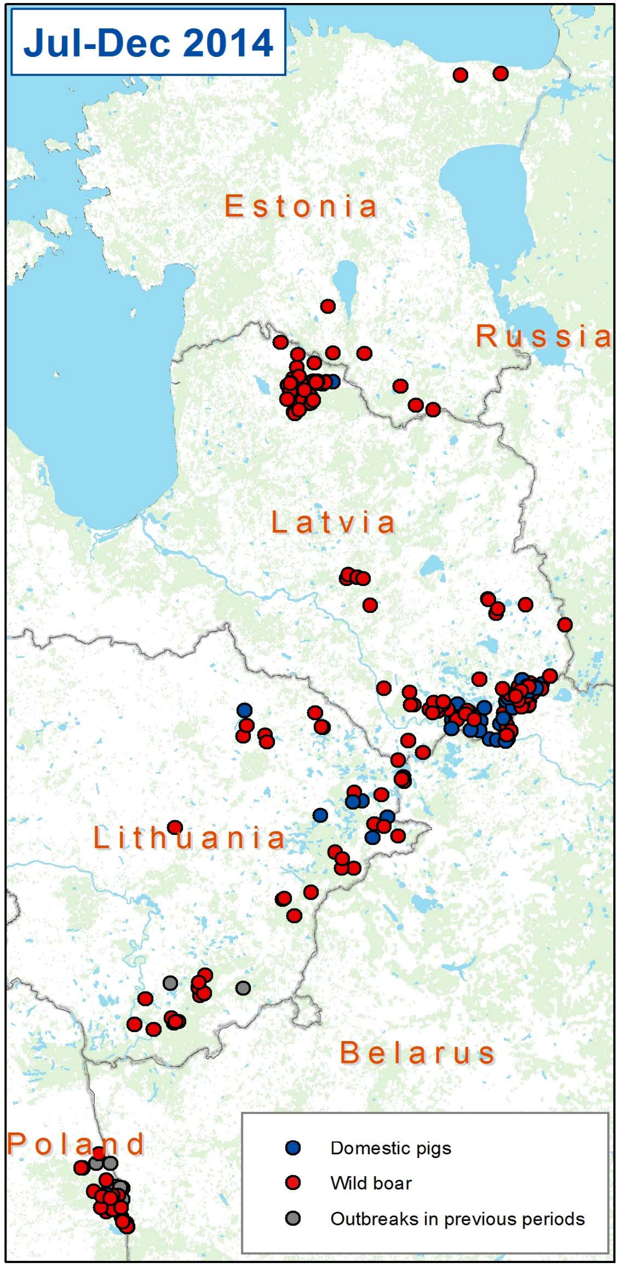
Scientific Opinion on African swine fever

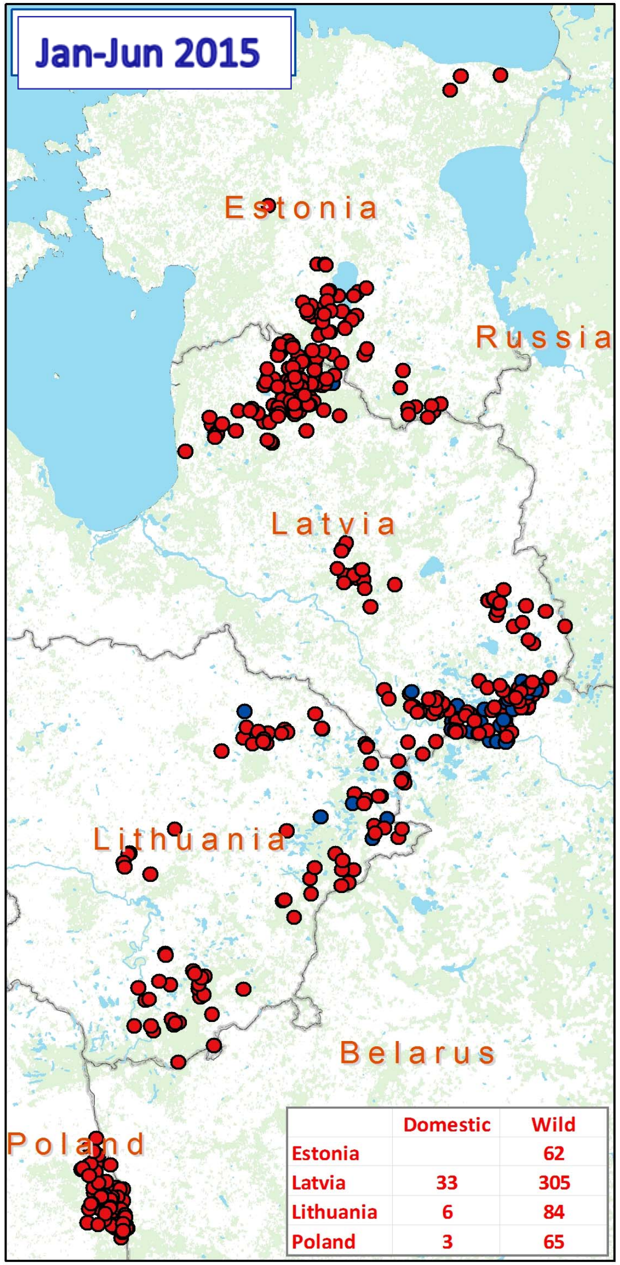
STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED
7 July 2015
Brussels

European Food Safety Authority

Background and current situation

	Confirmation	Status
Lithuania	24/01/2014	Continuing
Poland	13/02/2014	Continuing
Latvia	25/06/2014	Continuing
Estonia	02/09/2014	Continuing





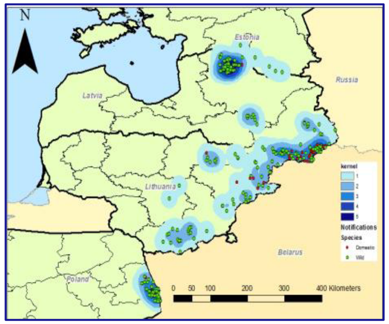
	Domestic	Wild
Estonia		62
Latvia	33	305
Lithuania	6	84
Poland	3	65

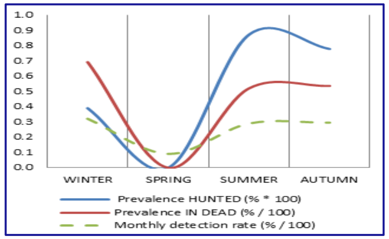
TOR 1. ASF-BEHAVIOUR IN WB POPULATION

- Evaluate the epidemiological data on ASF from Lithuania, Poland, Latvia and Estonia in order to obtain indications on the local behaviour of ASF in the wild boar population and its interaction with domestic pigs

Assessment was based on:

- Chronological description of the ASF outbreaks in Lithuania, Poland, Latvia and Estonia
- Spatio-temporal observations
  - Wild boar-domestic pig interface
  - Short and long distance spread of ASFV
  - Clustering of ASF notifications
  - Laboratory surveillance (PCR, Ab)
- Expert opinion on factors contributing to further spread of ASFV between sub-populations of a wild boar meta-population





TOR 1. CONCLUSIONS

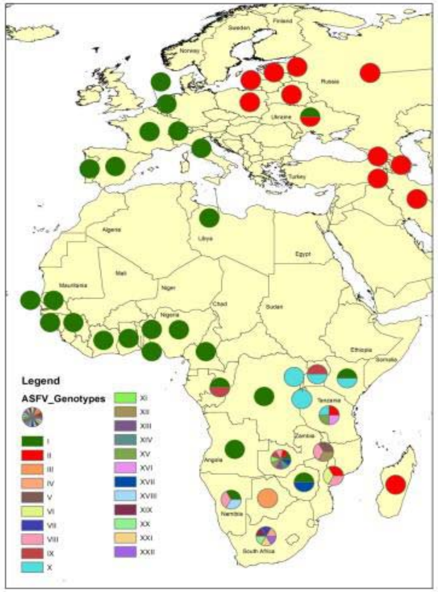
- Spread of ASFV to new areas which could not be related to wild boar movement occurred mostly during periods of outbreaks in domestic pig populations.
- ASF spreads locally in the wild boar population, independent of outbreaks in domestic pigs.
- The low biosecurity level appeared to be the source of virus introduction in the backyard farms; yet, direct contact between pigs and wild boar was not reported.
- All primarily ASF outbreaks in pig holdings or cases in wild boar were found by passive surveillance.

TOR 1. CONCLUSIONS BASED ON EXPERT OPINION

- There is a high likelihood that contact of susceptible wild boar with infectious material (e.g. blood, carcass or excreta from an infected animal) in the environment will lead to further spread of ASFV.
- There is a moderate to high likelihood that direct contact between wild boar will lead to further spread of ASFV, especially in places where animals are gathered, such as feeding places.
- Very intense and frequent drive hunts during depopulation campaigns are important factors leading to the movement of wild boar and possible spread of ASFV.

TOR 2. CARRIERS: EVIDENCE - ROLE IN SPREAD?

- An assessment of the possible risk of spread of ASF-Genotype II strains/isolates currently or recently circulating in Europe, and specially in Russia or the Baltic States, by pigs or wild boar becoming "carrier" that might play a role in virus transmission while remaining non-symptomatic.



Assessment was based on:

- Description of experimental infections with ASFV genotype II strains currently circulating in Eastern European countries
- Observations on possible shedding of ASFV by experimentally infected animals

TOR 2. CONCLUSIONS

- The Genotype II ASFV strain is highly virulent and induces an acute form of ASF with a high lethality in both wild and domestic pigs. As yet, no scientific data has demonstrated the presence of carrier pigs in the Eastern European Union.
- Intermittent viraemia following survival from experimental inoculation with Genotype II ASF has been observed in one animal and DNA could be identified in tissues for 61 days post infection.
- Even if there are no carriers, there are several mechanisms that can lead to long-term circulation of ASFV in pig or wild boar populations
- ASF virus presence in tissues has been demonstrated to persist up to 6 months and can be infectious for susceptible animals fed with it.

TOR 3. TRENDS IN WILD BOAR POPULATION DYNAMICS

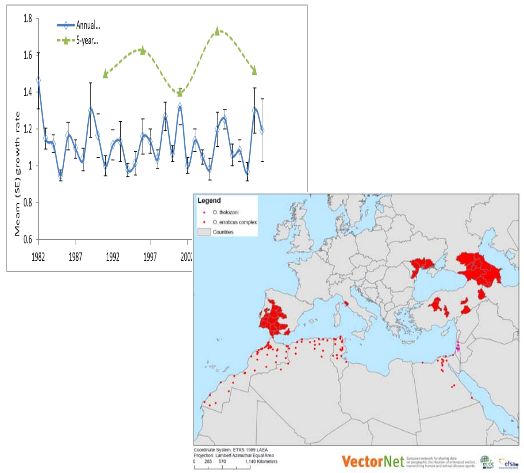
- Where new data is available, provide an update of previous Scientific Opinions on ASF, in particular:

i. describe identifiable relevant trends in wild boar population dynamics in the EU and its Eastern neighbouring territories; and

ii. provide an updated distribution of ASF competent vectors (soft ticks) and its possible role on ASF epidemiology specially in Russia or the Baltic States.

Assessment was based on:

- Relatively abundance of wild boar in the Eastern European countries
- Temporal trends in harvested wild boar
- Systematic literature review



TOR 3. CONCLUSIONS

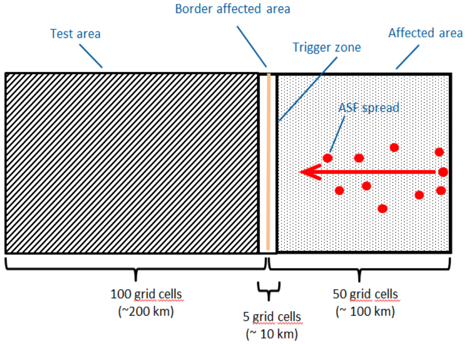
- There is an increase in the number of harvested wild boar in most European countries, likely to reflect increased numbers of wild boar.
- There is a decrease in the number of hunters in most European countries
- There is no indication that the population growth will slow down in the next few years.
- Wild boars have never been found infested by *Ornithodoros spp.* because wild boar normally do not rest inside burrows, but on the ground surface
- In Europe, ticks of the *O. erraticus* complex have been reported in some countries around the Mediterranean Basin (Portugal, Spain and Italy and Turkey), the Black sea (Moldavia, Romania, Georgia), and in Armenia and Azerbaijan.
- There is no report indicating the occurrence of *Ornithodoros spp.* in the 4 affected Member States.

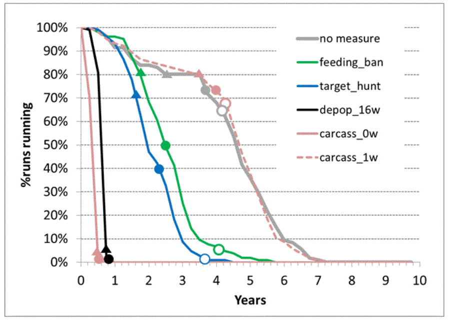
TOR 4. MANAGEMENT OPTIONS

Assessment of the suitability, effectiveness and the practical aspects of implementation of the main wild boar management measures in ASF infected areas and bordering risk areas

Assessment was based on:

- quantitative information on the efficacy of different wild boar management options (literature review)
- expert consultation organized to obtain unpublished information
- epidemiological simulation model





TOR 4. CONCLUSIONS

- As yet, a reduction below 60% of the wild boar population has never been documented in Europe with conventional hunting methods.
- Frequent and intense drive hunts can lead to adaptive behaviour among hunted wild boar, compensatory growth of the population, influx of wild boar from adjacent areas and extensive movements of wild boar outside of the focal area.
- To reduce wild boar populations, feeding should be prohibited and hunting rates increased for several consecutive years especially for females, as all age classes of females are highly reproductive.

TOR 4. CONCLUSIONS

- Currently there is not enough evidence to state the exact quantitative threshold separating baiting and feeding amounts of supplied feed resources.
- Required baiting quantities may differ greatly between different habitats and hunting practices and the type of feed provided. However, the experts agreed that baiting has to avoid the increased survival and reproduction in the populations.
- The model demonstrated that measures such as depopulation attempts for more than 70 % of the wild boar populations would be, theoretically, effective to control ASF but practically they are impossible to be achieved in one hunting season.

TOR 4. CONCLUSIONS

- On the other hand, conventional management strategies, such as implementing a feeding-ban or targeted hunting of females, can effectively prevent the spread of ASF in the control area only after multiple years of application.
- The model predicted that the combination of different tools, such as the exclusion of contact to carcasses and the intensification of conventional hunting, reducing reproduction in the following year by 30-40%, were effective to stop the spread of ASF in wild boar

ACKNOWLEDGEMENTS

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- **Hearing experts**: Belova Olgirda; Cellina Sandra; Dombrovska Linda; Fonseca Carlos; Gacic Dragan; Hohmann Ulf; Kamler Jiri; Kristian Maarjia; Lillemae Karolin; Markov Nickolay; Masiulis Marius; Mezhnev Anton; Monaco Andrea; Olsevskis Edvins; Ozolins Janis; Peep Männil; Plhal Radim; Pokorny Boštjan; Rosell Carme; Tijusas Eugenijus and
- **EFSA staff members:** Dhollander Sofie; Baù Andrea; Broglia Alessandro; Gogin Andrey; Ramović Sanel and Watts Matthew

Collection and review of updated scientific epidemiological data on porcine epidemic diarrhoea

European Food Safety Authority

www.efsa.europa.eu

TERMS OF REFERENCE

- **ToR1**: Guidance on PED data to be collected in Member States in order to optimise the coordination necessary to address the requests below. This may include a basic harmonisation of the **case definition**, the **eligible diagnostic methods**, the desired **data sets** and the **frequency of reporting**, as well as **guidance on epidemiological investigations** to facilitate data collection and to carry out the relevant epidemiological analysis.

TERMS OF REFERENCE

- **ToR2**: An **analysis of the epidemiological data** and metadata available in the Member States and in recent scientific literature within and outside the EU, focusing on the **occurrence** of infection with different PED virus strains/types, as well as on the actual morbidity and mortality rates and **severity of clinical disease** so as to **quantify the direct impact** on the pig production. In addition, the outcome of the analysis of the above data should allow EFSA to predict possible epidemiological trends of the evolution of the disease within and outside the EU.

CONCLUSIONS

- 2 data models were developed

  Herd-level reporting of **confirmed** case herds, based on a harmonised case definition developed in collaboration with the Network on PED

  Model to collect data on **surveillance and monitoring** activities

  - Herds meeting the case definition for PED were reported by Austria, Belgium, Spain, France, Italy, the Netherlands and Germany
  - Thirteen countries reported PEDV surveillance and monitoring activities
  - Data were not submitted by 15 countries

CONCLUSIONS

- Virus strains currently in circulation in European pig herds have greater than 99% similarity with the reference INDEL strain USA/OH851/2014
- The available data confirm that mortality is higher in suckling piglets and diarrhoea signs are observed in all age groups.
- These findings are in agreement with those reported in EFSA AHAW Panel (2014) that the impact of recently reported PED outbreaks in Asia and the USA seems to be more severe than what has been described in Europe
- However, the impact of different PEDV strains is difficult to compare between one country and another, since impact is dependent not only on pathogenicity but also on factors such as biosecurity, farm management, sanitary status or herd immune status.

ACKNOWLEDGEMENTS

This work is based on the effort of the participating countries, with EFSA playing a more coordinating role

- **EFSA wishes to thank** the members of the EFSA **Network on PED**: Adolf Steinrigl, Brigitte Cay, Hans Nauwynck, Lowiese Desmarets, Isaura Christiaens, Sebastiaan Theuns, Yves Van der Stede, Anette Bøtner, Bertel Strandbygaard, Imbi Nurmoja, Triin Tedersoo, Taina Laine, Laura London, Beatrice Grasland, Nicolas Rose, Loic Evain, Clara Marcé, Sandra Blome, Bernd-Andreas Schwarz, Spyridon Kritas, Paschalis Fortomaris, Ádám Bálint, Ádám Dán, John Moriarty, Eoin Ryan, Antonio Lavazza, Giovanni Alborali, Beatrice Boniotti, Monica Cerioli, Marius Masiulis, Wim van der Poel, Peter van der Wolf, Carl Andreas Grøntvedt, Berit Tafjord Heier, Anna Ondrejková, Miroslav Mojzis, Dalibor Polak, Luis Romero, Beatriz Gonzalo Martínez, Cecilia Hultén, Falko Steinbach, Helen Roberts, Susanna Williamson for the preparatory work on this scientific output

Scientific Opinion on Oyster mortality

European Food Safety Authority

MANDATE

- update previous opinion from 2010 with the latest scientific evidence on OsHV-1
- evaluate the role of Vibrio in mortality events. If any, indicate control measures
- effectiveness of current methods of water treatment in depuration plants in inactivating OsHV-1 and Vibrio – alternatives?
- feasibility, availability and effectiveness of the disease prevention and control measures

MANDATE

This is an update of a 2010 opinion

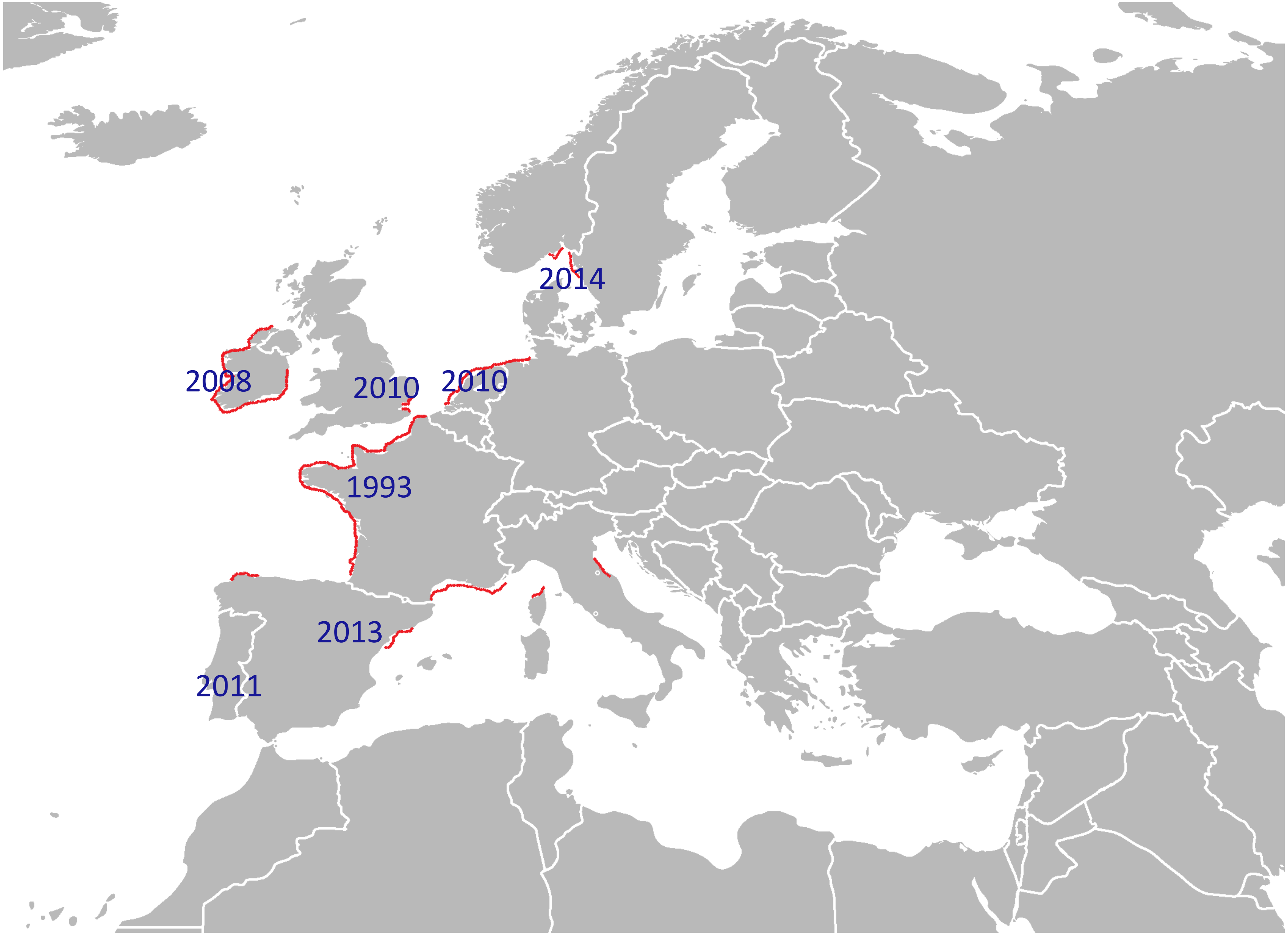
- OsHV-1 – updated information
- Vibrio – mostly new information
- Water treatment – entirely new
- The opinion also covers the role of
  - Host factors
  - Environmental factors
  - Husbandry practices

TOR1 OSTREID HERPESVIRUS

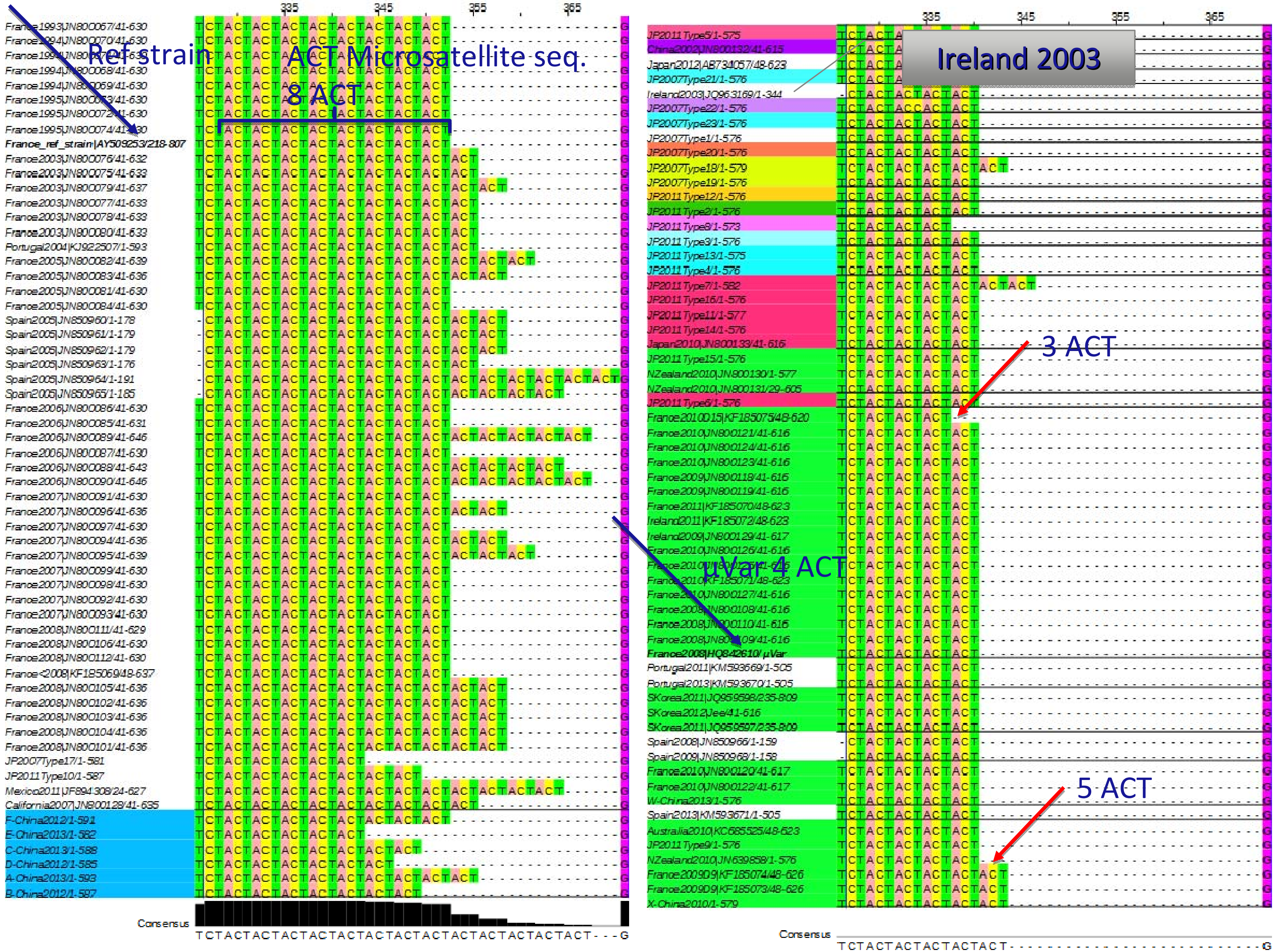
- OsHV-1 μVar is now the predominant strain in Europe
- Expansion of mortality in time and space is assessed using 3 case studies:
  - France
    - long time-series from scientifically conducted surveillance programs at multiple locations
  - Ireland
    - EU- approved surveillance program and the possible role of depuration plants
  - Norway
    - recent geographical expansion (NOT via cultivation)
  - Overview of global occurrence of OsHV-1

OsHV-1 μVar

- Significant mortality events associated with OsHV-1 μVar in
  - EU 2008-
  - Australia 2010-
  - New Zealand 2010
- OsHV-1 μVar also isolated in
  - South Korea 2011-
  - Japan 2007-
  - China 2002-



Known occurrence of OsHV-1 in Europe as of 2015. After 2008: µVar.



335
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Ref strain
ACT Microsatellite seq.
8 ACT
Ireland 2003
3 ACT
µVar 4 ACT
5 ACT
Consensus
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Conclusions on OsHV-1 μVar

- Continued spread in Europe since 2008
  - legislation in place has not been effective in controlling disease outbreaks or geographic spread
- Not possible to eradicate nor prevent introduction of virus
  - A good understanding of agent-host environment interaction may help to mitigate disease problems (generally reduced viral load)

CONCLUSIONS on OsHV-1 µVar

- First µVar-like isolate identified in Ireland 2003
- Phylogenetic analysis of OsHV-1 µVar suggests a recent introduction from the Pacific area, combined with rapid dissemination within Europe.
- The range of seawater temperature in which OsHV-1 induces mortality is between 16 and 24° C.
- A large number of OsHV-1 variants in several bivalve species have been described from the North Pacific area and Oceania
- It is not possible to conclude that strains from outside Europe would be less important than the current European strains in terms of disease risk.

TOR2 *VIBRIO AESTUARIANUS*

- *Vibrio aestuarianus* is a ubiquitous species in different geographic areas and is present in many aquatic organisms
  - Subspecies *francensis* and *aestuarianus*
- While Vibrio has been detected during oyster mortality since 2008, increased mortality observed since 2012 has not been unequivocally linked to Vibrio as the causative agent

CONCLUSIONS ON *V. AESTUARIANUS*

- Experimental induction of disease is possible and induction of mortality confirmed with many strains of *V. aestuarianus* subsp. *francensis*. There is no data on *V. aestuarianus* subsp. *aestuarianus*.

- No routine tools are available to differentiate the subspecies of *V. aestuarianus* or to determine the virulence of *V. aestuarianus* isolates.

- Available evidence does not support a primary role of *V. aestuarianus* in oyster mortality events. Nevertheless, *V. aestuarianus* may act as an opportunistic pathogen under adverse circumstances.

- Adult Pacific oysters are more susceptible to *V. aestuarianus* subsp. *francensis* than spat.

CONCLUSIONS ON WATER TREATMENT

- UV irradiation at 254 nm is effective at inactivating OsHV-1 and *V. aestuarianus*.
- Data for related microorganisms (i.e. other herpesviruses and other *Vibrio* spp.) indicates that chlorine, ozone, iodophors and heat is effective against both OsHV-1 and *V. aestuarianus*.
- Disinfection of the target pathogens is achievable in seawater containing minimal amounts of suspended material and/or organic material.
- The nature of the waste material discharged from an individual depuration or holding system will determine what disinfection processes and necessary concentrations may be appropriate.

CONCLUSIONS ON PREVENTION AND CONTROL

- Almost all OsHV-1 strains isolated after 2008 conform to the definition of mic unnecessary to microvariants fo
- Phylogenetic an between contine to maintain mea boundary spread
- The sensitivity c type, storage, e Latently infected infection are not

Not considered fulfilled:

3: The disease has shown, where it occurs, to have a detrimental environmental impact if introduced into a Member State free of the disease, to wild aquatic animal populations of species that is an asset worth protecting under Community law or international provisions.

5: The disease may be controlled at Member State level, experience having shown that zones or compartments free of the disease may be established and maintained, and that this maintenance is cost-beneficial.

7: Reliable and simple tests for infected aquatic animals are available. The tests must be specific and sensitive and the testing method harmonised at Community level

- The criteria in Directive 2006/88/EC for listing of non-exotic diseases are currently not fulfilled for mortality caused by OsHV-1 microvariants.

Questions:

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EFSA Scientific Opinion on canine leishmaniosis

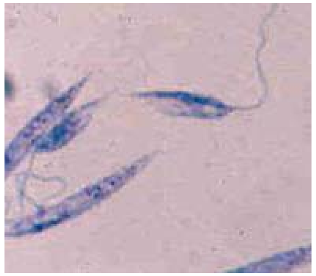
European Food Safety Authority

www.efsa.europa.eu

BACKGROUND

- **Leishmaniosis**
  - parasitic disease of humans and animals
  - non-notifiable in animals
  - cutaneous and visceral form
  - protozoa of the genus *Leishmania*
  - *Leishmania infantum* in Mediterranean area
  - transmitted by sandflies (*Phlebotomus*)
  - domestic dogs principal reservoir hosts
    - efficiently replicate the protozoan parasite
    - preferred hosts for vector phlebotomine sandflies






TERMS OF REFERENCE

- **Characterise canine leishmaniosis in Europe and in particular:**
  - **epidemiology of the disease, i.e. affected species, life cycle, modes of transmission and potential persistence of the parasite, distribution of the disease (free and endemic areas);**
  - **impact of *Leishmania infantum* infections on animal health and welfare, human health, as well as its environmental impact in the regions of the EU where the disease is endemic.**
- **Efficacy of available preventive measures to protect dogs against *Leishmania infantum* infection, with the objective of mitigating the probability of introduction of the infection into free areas in the EU through movements of infected dogs.**
- **Probability that infection would become established in free areas of the EU if *Leishmania infantum* were introduced by infected dogs.**

LITERATURE REVIEW, SURVEY, MODEL

ELSEVIER
Preventive Veterinary Medicine
journal homepage: www.elsevier.com/locate/prevetmed

A systematic review of the efficacy of prophylactic control measures for naturally-occurring canine leishmaniosis, part I: Vaccinations

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ABSTRACT

Canine leishmaniosis (CanL) is an important zoonotic disease; however, the
able vaccines for the prevention of naturally-occurring Leishmania infanl
currently a
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ELSEVIER
The Veterinary Journal
journal homepage: www.elsevier.com/locate/tvjl

The frequency and distribution of canine leishmaniosis diagnosed by veterinary practitioners in Europe

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Keywords:
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Dog
Epidemiology
Leishmaniosis
Prevalence

ABSTRACT

This study aimed to evaluate the frequency and spatial distribution of canine leishmanio
Greece, Italy, Portugal and Spain. An online questionnaire investigated the location anc
cases diagnosed by veterinary practitioners. Further data from the practice managem
erinary clinics in France were provided by a financial benchmarking company in re
ment and test invoice data from participating practices. The geographical and tempc
leishmaniosis was explored using Google Trends.
Veterinary practitioners from France, Greece, Italy, Portugal and Spain complet
naires. The percentage of practice-attending dogs with a veterinary diagnosis of CanL
in France to 7.80% in Greece. However, due to regional differences in response rates, pa
the mean regional estimates may better reflect the disease burden. Benchmarking c
proximately 180,000 dogs estimated that 0.05% of dogs attending veterinary clinics we

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Preventive Veterinary Medicine
journal homepage: www.elsevier.com/locate/prevetmed

Review

A systematic review of the efficacy of prophylactic control measures for naturally occurring canine leishmaniosis. Part II: Topically applied insecticide treatments and prophylactic medications

C.E. Wylie[a,*], M. Carbonell-Antoñanzas[a], E. Aiassa[b], S. Dhollander[b], F.J. Zagmutt[c], D.C. Brodbelt[d,1], L. Solano-Gallego[a,1]

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Modelling canine leishmaniasis spread to non-endemic areas of Europe

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SUMMARY

Expansion of sandflies and increasing pet travel have raised concerns about canine leishmaniasis (CanL) spread to new areas of Europe. This study aimed to estimate the probability of CanL introduction and persistence following movements of infected dogs. Stochastic modelling was used to estimate the probabilities of (1) CanL infection during travels or imports of infected dogs (P_{inf} and P_{infCA}, respectively), (2) CanL persistence in a dog network with sandflies after introduction of an infected dog (P_{per}), and (3) persistence in a CanL-free region ($P_{per\ region}$) for

CHARACTERISE CANINE LEISHMANIOSIS IN EUROPE

- CanL is endemic in the **European countries or regions surrounding the Mediterranean** where disease distribution matches that of the phlebotomine vectors.
- On average, around **10 %** of dogs in endemic countries are **seropositive** for *L. infantum*, with wide variations between territories.
- Studies conducted in endemic areas have given much higher prevalences than serology, with up to **80 %** of the dog population being **PCR-positive**.
- Infection in the canine population in endemic areas of Europe is widespread and the **prevalence of infection** in dogs is **much higher than the fraction that shows clinical illness or seroconversion**.

CHARACTERISE CANINE LEISHMANIOSIS IN EUROPE

- **Limited knowledge** in **central European** countries about **presence** of competent vectors and presence of endemic CanL.

- **Data on sandflies** are **limited** because of the absence of systematic sampling programmes and expertise.
- Available field data suggest that **sandflies are spreading northwards** in Europe and their **densities are increasing** in some newly colonised areas.
- Once infected, a **sandfly** remains **infected for life**, that is, on average, two to three weeks. Vertical transmission of Leishmania has not been reported in sandflies.

CHARACTERISE CANINE LEISHMANIOSIS IN EUROPE

- **No CanL endemic situation** has been observed **in areas without competent vectors**, suggesting that none of the transmission routes appears to sustain infection in a large population (i.e. larger than that of a household or a kennel).

- In northern European countries, where competent vectors have not been found, "imported" cases in dogs with a history of travelling from endemic areas and **CanL foci in households or in kennels** have been described. These foci can last for several years because of **non-vectorial transmission**.

CHARACTERISE CANINE LEISHMANIOSIS IN EUROPE

- Infection **spreads quickly** and **extensively** among the dog population in **optimal environmental conditions** (vectors, contacts).

- **All seropositive** *L. infantum*-infected dogs, whether they express clinical disease or not, are **potential sources** of infection for vectors and may transmit the parasite.

- Role of wild mammals as reservoirs not fully demonstrated. **Black rats**, **wild rabbits** and **hares** may contribute to **maintaining** *L. infantum* circulation in some areas of southern Europe.

- **Impact** of *L. infantum* infection on dog health/ welfare depends on **severity**, which ranges from subclinical to very severe, including euthanasia.

CHARACTERISE CANINE LEISHMANIOSIS IN EUROPE

Humans:

- Average incidence of **visceral leishmaniosis** reported in humans in southern Europe **2-134 cases** per year / country
- Average incidence of **cutaneous form** reported in humans in southern Europe **1-50 cases** per year / country.
- **Most** human *L. infantum* infections **asymptomatic**.
- Risk factors for clinical disease: young age, HIV infection, other i**mmuno-suppressive** states.

EFFICACY MITIGATION INTRODUCTION INFECTED DOGS

- **Vaccine**: no full protection against infection or disease. Some vaccines, e.g. CaniLeish®, the only vaccine authorised in the EU, provide **partial protection** against active *L. infantum* infection and clinical disease in dogs.

- **Topically applied insecticides**: demonstrated mass treatment efficacy, efficacy of insecticides in individual dogs when application is their owners' responsibility **uncertain**.

EFFICACY MITIGATION INTRODUCTION INFECTED DOGS

- **Prophylactic medication** with domperidone: **limited data** on efficacy in endemic areas, data on treatments of immunologically naive dogs and its potential long-term toxicity are lacking.

- **Drug therapy**: appears to mainly **slow down** the progression of infection, **decrease infectiousness** and **improve clinical manifestations** by reducing parasite loads in infected tissues, but no treatment (drugs and regime) tested so far has demonstrated 100 % efficacy in the elimination of the parasites.

ESTABLISHMENT PROBABILITY INFECTED DOGS

- Owing to the limited available knowledge on factors such as vector competence and abundance, dog distribution and movements, the average **probability** of **introduction** and **establishment** of CanL in a **theoretical dog network** or a network of networks was **estimated**, assuming the presence of competent vectors in some areas in a CanL-free area.
- The model assessed the average probability of disease establishment, defined as the **local transmission of from vector to host and vice versa**, leading to the temporal presence of at least one indigenous infectious host and at least one indigenous infectious vector. The **probability** of **establishment** was **very high** in these areas.

ESTABLISHMENT PROBABILITY INFECTED DOGS

- Even in areas where sandfly populations are likely to have a **lower vectorial capacity than in endemic** areas, e.g. in some foci with low vector densities, the average probability of establishment following introduction of an infected dog remains **high**, according to the model.
- Although the average probability of establishment in a non-endemic region with competent sandflies may be very high, according to the model, the **prevalence** in that region in the event of CanL introduction and establishment may vary from **extremely low to high**, depending mainly on the **vectorial capacity**.

ESTABLISHMENT PROBABILITY INFECTED DOGS

- Owing to the wide distribution of susceptible dogs and the high host–vector contact rates, the main **limitation** to CanL **spread** is represented by the vectors. This reinforces the **need for knowledge** of the **vectorial competence** of some sandfly species and of the **distribution and abundance** of known vectors.
- Results from the model indicated that the **probability** of introduction and establishment can be **reduced by mitigation measures**, separately or in combination. The **most effective** mitigation measure to reduce the probability of introduction and establishment of CanL was **topically applied insecticide**.

ESTABLISHMENT PROBABILITY INFECTED DOGS

- The model indicated that **vaccination** of dogs **prior** to travelling to endemic areas had only a **limited effect** on the probability of establishment in a non-endemic region, and this effect seems more apparent when the vectorial capacity and the number of introduced dogs were low.
- The use of **topical insecticide and vaccination** in travelling dogs had a **synergistic** effect in reducing the probability of establishment in a dog network and in reducing the probability of establishment in a region after their return to a non-endemic area, according to the model. Again, this effect was more marked in areas where a low vectorial capacity of the vectors was assumed.

ESTABLISHMENT PROBABILITY INFECTED DOGS

- **Testing** dogs **before** their introduction into a **non-endemic** area is of limited value if applied shortly after exposure to infected sandflies. This is mainly because of it takes several months after exposure before testing gives a positive result.
- **Test and treatment** in the **endemic** area, prior to movement into a non-endemic area, will reduce disease risk in individual animals; however, it does **not** appear to be an **efficient** and realistic option to **mitigate the risk of introduction** of CanL into the non-endemic area, as no treatment against *L. infantum* infection can provide permanent parasitological cure.

RECOMMENDATIONS FOR PREVENTING INTRODUCTION

- **Owners** of dogs travelling from free areas to endemic areas should be **informed about the risks** posed by CanL and **potential risk mitigation measures**.
- The most useful **diagnostic approaches** for investigation of infection in sick and clinically healthy infected dogs include (1) detection of specific anti-leishmanial antibodies in serum using **quantitative serological techniques** and (2) demonstration of **parasite DNA in tissues** by applying molecular techniques. To optimise the sensitivity of CanL diagnostics, especially in subclinical dogs, the two techniques should be **used in parallel**.
- Dogs born in endemic areas, which are confirmed to be infected with *L. infantum* by an appropriate test, should **not be moved from endemic areas into non-endemic areas**.

RECOMMENDATIONS FOR PREVENTING INTRODUCTION

- To prevent CanL introduction and establishment in non-endemic areas via measures imposed on dogs travelling to and from or imported from endemic areas, the use **topical insecticides** is strongly recommended.
- Exclusion of **travelling dogs testing positive** by means of serology and/or PCR after their return may not be imposed on dog owners. However, the **close clinical monitoring** of these dogs is recommended, including **medical treatment**, which will mitigate the risk of disease and its impact on welfare, and which will reduce parasite loads and infectiousness of the dog.
- In addition, when the **presence of competent vectors** in a free area is known, the use of **insecticide collars in those infected dogs** in non-endemic areas would further reduce the risk of CanL vectorial transmission.

RECOMMENDATIONS FOR FURTHER RESEARCH

- Well-designed, adequately powered **RCTs** on the **efficacy** of the **preventative measures**, such as vaccination and application of topical insecticides, alone and in combination, should be carried out.
- **Sensitivity** and **specificity** of **diagnostic tests** for detecting *L. infantum* should be quantified, e.g. by latent class analysis, using two different test principles (serology and PCR).
- **Diagnostics** and **prognostic tests** in dogs should be improved and developed, e.g. biomarkers to differentiate **status of infection and infectiousness** should be developed.