y} s_i + 1\right) + 1)$ where y is the number of years/rounds of test.

[c]In 2020, an internal validation exercise was performed, but the quality of the positive samples (i.e. the eggs in the sample) was not considered comparable to the ones used in other years.

An exact binomial test shows a 'probability of success' ('best guess' of the sensitivity) equal to 0.89, with a confidence interval going from 0.85 to 0.92 (bottom row of Table 9) and a Bayesian approach leads substantially to the same results.

4.1.2 | Selection of the target population

Definition of susceptible host population target by the system

The selection of raccoon dogs and red fox species as target populations was based on their role as definitive hosts in the cycle. This is an assumption also confirmed by the EFSA Scientific opinion on *E. multilocularis* infection in animals (EFSA AHAW Panel, 2015). It is not possible to draw conclusions regarding the role of the age and gender composition of the target population in the epidemiology and lifecycle of *E. multilocularis*, due to lack of appropriate data and studies (EFSA AHAW Panel, 2015).

Size of susceptible host population targeted by the system

Estimation of host population sizes was based on a scientific study performed in 2007 updated with data on recent hunting statistics. The decision to accept the size of the population as published by Kauhala (2007) and adjusting for the change of the size of the hunting bag is scientifically sound, particularly considering that the sample size calculation is not heavily affected when the population size has these dimensions (~ infinite population) (see EFSA AHAW Panel, 2015). The fact of considering the sum of the red fox and raccoon dog populations as the target population size seems to be correct, as raccoon dogs can act as DHs in conjunction with the red fox (EFSA AHAW Panel, 2015).

4.1.3 | Sampling strategy

Epidemiological unit

The epidemiological unit appears in the report and is defined as the individual animal. Individual rectal contents were collected by Finnish Food Authority from hunter-submitted carcasses.

Sample size calculation

The method used to calculate the sample size of Finland was the RIBESS tool. The sample size was calculated with an overall sensitivity of the diagnostic approach of 0.78 and a population size of 394,840 (sum of red fox and raccoon dog population). The sample size required in this case is 383. The sample size collected (*N* = 547) is sufficient to satisfy the legal requirements.

Implementation of the sampling activity

The geographical information shows that, in 2023, 15 (the same as 2022) of 19 NUTS3 regions were included in the sampling activity (see Figure 4). There was a higher intensity of the sampling in the south-east of the country. The date of hunting is not always communicated to the laboratory and for this reason only the month of sampling is submitted to EFSA. The surveillance strategy as described in the Finnish report cannot be considered a simple random sample, but rather a 'convenience sample', biologically driven. Most of the samples were collected by hunters and efforts were concentrated in the north and south-east of the country. However, in the case of wildlife animals, 'convenience sampling' is the most frequently used method. To mitigate the potential bias caused by this sampling activity, more samples than required were collected. Samples were collected during a period of 12 months as established in the relevant Regulation. The reduction of the intensity of the sampling during the summer months (May, June and July) is well justified and may not compromise the success of the detection of the parasite. A previous EFSA assessment suggested that a sampling distribution concentrated in the second half of the year – in a Freedom from Disease framework – could be more effective than a sampling distributed over the whole year; however, a quantitative evaluation was not performed (EFSA, 2013).

4.1.4 | Methodology

Design prevalence

The DP was equal to 1% (0.01), as it is specified in Annex I to Commission Delegated Regulation (EU) 2018/772.

Epidemiological geographical unit

The geographical unit was specified to be the entire territory of Finland. The choice is sound as no risk factors were reported to justify the identification of subareas within the Finnish territory.

Methodology for calculation of the area sensitivity

The area sensitivity was estimated by FI using the RiBESS tool. The parameters included for the calculation were the following, all fully documented:

- DP of 1% (0.01),
- test sensitivity of 0.78,
- population size of 394,840 (raccoon dogs + red foxes),
- sample size of 547.

The value of the area sensitivity (0.986) exceeded the established minimum value of 0.95 needed to fulfil the technical legal requirements of Commission Delegated Regulation (EU) 2018/772. In summary, the set of data relative to the surveillance activity in 2023 ensures the fulfilment of all the technical legal requirements included in the Annex I of Commission Delegated Regulation (EU)2018/772.

4.2 | Ireland

4.2.1 | Type and sensitivity of the detection method

Type of the detection method

The diagnostic test chosen by Ireland is well described (PCR Cest1- Cest2 NAD1) and is based on a peer-reviewed method with a correct reference included in the report.

Test sensitivity

Ireland followed EFSA's advice regarding the setting of the conservative, lowest value of the sensitivity (0.78) (EFSA AHAW Panel, 2015).

4.2.2 | Selection of the target population

Definition of susceptible host population target by the system

The red fox has been recognised as the main wildlife definitive host species for this parasite (EFSA AHAW Panel, 2015). The selection of this species to perform the pathogen surveillance is well explained and referenced. The absence of other important definitive wild hosts (raccoon dogs and wolves) is also supported by scientific literature. Regarding the age or gender of the target population, their role in the epidemiology and in the lifecycle of *E. multilocularis* is not known due to the lack of appropriate data and studies (EFSA AHAW Panel, 2015).

Size of susceptible host population targeted by the system

Although the original information regarding the red fox population size was published in 2000 and 2009 (Hayden & Harrington, 2000; Marnell et al., 2009), Dr Tomás Murray, of the National Biodiversity Data Centre, Ireland, specifically provided additional information regarding the Irish fox population in 2015, including more recent data on the relative population density distribution based on ongoing observation records. Nevertheless, at a population size greater than 10,000, moderate fluctuations in the population size would not significantly change the sample size required to achieve the same statistical confidence of less than 1% (0.01) prevalence at a specific test sensitivity (EFSA, 2014). Therefore, fluctuations in the previous population size of 150,000 do not significantly alter the sample size required (EFSA, 2014).

4.2.3 | Sampling strategy

Epidemiological unit

The epidemiological unit is defined in the report as the individual animal. Faeces samples were obtained post-mortem from culled (control programmes) or animals trapped inadvertently.

Sample size calculation

The method used to calculate the sample size for Ireland was the RIBESS tool. The sample size was calculated with: (a) an overall sensitivity of 0.78 (as recommended by EFSA AHAW Panel, 2015) and (b) a population size of 150,000 (red fox population). With these conditions, the minimum number of samples to collect in order to obtain a minimum of 0.95 of area sensitivity is 383. The total number of samples collected by Ireland was 384, which ensures the fulfilment of the technical legal requirements in Commission Delegated Regulation (EU) 2018/772 concerning a confidence level of at least 0.95 against a design prevalence of 1%. Although EFSA would recommend considering the population size as the maximum value of the range instead of the minimum number (200,000 instead of 150,000), the minimum sample size thus calculated to achieve the same confidence would not differ significantly.

Implementation of the sampling activity

The geographical information shows that all regions were included in the sampling activity. The sampling activity per 1000 km^2 shows a homogenous intensity, i.e. the target sample size is distributed across the territory as a function of the area size, adjusted for the density of the population. Such a sampling strategy, leading to a so-called proportional sample, is more likely to be representative compared to other strategies. Samples were obtained during 9 months, excluding June, July and August. The reduction of collection of samples during spring and summer is justified to avoid culling adult female foxes during the nursing period. This fact might not influence the representativeness of the sample, as suggested in a previous EFSA assessment (EFSA, 2013). A sampling distribution concentrated in the second half of the year – in a Freedom from Disease framework – could be more effective than a sampling distributed across the whole year (EFSA, 2013).

4.2.4 | Methodology

Design prevalence

The DP was equal to 1% (0.01), as it is specified in Annex I Commission Delegated Regulation (EU) 2018/772.

Epidemiological geographical unit

The geographical unit was specified to be the entire territory of Ireland. The choice is sound as no risk factors were reported to justify the identification of subareas within the Irish territory.

Methodology for calculation of the area sensitivity

The area sensitivity was estimated by Ireland using the RiBESS tool. The parameters included for the calculation were the following:

- design prevalence of 1%,
- test sensitivity of 0.78,
- population size of 150,000,
- sample size of 384.

The value of the area sensitivity 0.951 exceeded the established minimum value of 0.95 needed to fulfil the technical legal requirements described in Commission Delegated Regulation (EU) 2018/772. With a population size of 200,000, the value of the area sensitivity would be exactly the same (0.951). In summary, the set of data relative to the surveillance activity in 2023 ensures the fulfilment of the technical legal requirements included in all the paragraphs in Annex I of Commission Delegated Regulation (EU) 2018/772.

4.3 | United Kingdom (Northern Ireland)

4.3.1 | Type and sensitivity of the detection method

Type of test

The sedimentation and counting technique (SCT) test (Eckert, 2003), considered as the reference standard for detection of *E. multilocularis* from individual intestinal content, was used.

Test sensitivity

The United Kingdom (Northern Ireland) followed EFSAs advice regarding the setting of the conservative, lowest value of the sensitivity (0.78) (EFSA AHAW Panel, 2015).

4.3.2 | Selection of the target population

Definition of susceptible host population target by the system

The selection of red fox to perform the pathogen surveillance seems appropriate, as this species has been recognised as the main wildlife definitive host species for this parasite (EFSA AHAW Panel, 2015). Regarding the absence of other potential wild definitive hosts (e.g. raccoon dogs, wolves), the information is consistent with the report of Ireland. However, no reference has been provided.

Size of susceptible host population targeted by the system

Data of fox population size are well documented (14,000) and it can be assumed to be almost stable.

4.3.3 | Sampling strategy

Epidemiological unit

For NI, the epidemiological unit was the individual animal. Intestinal contents were sampled from hunted animals and road kills.

Sample size calculation

NI utilised the RIBESS tool to determine the sample size. This calculation was based on an overall sensitivity of the diagnostic approach, set at 0.78 and a population size of 14,000 (red fox population). With these parameters, the minimum number of samples necessary to achieve a minimum area sensitivity of 0.95 is 379, aligning precisely with the total collected by NI. Considering a test sensitivity of 0.78, the total number of NI samples yields a confidence level of 0.950, precisely the minimum requirement of 0.95, as mandated by the technical legal standards outlined in the Commission Delegated Regulation (EU) 2018/772.

Implementation of the sampling activity

The sampling process has more of the characteristics of a convenience sampling, rather than a simple random sample. The difficulties in performing a simple random sampling technique, however, are well known and are broadly discussed in previous reports. The reduction in sampling intensity during several months beginning in March is justified and may not compromise the success of detecting the parasite. A previous EFSA assessment suggested that a sampling distribution concentrated in the second half of the year – in a Freedom from Disease framework – could be more effective than a sampling distributed over the whole year; however, a quantitative evaluation was not performed (EFSA, 2013).

4.3.4 | Methodology

Design prevalence

The DP used was equal to 1%, as it is specified in Annex I to Commission Delegated Regulation (EU) 2018/772.

Epidemiological geographical unit

The geographical unit was specified to be the entire territory of Northern Ireland.

Methodology for calculation of the area sensitivity

The area sensitivity was estimated by Northern Ireland using the RiBESS tool. The parameters included for the calculation were the following:

- design prevalence of 1%,
- test sensitivity of 0.78,
- population size of 14,000,
- sample size of 379.

The value of the area sensitivity (0.950) is in line with the minimum value of 0.95. In summary, the set of data relative to the surveillance activity in 2023 ensure the fulfilment of the technical legal requirements of Annex I of Commission Delegated Regulation (EU) 2018/772. From a purely epidemiological point of view, considering the whole island of Ireland as one epidemiological unit would be a scientifically sound approach. The fox population is widely distributed in the island of Ireland and individual animals move freely throughout the territory without physical barriers. EFSA conducted a theoretical analysis considering the population of foxes of the whole territory of Ireland by means of combining the results of NI and Ireland. The global area sensitivity achieved would be 0.998, significantly above the confidence required by the legislation.

	Component sensitivity	Overall area sensitivity
IE	0.951	0.998
NI	0.950	

4.4 | Norway

4.4.1 | Type and sensitivity of the detection method

Type of the detection method

Norway used a DNA-fishing technique, the PCR 12S rRNA (Isaksson et al., 2014), which is well described and appropriately referenced in the report.

Test sensitivity

For precautionary reasons, the diagnostic sensitivity was set to the sensitivity obtained by Øines et al. (2014) (0.63), a lower value than the minimum recommended by EFSA (0.78). Such a low test sensitivity implies a much higher effort to reach the 95% of confidence stated in the legislation, as a large sample size is required. Table 10 summarises the results of the set of trials performed in Norway on samples spiked with different concentrations of eggs and worms (Inger Sofie Hamnes, 2022, personal communication).

TABLE 10 Summary of the number of tested spiked samples (n) and number of samples testing positive (s) for each concentration of egg/worm. The last column reports the outcome of an exact binomial test (R Core Team, 2022).

Spike	S	n	Test Se 50th perc (95% CI)
1 egg	30	54	0.56 (0.41–0.69)
5 eggs	34	42	0.81 (0.66–0.91)
10 eggs	77	87	0.89 (0.80–0.94)
50 eggs	2	2	1 (0.16–1)
1 worm	61	65	0.94 (0.85–0.98)
Overall	**204**	**250**	**0.82 (0.76–0.86)**

Taken individually and looking at the 50th percentile, there is a positive correlation between the concentration of the parasite in the sample and the sensitivity. The small number of samples used to test high concentrations (50 eggs) brings a huge uncertainty around the estimate associated with the results (95% CI: 0.16–1). This uncertainty also affects the estimation of the overall performance of the test. Pooling all the results together allows to estimate the performance of the test in a condition that may reflect the situation in the field, i.e. where the amount of the parasite or its eggs is unknown.

The bottom line in the table shows the result of this estimation. Based on the available data, the test appears to have a sensitivity equal to 0.82 in 50% of the cases; however, the lower bound of the confidence interval suggests that a more conservative value would be 0.76. This low value, as said, is data driven and affected by the sample size: Additional testing will contribute to narrow the uncertainty around the 50th percentile. On the other hand, the likelihood of analysing samples with 50 eggs appears to be quite low, based on expert opinion. More studies on this topic should be performed in order to assign a weight to each spiked sample based on the egg content. To check whether the number of eggs in a sample has an impact on the performance of the test (i.e. the test sensitivity), two models were fit to the data shown in Table 9. Both models have as dependent variable the test sensitivity, i.e. the ratio between the number of spiked samples that were correctly detected as positive and the total number of spiked samples. The first model, a log-logistic model, was fit to the data with the predictor containing the number of eggs in a sample. The second one, a logistic model, with no information about the number of eggs, was also fit to the data. By comparing the two models by means of a likelihood ratio test, the log-logistic model fits the data better compared to the logistic model with no predictors. This modelling exercise confirms that the number of eggs in the samples has an impact on the ability of the test to detect truly positive samples: the higher the number of eggs, the higher the test sensitivity. Further analysis should be performed to better estimate what value of the test sensitivity could better fit a field situation.

4.4.2 | Selection of the target population

Definition of susceptible host population target by the system

Red fox was considered the target species for Norway, and only few numbers of wolves were also included in the surveillance, but not reported. The reasons put forward by Norway to justify its decision of not including other wild definitive hosts (arctic foxes and raccoon dogs) are valid.

Size of susceptible host population targeted by the system

In the absence of data on fox populations in Norway, the size was estimated considering the annual hunted foxes.

4.4.3 | Sampling strategy

Epidemiological unit

The epidemiological unit appears in the report and is defined as the red fox. Individual rectal contents were collected directly by hunters.

Sample size calculation

The EFSA RiBESS tool was used to verify that the sample size was sufficient to claim a prevalence of not more than 1% at a confidence level of at least 95%. Considering design prevalence of 1%, a test sensitivity of 0.63 and a population size of 151,000, the sample size required is 474. The number of samples collected by Norway in 2023 (512 samples) is more than required.

Implementation of the sampling activity

Samples were collected from all the Norwegian NUTS3 regions with an increase of the sampling in the southeast of the country. The differences of sampling intensities among the different areas have also been justified in the report.

4.4.4 | Methodology

Design prevalence

The DP was equal to 1% (0.01), as it is specified in Annex I to Commission Delegated Regulation (EU) 2018/772.

Epidemiological geographical unit

The geographical unit is deduced to be the entire territory of Norway. The choice is sound as no risk factors were reported to justify the identification of subareas within the Norwegian territory.

Methodology for calculation of the area sensitivity

The area sensitivity was estimated for Norway using the RiBESS tool and considering the following parameters:

- design prevalence of 1%,
- test sensitivity of 0.63,
- population size of 151,000,
- sample size of 512.

The area sensitivity value is 0.961 which exceeds the established minimum value of 0.95 needed to fulfil the technical legal requirements of Commission Delegated Regulation (EU) 2018/772. In summary, the set of data relative to the surveillance activity in 2023 ensures the fulfilment of the technical legal requirements of all the paragraphs included in the Annex I of Commission Delegated Regulation (EU) 2018/772.

5 | CONCLUSIONS

- *E. multilocularis* was not detected in any of the samples from the four countries (Finland, Ireland, the United Kingdom (Northern Ireland) and Norway) collected in 2023.
- All the countries that participated in this surveillance (Finland, Ireland, the United Kingdom (Northern Ireland), and Norway) fulfil the technical legal requirements regarding the use of appropriate techniques for the detection of *E. multilocularis* in intestinal contents or faeces. All these countries use different methods for detection of the parasite as described in the report. Sensitivity (and specificity) values of the techniques have been reported for a proper assessment of the surveillance performance.
- All the countries that participated in this surveillance (Finland, Ireland, the United Kingdom (Northern Ireland) and Norway) fulfil the technical legal requirements regarding the collection of samples from wild definitive hosts. The four countries selected adequate wild definitive hosts in order to perform the surveillance.
- The sampling strategies performed by Finland, Ireland, the United Kingdom (Northern Ireland) and Norway cannot be considered 'based on a simple random sampling'. For contingent, technical reasons, the sampling strategy in wild live animals cannot be random sampling but rather convenience sampling. Obtaining representative samples from wildlife populations is often hampered by the lack of precise knowledge on the distribution of wild host populations (EFSA, 2015); however, the four countries provided scientifically sound estimations.
- All the countries that participated in this surveillance (Finland, Ireland, the United Kingdom (Northern Ireland) and Norway) fulfil the technical legal requirements regarding the 12-month surveillance period collection. In general, the lower number of wild animal samples during spring and summer was well justified and historical data show that this lower number does not compromise the success of the detection of the parasite.
- All the countries that participated in this surveillance (Finland, Ireland, the United Kingdom (Northern Ireland) and Norway) fulfil the technical legal requirements regarding the confidence level of at least 0.95 against a design prevalence of 1%.

6 | RECOMMENDATION

- Norway and Finland are recommended to publish the results of their internal trials performed in order to estimate the sensitivity of the diagnostic assays used. The scientific publication(s) may serve as a basis for an overall project that enable a sound scientific approach in order to validate and estimate the diagnostic sensitivity (and specificity) of the diagnostic assays used for **E. multilocularis** at EU level. This project could be set up in collaboration with EFSA and the EURLP.

GLOSSARY

Alveolar echinococcosis	The human disease caused by infection with the larval stage (metacestode) *of E. multilocularis*. It is characterised by infiltrative, tumour-like growth, initially in the liver, potentially causing high fatality rates.
EFSA Data Collection Framework (DCF)	The EFSA web interface accessible by most common web browsers through which data providers can submit their files. The system provides automatic feedback on errors in structure and content, and confirmation of successful submissions.
Enzyme-linked Immunosorbent Assay (ELISA)	The test that applies the immunological concept of an antigen binding to its specific antibody, which allows detection of very small quantities of antigens such as proteins, peptides, hormones, or antibody in a fluid sample, utilising enzyme-labelled antibodies or antigens and a chromogenic substrate for the enzyme to detect the target molecules.
Geographical epidemiological unit	The portion of territory within a given Member State characterised by a specific risk of presence which differs from other portions, if any. An example could be the portion of territory within a defined distance from the border. In this assessment, all countries have assumed the entire territory as a unique geographical epidemiological unit.
NUTS	The Nomenclature of Territorial Units for Statistics (NUTS), or in French Nomenclature Unités Territoriales Statistiques, is a geocode standard for referencing the administrative divisions of countries for statistical purposes. The standard was developed by the EU and subdivides the territory of the EU into regions at three different levels (NUTS 1, 2 and 3, moving from larger to smaller territorial units (see also https://epp.eurostat.ec.europa.eu/statistics_explained/index.php/Glossary:NUTS).
Odds Ratio (OR)	The ratio of the odds of an event occurring in one group to the odds of it occurring in another group. It estimates the probability of the event given exposure to a specific factor by measuring the probability of exposure given the presence of the event.
Risk-based Estimate of System sensitivity and Sample size (RiBESS) tool	The Microsoft Excel based tool developed by EFSA for the calculation of the sample size needed to substantiate absence of a given disease and/or to calculate the survey sensitivity (confidence) once the samples have been collected.
Sedimentation and Counting Technique (SCT)	The technique for the quantitative assessment of the *E. multilocularis* burden of foxes or other definitive hosts, where intestinal material is washed and sedimented several times and the resulting sediment is examined under a stereomicroscope for the presence of the parasite.

ABBREVIATIONS

ASe	Area sensitivity
CL	Confidence Level
DCF	EFSA Data Collection Framework
DH	Definitive host
DNA	Deoxyribonucleic acid
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
EM	*Echinococcus multilocularis*
EU	European Union
GB	Great Britain (including England, Wales and Scotland)
N	Target population size
NI	Northern Ireland
OR	Odds ratio
PCR	Polymerase Chain Reaction
RC	Reporting Countries
RR	Relative risk
SCT	Sedimentation and Counting Technique

Se   Sensitivity
Sp   Specificity

CONFLICT OF INTEREST
If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

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EFSA-Q-2023-00578

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REFERENCES

Atterby, H., Allnutt, T. R., MacNicoll, A. D., Jones, E. P., & Smith, G. C. (2015). Population genetic structure of the red fox (Vulpes vulpes) in the UK. *Mammal Research*, *60*, 9–19.

Balen Topić, M., Papić, N., Višković, K., Sviben, M., Filipec Kanižaj, T., Jadrijević, S., Jurković, D., & Beck, R. (2023). Emergence of *Echinococcus multilocularis* in central continental Croatia: A human case series and update on prevalence in foxes. *Lifestyles*, *13*(6), 1402. https://doi.org/10.3390/life13061402

Balog, T., Nagy, G., Halász, T., Csányi, E., Zomborszky, Z., & Csivincsik, Á. (2021). The occurrence of Echinococcus spp. in golden jackal (Canis aureus) in southwestern Hungary: Should we need to rethink its expansion? *Parasitology International*, *80*, 102214. https://doi.org/10.1016/j.parint.2020.102214

Casulli, A., Possenti, A., La Torre, G., Boue, F., Busani, L., Colamesta, V., Conraths, F. J., D'Aguanno, S., De Giusti, M., De Vito, C., Karamon, J., Maas, M., Mannocci, A., Maffongelli, E., Mipatrini, D., Oksanen, A., Probst, C., Saulle, R., Siles-Lucas, M., … Villari, P. (2015). *E. Multilocularis* infection in animals (GP/EFSA/AHAW/2012/01). *EFSA Supporting Publication*, *12*(12), EN-882. https://doi.org/10.2903/sp.efsa.2015.EN-882

CDC (Centers for disease control and prevention). (online). Parasites-Echinococcosis. https://www.cdc.gov/parasites/echinococcosis/biology.html

Conserve Ireland. (2009). Red Fox. https://www.lhnet.org/red-fox/

Davidson, R. K., Romig, T., Jenkins, E., Tryland, M., & Robertson, L. J. (2012). The impact of globalisation on the distribution of *Echinococcus multilocularis*. *Trends in Parasitology*, *28*, 239–247.

Deplazes, P. (2006). Ecology and epidemiology of *Echinococcus multilocularis* in Europe. *Parassitologia*, *48*, 37–39.

Dezsényi, B., Tóth, S., Horváth, A., Szlávik, J., Makrai, Z., Strausz, T., Nagy, T., Dubóczki, Z., Mersich, T., Csomor, J., Somorácz, A., Nehéz, L., Patonai, A., Doros, A., Danka, J., Kucsera, I., Auer, H., Rezza, G., Barth, T. F., & Casulli, A. (2019). Emerging human alveolar echinococcosis in Hungary. Early experiences in clinical management in a single center study from 2005–2018. *Journal of Infectious Diseases*, *79*, 118–119.

Dušek, D., Vince, A., Kurelac, I., Papić, N., Višković, K., Deplazes, P., & Beck, R. (2020). Human alveolar echinococcosis, Croatia. *Emerging Infectious Diseases*, *26*(2), 364–366. https://doi.org/10.3201/eid2602.181826

ECDC (European Centre for Disease Prevention and Control). (2016). Annual Epidemiological Report 2016 – Echinococcosis., Stockholm, Sweden. https://ecdc.europa.eu/en/publicationsdata/echinococcosis-annual-epidemiological-report-2016-2014-data

Eckert, J. (2003). Predictive values and quality control of techniques for the diagnosis of *Echinococcus multilocularis* in definitive hosts. *Acta Tropica*, *85*, 157–163.

Eckert, J., & Deplazes, P. (1999). Alveolar echinococcosis in humans: The current situation in Central Europe and the need for countermeasures. *Parasitology Today*, *15*, 315–319.

EFSA (European Food Safety Authority). (2012a). Scientific and technical assistance on *Echinococcus multilocularis* infection in animals. *EFSA Journal*, *10*(11), 2973. https://doi.org/10.2903/j.efsa.2012.2973

EFSA (European Food Safety Authority). (2012b). 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*. *EFSA Supporting Publications*, *9*(12), EN-366. https://doi.org/10.2903/sp.efsa.2012.EN-366

EFSA (European Food Safety Authority). (2013). Assessment of *Echinococcus multilocularis* surveillance reports submitted 2013 in the context of commission regulation (EU) No 1152/2011. *EFSA Journal*, *11*(11), 3465. https://doi.org/10.2903/j.efsa.2013.3465

EFSA (European Food Safety Authority). (2014). Assessment of *Echinococcus multilocularis* surveillance reports submitted in 2014 in the context of commission regulation (EU) No 1152/2011. *EFSA Journal*, *12*(10), 3875. https://doi.org/10.2903/j.efsa.2014.3875

EFSA (European Food Safety Authority). (2015). Assessment of *Echinococcus multilocularis* surveillance reports submitted in 2015 in the context of commission regulation (EU) No 1152/2011. *EFSA Journal*, *13*(11), 4310. https://doi.org/10.2903/j.efsa.2015.4310

EFSA (European Food Safety Authority) and ECDC (European Centre for Disease Prevention and Control). (2017). The European Union summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2016. *EFSA Journal*, *15*(12), 5077. https://doi.org/10.2903/j.efsa.2017.5077

EFSA (European Food Safety Authority), & Zancanaro, G. (2019). Scientific report on the annual assessment of *Echinococcus multilocularis* surveillance reports submitted in 2019 in the context of commission delegated regulation (EU) 2018/772. *EFSA Journal*, *17*(11), 5906. https://doi.org/10.2903/j.efsa.2019.5906

EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare). (2015). Scientific opinion on *Echinococcus multilocularis* infection in animals. *EFSA Journal*, *13*(12), 4373. https://doi.org/10.2903/j.efsa.2015.4373

EFSA and ECDC (European Food Safety Authority and European Centre for Disease Prevention and Control). (2023). The European Union one health 2022 Zoonoses report. *EFSA Journal*, *21*(12), e8442. https://doi.org/10.2903/j.efsa.2023.8442

Hayden, T., & Harrington, R. (2000). *Exploring Irish mammals* (p. 340). Town House & Country House Ltd. .

Hofer, S., Gloor, S., Muller, U., Mathis, A., Hegglin, D., & Deplazes, P. (2000). High prevalence of *Echinococcus multilocularis* in urban red foxes (Vulpes vulpes) and voles (Arvicola terrestris) in the city of Zurich, Switzerland. *Parasitology*, *120*(2), 135–142.

Isaksson, M., Hagström, Å., Armua-Fernandez, M. T., Wahlström, H., Ågren, E. O., Miller, A., Holmberg, A., Lukacs, M., Casulli, A., Deplazes, P., & Juremalm, M. (2014). A semi-automated magnetic capture probe based DNA extraction and real-time PCR method applied in the Swedish surveillance of *Echinococcus multilocularis* in red fox (Vulpes vulpes) faecal samples. *Parasites & Vectors*, *7*, 583.

Kapel, C. M. O., Torgerson, P. R., Thompson, R. C. A., & Deplazes, P. (2006). Reproductive potential of *Echinococcus multilocularis* in experimentally infected foxes, dogs, raccoon dogs and cats. *International Journal for Parasitology*, *36*, 79–86.

Kauhala, K. (2007). Paljonko Suomessa on pienpetoja? Riista-ja kalatalous Selvityksiä 1. Riista-ja kalatalouden tutkimuslaitos, Helsinki 2007. https://jukuri.luke.fi/bitstream/handle/10024/532812/paljonko_suomessa_on_pienpetoja_julkaisu_nettiin.pdf?sequence=1\h

Lalošević, D., Lalošević, V., Simin, V., Miljević, M., Čabrilo, B., & Čabrilo, O. B. (2016). Spreading of multilocular echinococcosis in southern Europe: The first record in foxes and jackals in Serbia, Vojvodina Province. *European Journal of Wildlife Research*, *62*, 793–796.

Lalošević, D., Živojinov, M., Isaković, V., Ivanov, D., Trivunović, V., & Ružić, M. (2023). The first human case of multilocular echinococcosis recognized in Serbia. *Srpski Arhiv Zza Celokupno Lekarstvo*, *151*, 453–456.

Marnell, F., Kingston, N., & Looney, D. (2009). Irish red list No. 3 - terrestrial mammals. National parks & wildlife service, Dublin, Ireland. https://www.npws.ie/content/publications/irishred-list-no-3-terrestrial-mammals

Mihmanli, M., Idiz, U. O., Kaya, C., Demir, U., Bostanci, O., Omeroglu, S., & Bozkurt, E. (2016). Current status of diagnosis and treatment of hepatic echinococcosis. *World Journal of Hepatology*, *8*, 1169–1181.

Moro, P., & Schantz, P. M. (2009). Echinococcosis: A review. *International Journal of Infectious Diseases*, *13*, 125–133.

National Veterinary Institute (SVA). (2022). Surveillance of infectious diseases in animals and humans in Sweden. *SVA:s Rapportserie*, *89*, 1654–7098.

Øines, Ø., Isaksson, M., Hagström, Å., Tavornpanich, S., & Davidson, R. K. (2014). Laboratory assessment of sensitive molecular tools for detection of low levels of *Echinococcus multilocularis*-eggs in fox (Vulpes vulpes) faeces. *Parasites & Vectors*, *7*, 246.

Oksanen, A., Siles-Lucas, M., Karamon, J., Possenti, A., Conraths, F. J., Romig, T., Wysocki, P., Mannocci, A., Mipatrini, D., La Torre, G., Boufana, B., & Casulli, A. (2016). The geographical distribution and prevalence of *Echinococcus multilocularis* in animals in the European Union and adjacent countries: A systematic review and meta-analysis. *Parasites & Vectors*, *9*, 519.

Peregrine, A. S., Jenkins, E. J., Barnes, B., Johnson, S., Polley, L., Barker, I. K., De Wolf, B., & Gottstein, B. (2012). Alveolar hydatid disease (*Echinococcus multilocularis*) in the liver of a Canadian dog in British Columbia, a newly endemic region. *The Canadian Veterinary Journal*, *53*, 870–874.

Phillips, S. J., Anderson, R. P., & Schapire, R. E. (2006). Maximum entropy modeling of species geographic distributions. *Ecological Modelling*, *190*, 231–259.

R Core Team. (2022). *R: A language and environment for statistical computing*. R Foundation for Statistical Computing. https://www.R-project.org/

Tamarozzi, F., Deplazes, P., & Casulli, A. (2020). Reinventing the Wheel of Echinococcus granulosus sensu lato Transmission to Humans. *Trends in Parasitology*, *36*(5), 427–434. https://doi.org/10.1016/j.pt.2020.02.004

Tamarozzi, F., Ronzoni, N., Degani, M., Oliboni, E., Tappe, D., Gruener, B., & Gobbi, F. (2024). Confirmed autochthonous case of human alveolar echinococcosis, Italy, 2023. *Emerging Infectious Diseases*, *30*(2), 350–353. https://doi.org/10.3201/eid3002.231527

Torgerson, P. R., Keller, K., Magnotta, M., & Ragland, N. (2010). The global burden of alveolar echinococcosis. *PLoS Neglected Tropical Diseases*, *4*, e722.

Trachsel, D., Deplazes, P., & Mathis, A. (2007). Identification of taeniid eggs in the faeces from carnivores based on multiplex PCR using targets in mitochondrial DNA. *Parasitology*, *134*, 911–920.

Ulvund, K., Flagstad, Ø., Rød-Eriksen, L. & Arntsen, L. G., Birkeland, L. E., Jackson, C. , Kleven, O., Sandercock, B. K. , & Eide, N. E. (2023). Fjellrev i Norge 2023 Resultater fra det nasjonale overvåkingsprogrammet for fjellrev. NINA Rapport 2344. *Norsk institutt for naturforskning*, https://www.who.int/mediacentre/factsheets/fs377/en/

WHO (World Health Organization). (2017). *Echinococcosis- fact sheet 2017*. WHO. https://www.who.int/mediacentre/factsheets/fs377/en/

Wilson, J. F., Rausch, R. L., McMahon, B. J., & Schantz, P. M. (1992). Parasiticidal effect of chemotherapy in alveolar hydatid disease: Review of experience with mebendazole and albendazole in Alaskan Eskimos. *Clinical Infectious Diseases*, *15*, 234–249. https://doi.org/10.1093/clinids/15.2

APPENDIX A

Finland. Assessment tables of the surveillance report

A.1 | FINLAND – PART I OF SURVEILLANCE REPORT: CHECKLIST ON THE SURVEILLANCE SYSTEM FOR A REPRESENTATIVE SAMPLE SURVEY AND COMMENTS

Points addressed in Annex I	Element	Description of element	Information provided in surveillance report	Requirement fulfilled	Comments
Type and sensitivity of the detection method	Type of test	The diagnostic test used for the detection of EM must be defined. Modifications of the original method should be indicated	Yes	Yes	Technique well described. A slight modification has been realised and is indicated in the report
	Test sensitivity	The sensitivity and specificity of the test used in the surveillance system must be reported. This would ideally be estimates from each participating laboratory reported as a point estimate (average) of the values across the country with minimum and maximum values or a probability distribution. Alternatively, a value of 0.78, as recommended by EFSA (2015), shall be used	Yes	Yes	An exact binomial test indicates that the actual value may lie between 0.86 and 0.92 (95% CL). A Bayesian approach gives similar results. Therefore, the lowest value (0.86) may be the most conservative choice for estimating the overall system sensitivity considering a worst-case scenario
Selection of the target population	Definition of susceptible host population targeted by the system	The susceptible wild definitive host population(s) targeted by the surveillance system should be described and the choice justified. If domestic host species are sampled, evidence for the absence of wild definitive hosts and for these domestic animals having had access to outdoors should be provided	Yes	Yes	No information on age or gender structure of the target population is available
	Size of susceptible host population targeted by the system	The size of the targeted (wildlife) population should be reported, together with the evidence for this. Historical population data should be updated since these may not reflect current populations	Yes	Yes	Although population data have not been updated since 2007, new information regarding annual hunting bags has been included in the report. The decision to use the size of the population as published by Kauhala in the estimations is scientifically sound, considering that the sample size calculation is not heavily affected when the population size has large dimensions (see EFSA AHAW Panel, 2015). The fact of considering the sum of the red fox and raccoon dog populations as the target population size seems to be correct, as raccoon dogs can act as DHs in conjunction with the red fox (EFSA AHAW Panel, 2015)

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Points addressed in Annex I	Element	Description of element	Information provided in surveillance report	Requirement fulfilled	Comments
Sampling strategy	Epidemiological unit	It should be clearly defined if individual animals or individual faeces samples collected from the environment constitute the epidemiological unit. If individual faeces samples are collected from the environment, the method applied to establish the species from which the faeces originated has to be reported	Yes	Yes	NA
	Sample size calculation	The applied survey design should be fully documented, including considerations regarding potential biases inherent in the survey design. The method and the formula used to calculate the sample size should be fully documented	Yes	Yes	NA
	Implementation of the sampling activity	The sampling methods used should be fully documented including the related assumptions and uncertainties, and a justification for choosing the approach should be provided. Timeframe of the surveillance data and geographical clustering of the infection must be reported. The sample collection period must comprise the whole year and the spatial distribution of the sampling must be homogeneous	Yes	Yes	NA
Methodology	Design Prevalence (DP)	DP is specified in Annex I to Commission Delegated Regulation (EU) 2018/772 and must be 1% or lower	Yes	Yes	NA
	Geographical epidemiologic unit	The geographic epidemiological unit(s) identified as target for the surveillance activity has to be clearly indicated and supported by justification	Yes	Yes	NA
	Methodology for calculation of area sensitivity	For the calculation of the area sensitivity, the diagnostic sensitivity should be set conservatively to the lowest value, excluding the lowest 20th percentile, from the ones reported in the scientific literature and related to the diagnostic tests implemented by the countries listed in Annex I of the Commission Delegated Regulation (EU) 2018/772. In this case, is 78% EFSA AHAW Panel, 2015)	Yes	Yes	NA

A.2 | FINLAND – PART II OF SURVEILLANCE REPORT: DESCRIPTIVE STATISTICS FOR A REPRESENTATIVE SURVEY

Parameter	Evidence	Requirement fulfilled	Action
Theoretical Sampling period	From 1 January 2023 to 31 December 2023	NA	NA
Actual Sampling Period	1 January 2023 to 20 December 2023	Yes	NA
Number of samples	547	Yes	The sample size achieves an area sensitivity of 0.986 (> 0.95)
Number of test results	547	Yes	NA
Laboratory test completion	100%	Yes	NA
Sensitivity	0.78	Yes	NA
Host	Raccoon dog and red fox	Yes	NA
Animal sample	Yes	Yes	NA
Sampling strategy and design objective sampling	Objective sampling and simple random sample	Yes	The sampling strategy is a convenience sampling, biologically driven. The latter, in wildlife, is considered adequate
Sampling point	Wild (Hunting)	Yes	NA

APPENDIX B

Ireland. Assessment tables of the surveillance report

B.1 | IRELAND – PART I OF SURVEILLANCE REPORT: CHECKLIST OF THE DESCRIPTION OF THE SURVEILLANCE SYSTEM FOR A REPRESENTATIVE SAMPLE SURVEY

Points addressed in annex I	Element	Description of element	Information provided in surveillance report	Requirement fulfilled	Comments
Type and sensitivity of the detection method	Type of test	The diagnostic test used for the detection of EM must be defined. Modifications of the original method should be indicated	Yes	Yes	The diagnostic test chosen by Ireland is well described (PCR Cest1-Cest2 NAD1) and a reference for this peer-reviewed published method is provided
	Test sensitivity	The sensitivity and specificity of the test used in the surveillance system must be reported. This would ideally be estimates from each participating laboratory reported as a point estimate (average) of the values across the country with minimum and maximum values or a probability distribution. Alternatively, a value of 0.78, as recommended by EFSA (2015), shall be used	Yes	Yes	NA
Selection of the target population	Definition of susceptible host population targeted by the system	The susceptible wild definitive host population(s) targeted by the surveillance system should be described and the choice justified. If domestic host species are sampled, evidence for the absence of wild definitive hosts and for these domestic animals having had access to outdoors should be provided	Yes	Yes	The absence of other important definitive wild hosts is also supported by scientific literature
	Size of susceptible host population targeted by the system	The size of the targeted (wildlife) population should be reported, together with the evidence for this. Historical population data should be updated since these may not reflect current populations	Yes	Yes	The last update on the population size is from 2015. However, with a population size greater than 10,000, moderate fluctuations in the population size would not significantly change the sample size required
Sampling strategy	Epidemiological unit	It should be clearly defined if individual animals or individual faeces samples collected from the environment constitute the epidemiological unit. If individual faeces samples are collected from the environment, the method applied to establish the species from which the faeces originated has to be reported	Yes	Yes	NA
	Sample size calculation	The applied survey design should be fully documented, including considerations regarding potential biases inherent in the survey design. The method and the formula used to calculate the sample size should be fully documented	Yes	Yes	NA

(Continued)

Points addressed in annex I	Element	Description of element	Information provided in surveillance report	Requirement fulfilled	Comments
	Implementation of the sampling activity	The sampling methods used should be fully documented including the related assumptions and uncertainties, and a justification for choosing the approach should be provided. Timeframe of the surveillance data and geographical clustering of the infection must be reported. The sample collection period must comprise the whole year and the spatial distribution of the sampling must be homogeneous	Yes	Yes	NA
Methodology	Design prevalence (DP)	DP is specified in Annex I to Commission Delegated Regulation (EU) 2018/772 and must be 1% or lower	Yes	Yes	NA
	Geographical epidemiologic unit	The geographic epidemiological unit(s) identified as target for the surveillance activity has to be clearly indicated and supported by justification	Yes	Yes	NA
	Methodology for calculation of area sensitivity	For the calculation of the area sensitivity, the diagnostic sensitivity should be set conservatively to the lowest value, excluding the lowest 20th percentile, from the ones reported in the scientific literature and related to the diagnostic tests implemented by the countries listed in Annex I of the Commission Delegated Regulation (EU) 2018/772. In this case, is 78% (EFSA AHAW Panel, 2015)	Yes	Yes	NA

B.2 | IRELAND – PART II OF SURVEILLANCE REPORT: DESCRIPTIVE STATISTICS FOR A REPRESENTATIVE SURVEY

Parameter	Evidence	Requirement fulfilled	Action
Theoretical sampling period	From 1 January 2023 to 31 December 2023	NA	NA
Actual sampling period	1 January 2023 to 19 December 2023	NA	NA
Number of samples	384	Yes	The sample size achieves an area sensitivity of 0.951 (>0.95)
Number of test results	384	Yes	NA
Laboratory test completion	100%	Yes	NA
Sensitivity	0.78	Yes	NA
Host	Red fox	Yes	NA
Animal sample	Yes	Yes	NA
Sampling strategy and design objective sampling	Objective sampling and simple random sample	Yes	The sampling strategy is a convenience sampling, biologically driven. The latter, in wildlife, is considered adequate
Sampling point	Wild (Hunting and wildlife research station)	Yes	NA

APPENDIX C

United Kingdom (Northern Ireland). Assessment tables of the surveillance report

C.1 | NORTHERN IRELAND – PART I OF SURVEILLANCE REPORT: CHECKLIST OF THE DESCRIPTION OF THE SURVEILLANCE SYSTEM FOR A REPRESENTATIVE SAMPLE SURVEY

Points addressed in Annex II	Element	Description of element	Information provided in surveillance report	Requirement fulfilled	Comments
Type and sensitivity of the detection method	Type of test	The diagnostic test used for the detection of EM must be defined. Modifications of the original method should be indicated	Yes	Yes	The method used for detection of *E. multilocularis* in NI is cited
	Test sensitivity	The sensitivity and specificity of the test used in the surveillance system must be reported. This would ideally be estimates from each participating laboratory reported as a point estimate (average) of the values across the country with minimum and maximum values or a probability distribution. Alternatively, a value of 0.78, as recommended by EFSA (2015), shall be used	Yes	Yes	NA
Selection of the target population	Definition of susceptible host population targeted by the system	The susceptible wild definitive host population(s) targeted by the surveillance system should be described and the choice justified. If domestic host species are sampled, evidence for the absence of wild definitive hosts and for these domestic animals having had access to outdoors should be provided	Yes	Yes	NA
	Size of susceptible host population targeted by the system	The size of the targeted (wildlife) population should be reported, together with the evidence for this. Historical population data should be updated since these may not reflect current populations	Yes	Yes	NA
Sampling strategy	Epidemiological unit	It should be clearly defined if individual animals or individual faeces samples collected from the environment constitute the epidemiological unit. If individual faeces samples are collected from the environment, the method applied to establish the species from which the faeces originated has to be reported	Yes	Yes	NA
	Sample size calculation	The applied survey design should be fully documented, including considerations regarding potential biases inherent in the survey design. The method and the formula used to calculate the sample size should be fully documented	Yes	Yes	NA
	Implementation of the sampling activity	The sampling methods used should be fully documented including the related assumptions and uncertainties, and a justification for choosing the approach should be provided. Timeframe of the surveillance data and geographical clustering of the infection must be reported. The sample collection period must comprise the whole year and the spatial distribution of the sampling must be homogeneous	Yes	Yes	NA

(Continued)

Points addressed in Annex II	Element	Description of element	Information provided in surveillance report	Requirement fulfilled	Comments
Methodology	Design prevalence (DP)	DP is specified in Annex I to Commission Delegated Regulation (EU) 2018/772 and must be 1% or lower	Yes	Yes	NA
	Geographical epidemiologic unit	The geographic epidemiological unit(s) identified as target for the surveillance activity has to be clearly indicated and supported by justification	Yes	Yes	NA
	Methodology for calculation of area sensitivity	For the calculation of the area sensitivity, the diagnostic sensitivity should be set conservatively to the lowest value, excluding the lowest 20th percentile, from the ones reported in the scientific literature and related to the diagnostic tests implemented by the countries listed in Annex I of the Commission Delegated Regulation (EU) 2018/772. In this case, is 78% (EFSA AHAW Panel, 2015)	Yes	Yes	NA

C.2 | NORTHERN IRELAND – PART II OF SURVEILLANCE REPORT: DESCRIPTIVE STATISTICS FOR A REPRESENTATIVE SURVEY

Parameter	Evidence	Requirement fulfilled	Action
Theoretical Sampling period	From 1 January 2023 to 31 December 2023	NA	NA
Actual Sampling Period	3 January 2023 to 15 December 2023	NA	NA
Number of samples	379	Yes	The sample size achieves an area sensitivity of 0.950 (≥ 0.95)
Number of test results	379	Yes	NA
Laboratory test completion	100%	Yes	NA
Sensitivity	0.78	Yes	NA
Host	Red fox	Yes	NA
Animal sample	Yes	Yes	NA
Sampling strategy and design objective sampling	Objective sampling	Yes	The sampling strategy is a convenience sampling, biologically driven. The latter, in wildlife, is considered adequate
Sampling point	Wild (hunting and road transport)	Yes	NA

APPENDIX D

Norway. Assessment tables of the surveillance report

D.1 | NORWAY – PART I OF SURVEILLANCE REPORT: CHECKLIST OF THE DESCRIPTION OF THE SURVEILLANCE SYSTEM FOR A REPRESENTATIVE SAMPLE SURVEY

Points addressed in Annex II	Element	Description of element	Information provided in surveillance report	Requirement fulfilled	Comments
Type and sensitivity of the detection method	Type of test	The diagnostic test used for the detection of EM must be defined. Modifications of the original method should be indicated	Yes	Yes	Technique well described. A slight modification has been realised and is indicated in the report
	Test sensitivity	The sensitivity and specificity of the test used in the surveillance system must be reported. This would ideally be estimates from each participating laboratory reported as a point estimate (average) of the values across the country with minimum and maximum values or a probability distribution. Alternatively, a value of 0.78, as recommended by EFSA (2015), shall be used	Yes	Yes	Despite internal trials seem to indicate a better performance of the test (Se = 0.82), for precautionary reasons the diagnostic sensitivity was set to the sensitivity obtained by Øines et al. (2014) (0.63), a lower value than the minimum recommended by EFSA (0.78). Such a low test sensitivity implies a much higher effort to reach the 95% of confidence stated in the legislation, as a larger sample size is required
Selection of the target population	Definition of susceptible host population targeted by the system	The susceptible wild definitive host population(s) targeted by the surveillance system should be described and the choice justified. If domestic host species are sampled, evidence for the absence of wild definitive hosts and for these domestic animals having had access to outdoors should be provided	Yes	Yes	NA
	Size of susceptible host population targeted by the system	The size of the targeted (wildlife) population should be reported, together with the evidence for this. Historical population data should be updated since these may not reflect current populations	Yes	Yes	NA
Sampling strategy	Epidemiological unit	It should be clearly defined if individual animals or individual faeces samples collected from the environment constitute the epidemiological unit. If individual faeces samples are collected from the environment, the method applied to establish the species from which the faeces originated has to be reported	Yes	Yes	NA
	Sample size calculation	The applied survey design should be fully documented, including considerations regarding potential biases inherent in the survey design. The method and the formula used to calculate the sample size should be fully documented	Yes	Yes	NA

(Continued)

Points addressed in Annex II	Element	Description of element	Information provided in surveillance report	Requirement fulfilled	Comments
	Implementation of the sampling activity	The sampling methods used should be fully documented including the related assumptions and uncertainties, and a justification for choosing the approach should be provided. Timeframe of the surveillance data and geographical clustering of the infection must be reported. The sample collection period must comprise the whole year and the spatial distribution of the sampling must be homogeneous	Yes	Yes	NA
Methodology	Design Prevalence (DP)	DP is specified in Annex I to Commission Delegated Regulation (EU) 2018/772 and must be 1% or lower		Yes	Yes
	Geographical epidemiologic unit	The geographic epidemiological unit(s) identified as target for the surveillance activity has to be clearly indicated and supported by justification	Yes	Yes	NA
	Methodology for calculation of area sensitivity	For the calculation of the area sensitivity, the diagnostic sensitivity should be set conservatively to the lowest value, excluding the lowest 20th percentile, from the ones reported in the scientific literature and related to the diagnostic tests implemented by the countries listed in Annex I of the Commission Delegated Regulation (EU) 2018/772. In this case, is 78% (EFSA AHAW Panel, 2015)	Yes	Yes	NA

D.2 | NORWAY – PART II OF SURVEILLANCE REPORT: DESCRIPTIVE STATISTICS FOR A REPRESENTATIVE SURVEY

Parameter	Evidence	Requirement fulfilled	Action
Theoretical Sampling period	From 1 January 2023 to 31 December 2023	NA	NA
Actual Sampling Period	1 January 2023 to 17 December 2023	NA	NA
Number of samples	512	Yes	The sample size achieves an area sensitivity of 0.961 (>0.95)
Number of test results	512	Yes	NA
Laboratory test completion	100%	Yes	NA
Sensitivity	0.63	Yes	NA
Host	Red fox	Yes	NA
Animal sample	Yes	Yes	NA
Sampling strategy and design objective sampling	Objective sampling and simple random sample	Yes	The sampling strategy is a convenience sampling, biologically driven. The latter, in wildlife, is considered adequate
Sampling point	Wild (Hunting)	Yes	NA