

An assessment of the risk that EM is introduced with dogs entering Sweden from other EU countries without and with antihelmintic treatments.

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Svensk sammanfattning:

Sverige har som införselkrav att alla hundar och katter som kommer till Sverige från utlandet skall avmaskas av veterinär mot dvärgbandmask (*Echinoccocus multilocularis* härnå efter förkortat till EM).

I förordningen 998/2003/EU om förflyttning av sällskapsdjur ges Sverige, tillsammans med Förenade Kungariket, Irland och Malta rätt att under 5 år behålla sina nationella regler gällande rabies, dvärgbandmask och fästingar. Under denna perioden skall gemensamma regler utarbetas på basis av nationella rapporter från de nämnda länderna inklusive en värdering av riskerna för rabies, fästingar och EM, och på basis av ett utlåtande från EFSA. (Europeiska livsmedelssäkerhetsmyndigheten).

Jordbruksverket har anmodat SVA att värdera risken för introduktion och etablering av EM i Sverige om de nationella avmaskningskraven slopas vid införsel av i första hand hundar. Det bör också göras en värdering av effekten av avmaskning.

Fråga 1 (Terms of reference 1): Att värdera risken för att icke avmaskade hundar som kommer till Sverige introducerar EM.

Det förefaller vara en **hög sannolikhet att minst en EM infekterad hund** kommer in till Sverige årligen, om inte alla hundar som kommer från områden med EM avmaskas.

Förväntat antal hundar med EM som kommer till Sverige om kravet om avmaskning försvinner förefaller vara runt 30 per år.

Fråga 2: Att bedöma risken att EM etableras i Sverige samt eventuella konsekvenser därav.

Det förefaller vara **medelhögs till hög sannolikhet att EM etableras i Sverige** om den introduceras.

Konsekvenserna förefaller vara **betydande** på grund av parasitens zoonotiska potential; möjligheten att njuta av den svenska naturen och dess produkter minskar till skada för privatpersoner och industrin.

Fråga 3 Bedöma hur avmaskning före införsel påverkar risken att EM introduceras i Sverige.

För att reducera den årliga risken att en EM infekterad hund kommer till Sverige till låg (0.05-0.3) måste över 99% av hundarna som kommer från områden med EM avmaskas före införsel.

Executive summary:

Sweden requires that a veterinarian treats and certifies the treatment of all dogs entering Sweden with an antihelmintic against *Echinococcus multilocularis* (hereafter referred to as EM) before entry. Dogs from Finland, Norway, Ireland Malta and United Kingdom are exempted.

In the Regulation 998/2003/EC on pet movement, Sweden together with Finland, Ireland, Malta, Norway and United Kingdom was granted a derogation for a 5-year period to retain national rules for movements of pets with regard to rabies, ticks and EM. After the 5-year period, it is foreseen that a revised Community policy will be devised having regard to national reports and risk assessments from the mentioned countries. The national reports and risk assessments will inform the evaluation by the European Food Safety Agency (EFSA).

The Swedish Board of Agriculture (Jordbruksverket) has requested the National Veterinary Institute (SVA) to perform an assessment of the risk that EM is introduced with dogs entering Sweden from other EU countries without and with antihelmintic treatments.

Terms of reference 1: To assess the probability that EM is introduced into Sweden through the movements of dogs that have not been given antihelmintic treatment prior to entry.

It appears to be a **high probability** that at least one EM infected dog is introduced into Sweden, unless the current antihelminthic treatment requirement is retained with a very high compliance.

Without the antihelmintic treatment requirement, the expected number of EM infected dogs entering Sweden would be around 29 per year.

Terms of reference 2: To assess the risk that EM is permanently established in Sweden once introduced, and the consequences thereof.

The probability is **moderate to high** that EM would establish itself in Swedish wildlife if introduced into Sweden.

The consequences of EM introduction into Sweden are **serious**, due to the zoonotic potential of the parasite, that will lessen the possibilities of enjoying the Swedish nature and its resources.

Terms of reference 3: To assess the risk mitigation effect from the antihelmintic treatment of dogs prior to entering Sweden

To achieve a **low** (0.05-0.3) probability that at least one EM infected dog is introduced into Sweden per year, the required efficacy and compliance of the antihelminthic treatment is above 99%.

Background

In the Regulation 998/2003/EC on pet movement, Sweden together with Finland, Ireland, Malta, Norway and United Kingdom was granted a derogation for a 5-year period to retain national rules for movements of pets with regard to rabies, ticks and EM. After the 5-year period, it is foreseen that a revised Community policy will be devised having regard to national reports and risk assessments from the mentioned countries. The national reports and risk assessments will inform the evaluation by the European Food Safety Agency (EFSA).

Sweden requires that a veterinarian treats and certifies the treatment of all dogs entering Sweden with an antihelmintic against *Echinococcus multilocularis* (hereafter referred to as EM) before entry. Dogs from Finland, Norway, Ireland Malta and United Kingdom are exempted.

EM has never been reported in Sweden. As a response to the finding of EM in Denmark in both foxes and intermediate hosts, an active monitoring program of the definite host the red fox (*Vulpes vulpes*) was implemented in Sweden. During the years 2001-2005 approximately 1800 hunted red foxes from all over Sweden were examined for EM at the National veterinary institute (SVA) without any findings. (Swedish zoonoses report, 2005). It is foreseen that 200-400 red foxes will be examined annually for EM henceforward.

The national veterinary and food institute (EELA) in Finland produced a qualitative risk assessment for EM in 2001. Possible pathways for introduction of EM to Finland included infected dogs or cats, infected wildlife (foxes, wolves and racoon dogs) from Russia or contaminated foodstuffs (low growing berries, vegetables and mushrooms). It was concluded that there is an actual risk of introducing EM through movements of dogs and cats into Finland. It was recommended as a risk reduction measure that dogs, arriving from areas where EM is endemic, should be treated with an antihelminthic.

It is questionable whether EM can reproduce and produce viable eggs in cats (Thomson et al., 2006, Kapel et al., 2006). Moreover, the knowledge of movements of cats is limited. Hence, this risk assessment should focus on dogs.

Terms of reference

In Regulation 998/203/EC, the countries with transitional rules regarding EM protection were requested to send a report on the national EM status to the Commission before the end of the transition period. Therefore, the Swedish Board of Agriculture (Jordbruksverket) requested the National Veterinary Institute (SVA) to assess the risk that EM is introduced into Sweden with dogs entering Sweden from other EU countries without and with antihelmintic treatments prior to entry.

The assessment should be quantitative to the extent possible.

Hence, the terms of reference (TOR) are:

1. To assess the probability that EM is introduced into Sweden through the movements of dogs that have not been given antihelmintic treatment prior to entry.
2. To assess the risk that EM is permanently established in Sweden once introduced, and the consequences thereof.
3. To assess the risk mitigation effect from the antihelmintic treatment of dogs prior to entering Sweden.

The Office International des Epizooties (OIE) outline for risk assessment should be used.

Clarification of the link between qualitative and quantitative risks

As this will not be a fully quantitative risk assessment it is important to link and interpret the quantitative and qualitative elements of the assessment consistently. Appendix I outlines the interpretation of the qualitative risk terms quantitatively and also the reverse.

Hazard identification

The parasite

Echinococcus multilocularis (EM) is a tapeworm parasite that resides in the small intestine of medium sized carnivores (e.g., foxes) that eat small rodents. The tapeworm produces eggs that are infectious to intermediate hosts such as rodents. It forms cysts in the intermediate hosts. The zoonotic potential of EM is due to the ability to form cysts in humans as accidental intermediate hosts.

The parasite life cycle and reservoirs

The adult *Echinococcus multilocularis* (1 to 4 mm long) resides in the small bowel of the definitive hosts; foxes, raccoon dogs, wolves, dogs or cats. Gravid proglottids release eggs that are passed in the feces. After ingestion by a suitable intermediate host (a small rodent such as a vole, a rat or mouse), the eggs hatch in the small bowel and releases oncospheres that penetrate the intestinal wall and migrate through the circulatory system into various organs, especially the liver and lungs. The larval growth (in the liver) remains indefinitely in the proliferative stage, resulting in invasion of the surrounding tissues. After ingestion by the definitive host, the protoscolices evaginate, attach to the intestinal mucosa, and develop into adult stages in 32 to 80 days (CDC, 2006).

However, whether cats represent a risk is questioned in recent papers such as Kapel et al., (2006) and Thomsson et al., (2006) whom both questioned whether cats are able to produce worm eggs and if the excreted eggs are infective.

Zoonotic potential

Humans may become accidental intermediate hosts if ingesting eggs, either through contaminated foods or water, or upon contact with infected animals or the feces from these animals. The incubation period from exposure to clinical disease or diagnosis is estimated to be 5-15 years (Eckert and Deplazes, 2004). The disease is fatal in untreated patients with a 10-year survival rate of 29%; while with albendazole/mebendazole treatment the 10-year survival rate is 80%. The treatment is expensive and the annual cost per person is around 10000 € (Eckert and Deplazes, 2004). Since liver failure is a sequel of the disease, liver transplantation might be required.

It could be noted that dogs could be both intermediate and definitive hosts, as cysts as well as adult EM have occasionally been found in the same dog (Eckert and Deplazes, 2004).

The worm burden of the host

There is a huge variation in the worm burden a fox can carry; from a few to more than 100 000 worms per fox (Kapel et al., 2006). In a Swiss investigation of 133 foxes, the average worm burden was 3000, ranging between 1 and 57000 (Hofer et al., 2000). Around 67% of the foxes had worm burden less than 1000, while 8% had more than 10000 worms. Hofer et al., (2000) also found that juvenile foxes have a higher worm burden than older foxes. It appears that worm burden will have a similar variation in dogs.

Effect of antihelminthic treatment

EM in dogs can be treated with isoquinolone derivatives (Deplazes and Eckert, 2001) such as praziquantel or epsiprantel. Praziquantel eliminates virtually 100% of the worm burden, while epsiprantel eliminated 99.6% of the worm burden. To be on the safe side and to reduce the risk of a residual worm burden further Deplazes and Eckert (2001) recommend treatment for two consecutive days in agreement with the WHO/OIE (2001) recommendations.

Parasite resistance to heat, freezing and desiccation

Eggs are susceptible to desiccation and high temperatures, but may survive for up to one year in a moist environment (Eckert and Deplazes, 2003). Hansen et al., (2003) found when investigating the spatial heterogeneity of EM found that high-risk areas are characterized by environments with low temperatures and humid conditions.

Veit et al. (1995) investigated the sensitivity of eggs of *Echinococcus multilocularis* to environmental factors. The maximum survival time of eggs was 240 days in an experiment performed in autumn and winter, compared to 78 days in summer. Veit et al., (1995) found a high sensitivity to elevated temperatures and to desiccation:

- The infectivity was lost after 3 hours at 45 degrees C and 85-95% relative humidity, as well as after 4 h exposure to 43 degrees C suspended in water.
- Exposure to 27% relative humidity at 25 degrees C, as well as exposure to 15% relative humidity at 43 degrees C resulted in a total loss of infectivity within 48 and 2 h, respectively.

- The eggs are killed within 5 minutes at 60-80 C and instantly in 100 C (boiling water).
- Temperatures of 4 degrees C and of -18 degrees C were well tolerated (478 days and 240 days survival, respectively), while
- exposure to -83 degrees C and to -196 degrees C quickly killed off the eggs (within 48 h and 20 h, respectively).

Hence, it appears that eggs can survive for prolonged periods in environmental conditions similar to those typical for Sweden., a long cold and humid winter season.

Geographic distribution

EM is found all over the northern hemisphere with the same genotype (Eckert and Deplatzes, 2004).

In North America the parasite is present in sub arctic regions of Alaska and Canada and in a few northern states of the US. In Europe it is present in the central and eastern countries and in Asia in the former USSR, Turkey, Iraq, northern India, Japan and central China. In some regions of central Europe approximately 40-75% of the red fox populations are infected with *E. multilocularis*. On St. Lawrence Island, Alaska, most of the arctic foxes are infected (WHO, 2006).

Within the European Economic Area (EEA) consisting of the EU and EFTA countries), the alpine regions of Germany, France, Italy, Switzerland, Austria and Lichtenstein are considered as EM endemic areas (Eckert and Deplatzes, 2004). EM has also been found in Poland, Belgium, Czech republic, Slovak republic, Denmark, Luxemburg, Hungary, and Netherlands (Vuitton, et al., 2003; Eckert and Deplatzes, 2004; EELA, 2001).

Non-EU countries with findings of EM include the arctic and sub-arctic regions of Russia as well as Turkey, Bosnia, Croatia, Azerbadjan and Central Asia (China, Mongolia, Kazakhstan, Kyrgyzstan) (Vuitton, et al., 2003; Eckert and Deplatzes, 2004).

EM has also been found in the Norwegian archipelago of Svalbard.

Finland, Ireland, United Kingdom, Malta, Sweden and mainland Norway consider themselves free from EM.

Local variations in distribution

EM appears in at high prevalence among intermediate and definitive hosts, i.e. rodents and foxes only in certain high-risk regions within a country. Even within those regions there might be great spatial heterogeneity with both hot spots and certain areas where the parasite has not been found.

In hot spots, the prevalence may reach 70% in foxes (EELA, 2001) and 40% in musk rats and voles (Vuitton et al., 2003). Normally though even in endemic areas the prevalence in rodents is low; usually less than 1%. Hence, surveillance of definitive

hosts is presumed to more accurately reflect the actual prevalence of the parasite in a certain area than surveillance in the intermediate host.

Giraudoux et al., 2002 suggested the hypothesis that EM hot spots may be established in habitats where one or two species of rodents become predominant with high population densities in a habitat, making them easily accessible to foxes.

With the urbanisation of foxes, EM has been introduced in urban and suburban areas, for example Geneva, Zurich and Copenhagen, resulting in an elevated zoonotic risk as domestic dogs and cats housed by humans could become infected (Eckert and Deplatzes, 2004). Consequently, antihelminthic treatment of only hunting dogs will not suffice as a risk mitigating measure.

Geographical spreading of EM

EM appears to be spreading slowly geographically within Europe (Eckert and Deplatzes, 2004).

In the Japanese island of Hokkaido EM infected foxes were probably introduced in 1924-6, but the first outbreak of EM was reported in 1960. However, it was not until 1980 that EM was found almost all over the island (Eckert and Deplatzes, 2004; Schantz et al., 1995). Hokkaido is 83000 km² or which is 1/5 of Sweden. This indicates that although EM might be introduced into Sweden, it may take considerable time before EM emerges and is found all over the country.

Prevalence in foxes

The reported EM prevalence in foxes found in some EU member states ranged between 8 and 30% according to the community zoonoses report for 2004 (Table 1).

Table 1. EM prevalence in foxes from the Community Zoonoses report for 2004

Country	N animals investigated	Prevalence (%)
Austria	86	8%
Germany	5398	20%
France	986	8%
Luxembourg	35	14%
Slovakia	490	30%

Moreover, Eckert and Deplatzes (2004) reported that in Switzerland the EM prevalence in foxes was between 20 and 40%.

Prevalence in dogs in endemic areas

Eckert and Deplatzes (2004) reviewed the findings on EM in dogs in endemic areas of Europe. Studies of dogs at necropsy revealed prevalences ranging from 0.5% to 6% (Petavy et al., 2000, WHO/OIE 2001).

In Switzerland, study of randomly selected dogs revealed that 2 out of 660 dogs were EM positive i.e., a prevalence of approximately 0.3% (Deplatzes et al., 1999), while in western Switzerland 6 out of 86 dogs (7%) were positive (Gottstein et al., 2001).

Deplatzes and Eckert (2001) concluded that in endemic areas, dogs that have had access to rodents should be regarded as potential sources of human infection.

Release assessment – whether EM is introduced into Sweden

To evaluate the risk of introduction of EM to Sweden through movements of dogs from abroad, it is necessary to estimate the number of dogs entering Sweden from EM risk regions, and the prevalence of EM in these dogs.

Moreover, five scenarios were calculated, assuming that the dogs entering Sweden were without or with antihelminthic treatments prior to entry and assuming a combined compliance and efficacy of 90%, 95%, 99% or 99.9% for the treatment.

The results were the probability of at least one EM infected dog enters Sweden per year and the expected number of dogs entering Sweden per year for each scenario.

Estimation of the number of introduced dogs

The estimate for the number of dogs entering Sweden from EM risk regions is the synthesis of the collation, analysis and evaluation of several pieces of information and expert opinions. The main sources were the data derived from the Swedish Board of Agriculture's register on import permits and the registers of the Swedish Kennel Club.

During 2003, the last year before the implementation of the pet traveling regulation (998/2003/EC), approximately 30 000 import permits for dogs entering Sweden were issued by the Swedish Board of Agriculture. While it might be the case that several dogs were imported on one permit, and other permits might not be used, the number of import permits would by and large reflect the magnitude of the dogs entering into Sweden that year. It is however expected that the number of imported pets has increased, as more and more people bring their pets with them when traveling abroad, as a result of the simplified traveling regulation.

The Swedish Kennel Club registers dogs entering Sweden on a permanent basis. Approximately 50-200 dogs are registered annually that originate from either of Germany, France, Switzerland, Austria or Italy, all countries in which EM is endemic in certain regions. Another 1000 dogs originate from other countries within the EU and 3rd countries with EM infected areas.

It would be helpful for the risk assessment if a better definition of the EM endemic areas could be established at the community level.

A number of dogs entering Sweden from the risk areas are puppies (less than 3 months of age). It is assumed that these puppies are not exposed to EM.

The number of dogs entering Sweden is greater than number of dogs registered as imported in the Swedish Kennel Club. It includes in addition (1) dogs brought to Sweden by visiting foreigners, (2) dogs imported without pedigree such as dogs adopted from dog shelters around the world, (3) the Swedish dogs returning with their owners, (4) dogs that for different reasons are never registered with the Swedish Kennel Club, and (5) dogs in transit through Sweden.

Considering the above information a reasonable conservative estimate of the number of dogs entering Sweden from EM risk regions would be between 700 and 1500 annually with an expected mean of 1100 dogs per year.

EM prevalence in exposed dogs

The EM prevalence in exposed dogs is assumed to be around **0.3% but could be up to 7%** according to the EFSA zoonoses reports 2004; Deplatzen and Eckert 2001; and Deplatzen and Eckert, 2004.

Results of EM release assessment

In Appendix II a quantitative release assessment, of whether EM infected dogs enter Sweden, is presented and the results are summarized in Tables 1 and 2.

It appears to be a **high probability** that at least one EM infected dog enters Sweden, unless the current antihelminthic treatment requirement is retained with a very high combined compliance and efficacy for dogs originating from areas where they could be exposed to EM. The expected number of EM infected dogs entering Sweden would be around 29 per year.

Moreover, to achieve a *very low* (0.5-5%) or *low* (5-30%) probability that at least one EM infected dog enters Sweden per year, it is required a combined efficacy and compliance of the antihelminthic treatment program of above 99.9% or 99%, respectively.

Likewise, if the number of dogs entering Sweden from EM risk regions is doubled, the compliance and efficacy of the treatment must be above 99.9% for the probability of one EM infected dog entering Sweden to remain low (5-30%).

Exposure assessment – whether EM establishes itself in Sweden if introduced

The available information is not sufficient for a quantitative assessment of the risk that EM is established if one or more EM infected dogs enters Sweden.

Nevertheless, the qualitative assessment of Swedish wildlife disease risks conducted by the National Veterinary Institute (SVA, 2006) concluded that the probability is **moderate to high** that EM would establish itself in wildlife if introduced into Sweden. This assessment agrees with that conclusion, based on the following:

Both intermediate hosts (voles, rats and mice) and definitive hosts (foxes and wolves) are a part of the Swedish fauna,

The climate facilitates the survival of the parasite.

The feces from infected dogs will be accessible to intermediate hosts i.e., rodents irrespectively if it is left in nature or ends up in a refuse dump. Hence, it will be practically impossible to prevent the transmission of EM from infected dogs to native intermediate hosts.

The time period for EM to establish itself all over Sweden could be several years based on the example of the Japanese island of Hokkaido.

Thus, if the parasite is detected in Sweden it is likely that the parasite is already well established in large parts of the country (SVA 2006).

Once EM is established in Swedish wildlife it would remain for the foreseeable future.

To date there is no known practical way of eradicating EM from wildlife such as vaccination.

Consequences if EM is established

The consequences are connected to the zoonotic potential of the parasite. The public health and socio-economical consequences if EM is established in Sweden include:

1. Human alveolar echinococcosis – e.g., Switzerland, a country where EM is prevalent reported an annual human incidence of around 1 per million (Vuitton et al., 2003). Each infected person must undergo lifelong treatment with albendazole or equivalent. The costs are estimated to be around 10 000 € per year per person, and the cost of a lifelong treatment is around 300 000 € per person (Eckert and Deplatzes, 2001). Sometimes, liver transplantation is necessary for the survival of the patient.
2. People that professionally could come into contact with infected animals, such as hunters, forestry workers, farmers, veterinarians, would have to develop safe handling procedures that could be costly, cumbersome or time consuming.
3. Pet owners in EM infected areas would have to be advised on the possible risk involved in enjoying the company of their animals. Changes in the way of holding pets would have to be considered such as monthly treatments with anthelmintics.
4. Due to the zoonotic risks the right of common access to non-farmed land (allmansrätt) will be curbed. This right is a treasured and ancient freedom ingrained in the Swedish way of life. It makes Sweden quite unique as it allows for several possibilities to use and enjoy nature. For example, it is a

common Swedish pastime to pick wild berries and mushrooms. If EM were established in Sweden, people would have to change their habits e.g., ensuring that all berries and mushrooms are heat treated or at least thoroughly rinsed before consumption. The same will apply to all low-growing vegetables, berries in gardens and farmed fields accessible to foxes.

This loss of nature enjoyment is not possible to express in monetary terms, while it would be very tangible for a large part of the Swedish public.

5. The unspoiled nature in Sweden attracts tourists. To many eating raw berries is unthinkable except for when visiting the Nordic countries. If EM were introduced, the necessary public health warnings could be foreseen to make tourists less enthusiastic about visiting Sweden resulting in lower numbers of tourists.
6. The primary and processing industries for berries, mushrooms and low growing vegetables would need to change their processing procedures including heat treatment or at least thorough rinsing of the foodstuffs before placing them on the market. The finding of EM could also cause a sharp decrease in demand for the products resulting in lower prices and economic losses.
7. During the time period (20-50 years) when EM is spreading in Sweden the need to detect areas in which EM is emerging will necessitate a large-scale surveillance of foxes and possibly intermediate hosts that would be expensive. Currently, the surveillance of foxes costs around 50000 € per year and a large increase in costs should be foreseen under this scenario.

In conclusion, the consequences of EM introduction into Sweden would be a **serious loss of welfare**, due to the increased zoonotic risks and the management of these.

Risk management options

The only available option to prevent the introduction of EM into Sweden is antihelminthic treatment (praziquantel or equivalent) of dogs that originated from areas with EM.

Provided that dog owners fully comply with this requirement, the treatment is an efficient method of preventing the introduction of EM into Sweden.

In an endemic situation, it is recommended that dogs be given antihelminthic treatment with at monthly intervals (Eckert and Deplazes , 2004).

Conclusions - addressing TOR

Terms of reference 1: To assess the probability that EM is introduced into Sweden through the movements of dogs that have not been given antihelminthic treatment prior to entry.

It appears to be a **high probability** that at least one EM infected dog is introduced into Sweden, unless the current antihelminthic treatment requirement is retained with a very high compliance.

Without the antihelminthic treatment requirement, the expected number of EM infected dogs entering Sweden would be around 29 per year.

Terms of reference 2: To assess the risk that EM is permanently established in Sweden once introduced, and the consequences thereof.

The probability is **moderate to high** that EM would establish itself in Swedish wildlife reservoirs if introduced into Sweden.

The consequences of EM introduction into Sweden would be a **serious loss of welfare**, due to the increased zoonotic risks.

Terms of reference 3: To assess the risk mitigation effect from the antihelminthic treatment of dogs prior to entering Sweden

To achieve a **low** (5-30%) or **very low** (0.5-5%) probability that at least one EM infected dog is introduced into Sweden per year, it is required a combined efficacy and compliance of above 99% and 99,9% of the antihelminthic treatment, respectively.

Other conclusions and recommendations

The most important uncertainties in this analysis is the number of dogs entering Sweden every year from EM endemic areas. Moreover, it is recommended that a survey of dogs entering Sweden and their origin; is carried out on regular intervals such as every 5th year.

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Appendix 1

As guidance for risk managers it is suggested the following quantitative interpretation of qualitative risk terms.

Table 1 Quantitative interpretation of qualitative risk terms.

High (0.7 - 1)	i.e., between 70 and 100%
Moderate (0.3 - 0.7)	i.e., between 30 and 70%
Low (0.05 - 0.3)	i.e., between 5 and 30%
Very low (0.001 - 0.05)	i.e., between 0.1% and 5%
Extremely low (10^{-6} - 0.001)	i.e., between 0.0001% and 0.1%
Negligible ($< 10^{-6}$)	i.e., less than 0.0001

Appendix II

Quantitative release assessment of the risk of EM infected dogs entering Sweden

The risk was estimated per year for dogs entering Sweden.

Number of dogs entering Sweden from EM risk regions per year

It is assumed 700 to 1500 dogs are entering Sweden annually from areas with possibly EM infected rodents.

Since there are no most likely number, a uniform distribution is assumed (riskuniform (700; 1500)) with an expected mean of 1100 dogs. This is approximately 2 % of the dogs that are entering Sweden per year.

EM prevalence in exposed dogs

The EM prevalence in exposed dogs that is coming from areas with possibly EM infected rodents, is assumed to be around **0.3% but could be up to 7%** according to the EFSA zoonoses reports 2004; Deplatzen and Eckert 2001; and Deplatzen and Eckert, 2004.

The prevalence was presumed to follow a betapert distribution with minimum 0% most likely 0.3% and a maximum prevalence of 7%. (Riskbetapert 0;0.003; 0.07)

Sensitivity analysis

To illustrate the results from the sensitivity analyses we doubled the number of dogs introduced from risk areas see table 2.

The number of dogs was riskuniform (1400; 3000) and the prevalence was the same and the same scenarios with regard to combined efficacy and compliance of antihelminthic treatments were assumed.

Estimated parameters

The probability of having at least one dog introduced into Sweden was estimated from the formulae:

$P(\text{at least one infected dog or cat introduced into Sweden}) =$

(Equation 1) $1 - (1 - \text{prevalence})^{\text{number of dogs}}$

The number (N) of infected dogs was estimated from formulae

(Equation 2) $N = \text{prevalence} * \text{number of dogs}$

By Monte Carlo simulation the upper 95% percentile was estimated, through 2000 iterations.

Calculation of the risk reduction effects of antihelmintic treatment

The simulation procedure was repeated for the scenario when the dogs were treated with antihelmintics assuming a 90%, 95%, 99% or 99.9% combined efficacy and compliance. The results were compared to the results for untreated dogs. Thus in all 5 scenarios were calculated.

This efficacy and compliance includes following elements, the true efficacy of the drug (praxiquantel) presumed to be very close to 100% while the owner's compliance to the requirement that the dog should be treated could vary.

The reduction in prevalence would be:

(Equation 3) New prevalence = old prevalence (1- efficacy and compliance)

The new prevalence was then used to estimate the probability that at least infected dog was introduced into Sweden and the estimated number of infected dogs to be introduced with including the upper 95 percentile based on Monte-Carlo simulation (Equations 1 and 2).

Results main scenarios

Table 1 Annual assessment of risk of introduction of EM infected dogs to Sweden – release assessment including Monte-Carlo simulation of the upper 95 percentile.

Scenario	Probability that at least one EM infected dog is introduced per year	Upper 95 percentile of the probability that at least one EM infected dog is introduced	Expected number of EM infected dogs introduced per year	Upper 95 percentile of number of EM infected dogs introduced per year
No treatment	0.98	1	29	78
90% efficacy	0.80	0.999	3	7
95% efficacy	0.64	0.98	1	3
99% efficacy	0.24	0.54	0	0
99.9 efficacy	0.03	0.08	0	0

Illustration of sensitivity analyses

Table 2 Annual assessment of risk of introduction of EM infected dogs to Sweden – if doubling the number of dogs entering Sweden to 2200 and ranging from 1400 to 3000 (riskuniform(1400;3000)) including Monte-Carlo simulation of the upper 95 percentile.

Scenario	Probability that at least one EM infected dog is introduced per year	Upper 95 percentile of the probability that at least one EM infected dog is introduced per year	Expected number of EM infected dogs introduced per year	Upper 95 percentile of number of EM infected dogs introduced per year
No treatment	0.99	1	60	154
90% efficacy	0.9	1	6	15
95% efficacy	0.79	1	3	7
99% efficacy	0.39	0.7	0	1
99.9% efficacy	0.05	0.14	0	0