PAFF meeting 30 November 2022

AHW.A.03.(BL)

Assessment of the control measures of category A diseases of the Animal Health Law

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Terms of Reference

ToR 1

- Effectiveness of clinical and laboratory examination in their capacity to detector rule out disease (or estimate disease prevalence in an establishment), either in suspect or confirmed animals in a single establishment, or in establishments within restriction zones

ToR 2

- Effectiveness of the duration of the monitoring period (for different scenarios) in the control of suspected and confirmed outbreaks

ToR 3

- Effectiveness of the size (ToR 3.1) and duration (ToR 3.2) of the restriction zones, in their capacity for mitigating disease spread

ToR 4: addressed in separate scientific opinion

EFSA
Supporting Publications
Open Access

Technical report | Open Access

Technical report on the methodological approach used for the assessment of the control measures for Category A diseases in the context of the new Animal Health Law

European Food Safety Authority (EFSA), Julio Alvarez, Helen Clare Roberts, Karl Stahl, Arvo Viltrop, Kris De Clercq, Eyal Klement, Jan Arend Stegeman, Simon Gubbins, Sotiria-Eleni Antoniou, Gabriele Zancanaro, Inma Aznar ... See fewer authors

First published: 14 December 2020 | https://doi.org/10.2903/sp.efsa.2020.EN-1988 | Citations: 7

Requestor: European Commission – DG SANTE
Question number: EFSA-Q-2020-00198

- Approved in Nov 2020
- Applied in the assessments of all 14 Category A diseases

ToR 1 Sampling procedures

- Assess sampling procedures for detecting or ruling out the presence of each of the Category A diseases
- In the context of 21 scenarios described in different articles of Commission Delegated Regulation (EU) 2020/687 supplementing Regulation (EU) 2016/429 (Animal Health Law)
- Clinical examination
- Laboratory sampling

Annex 1 - Scenarios of ToR 1

ToRs	Legislation	Scenario	Description of the Scenario	Elements of the Scenario
ToR1.1 ToR1.2	6(2) Delegated Regulation	1st Scenario	To assess the effectiveness of disease-specific sampling procedures of **animals of listed species** in a suspected establishment , based on clinical examination (TOR1.1) and laboratory examination (TOR1.2), in their ability to detect a category A disease in kept animals if the disease is present in that establishment, or to rule it out if not present (Art. 6 (2)).	• event of suspicion of a category A disease • in an establishment • kept animals of listed species • the competent authority shall immediately conduct an investigation to confirm or rule out the presence of the suspected listed disease • official veterinarians perform clinical examinations and collect samples for laboratory examinations
ToR1.2	-Art. 12(3), -Art. 7 (4) (Preventive killing) Delegated Regulation -Art. 57 Reg.2016/429	2nd Scenario	To assess the effectiveness of disease-specific sampling procedures, based on laboratory examination (ToR1.2), in their ability to detect the disease in the event of preventive killing, and in their ability to support with the epidemiological investigation (disease detection, prevalence estimation, virus identification, etc.) in kept **animals of listed species** in an affected establishment, before or when they are killed or found dead. The purposes of the epidemiological enquiry are described in Article 57 of Regulation (EU)2016/429.	• affected establishment officially confirmed or suspect establishment where preventive killing is carried out • kept animals of listed species found dead or before/when they are killed • competent authority collects samples for laboratory examination for the purposes of: a) supporting the epidemiological enquiry: - to identify the likely origin of the disease - to calculate the likely length of time that the disease is present - to identify establishments where the animals could have contracted the disease and movements from the affected establishment that could have led to the spread of the disease - to obtain information on the likely spread of the listed disease in the surrounding environment, including the presence and distribution of disease vectors b) confirming/ruling out disease in the event of preventive killing
ToR1.1 ToR1.2	Article 13(3)c Delegated Regulation	3rd Scenario	To assess the effectiveness of disease-specific sampling procedures based on clinical (ToR1.1) and laboratory (ToR1.2) examinations of the **animals of listed species belonging to the categories described in article 13(2)** of an affected establishment, in order to grant a specific derogation from killing these animals, while ensuring that they do not pose a risk for the transmission of the disease.	• affected establishment officially confirmed • kept animals of listed species of specific categories • animal categories based on article 13(2): (a) animals kept in a confined establishment (b) animals kept for scientific purposes or purposes related to conservation of protected or endangered species (c) animals officially registered in advance as rare breeds (d) animals with a duly justified high genetic, cultural or educational value

Methodology ToR 1 Sampling procedures

- Existing procedures
  - If fixed number of samples (input-based surveillance)
    - ➢ Calculation of level of confidence achievable, comparison with minimum level of confidence (95%)
  - If number of samples to be collected were calculated to reach a 95% confidence
    - ➢ Assessment of appropriateness of assumptions (i.e., Design Prevalence, Test Sensitivity) and possible advantages of introducing a risk-based sampling
- No specific procedures
  - ➢ Calculation of number of samples needed to achieve 95% Round of tests Sensitivity/Confidence of Freedom

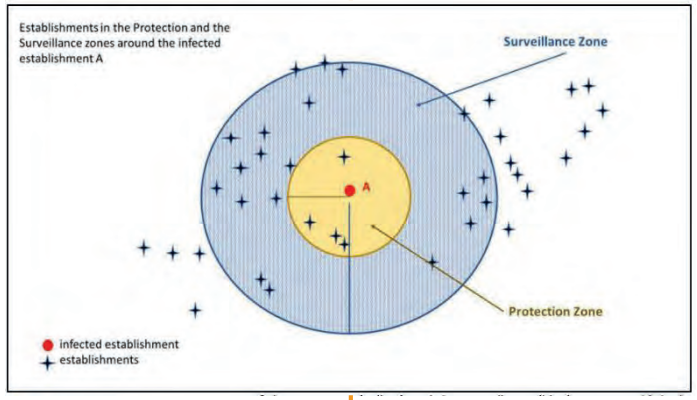
ToR 2 Monitoring period

- Assess the effectiveness of the length of the monitoring period
  - for 7 different scenarios
  - Long enough and not longer than necessary to obtain the information required and the level of confidence needed to perform the necessary actions
  - Comparison of expert opinion-based estimate with existing monitoring periods
    - >=non-effective
    - <=effective

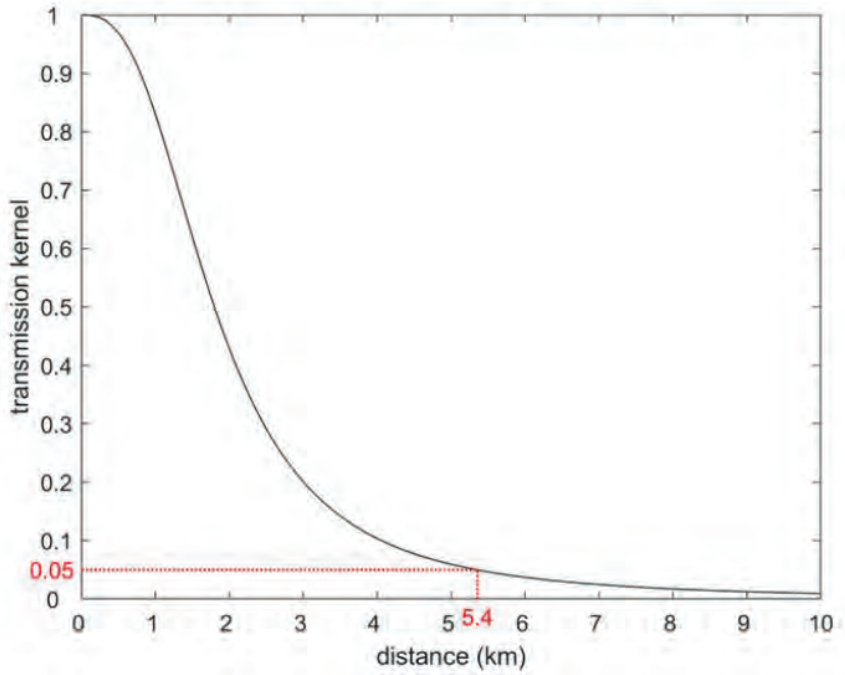
Annex 3 - Scenarios of ToR 2

ToRs	Legislation	Scenario	Description of the Scenario	Elements of the Scenarios
ToR 2	**Article 8** Delegated Regulation, Article 57 of 2016/429 Regulation, Annex II of the Delegated Regulation	1st Scenario	To assess the effectiveness of the length of the Monitoring Period, as the **time period** calculated **backwards from the date of the notification of the suspicion** of a category A disease in an establishment with kept animals of listed species, **for the purposes of the epidemiological enquiry** in the event of a suspicion.	• event of suspicion of a category A disease • in an establishment with kept animals of listed species • time period calculated backwards from the date of the of the notification of the suspicion • time period before the suspicion, **during which the pathogenic agent may have been introduced in the establishment and may have spread outside the establishment.** • the aim of the epidemiological enquire is: (a) identify the likely origin of the listed disease in question and the means of its spread (b) calculate the likely length of time that the listed disease has been present (c) identify establishments and epidemiological units therein, food and feed businesses or animal by–products establishments, or other locations, where animals of listed species for the suspected listed disease may have become infected, infested or contaminated (d) obtain information on the movements of kept animals, persons, products, vehicles, any material or other means by which the disease agent could have been spread during the relevant period preceding the notification of the suspicion or confirmation of the listed disease (e) obtain information on the likely spread of the listed disease in the surrounding environment, including the presence and distribution of disease vectors.
ToR 2	**Article 17(2)** Article 57 of 2016/429 Regulation, Annex II of the Delegated Regulation,	2nd Scenario	To assess the effectiveness of the length of the Monitoring Period, as the time period **calculated backwards from the date of notification of the suspicion** of a category A disease in an establishment with kept animals of listed species, for the purposes **of the epidemiological enquiry** in **the event of confirmation** of the disease.	• event of confirmation of a category A disease • in an establishment with kept animals of listed species • time period **calculated backwards from the date of the notification of the suspicion.** • time period before the suspicion, during which the pathogenic agent was introduced in the establishment and during which it could have spread outside the establishment. • The aim of the epidemiological enquire is the same as above.

ToR 3 Protection and Surveillance zones



Effectiveness of the minimum radius of the protection and surveillance zones for controlling disease spread

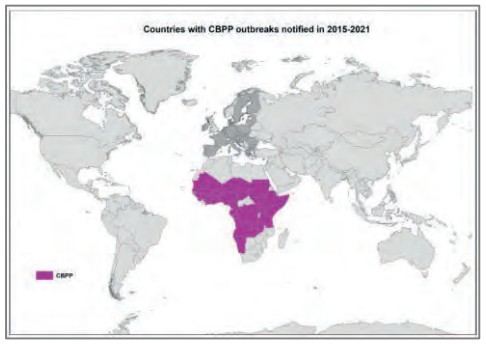


Effectiveness of minimum periods during which competent authority should apply restriction measures in zones

Reference	Country	Year	Species/farm type	Period (days)
Elbers et al. (1999)	Netherlands	1992	Pig/NA	42[1]
Laevens et al. (1998)	Belgium	1993	Pig/fattening	18[2]
Elbers et al. (1999)	Netherlands	1997	Pig/mixed Insemination center	42[3] 30[4]
Elbers et al. (1999)	Germany	1997	Pig/NA	56[1]
Elbers et al. (1999)	Spain	1997	Pig/NA	63[1]
Mintiens et al. (2001)	Belgium	1997	Pig/fattening	19[5]
Moennig et al. (2013)	Germany	2006	Pig/NA	70[6]
David et al. (2011) OIE (2009)	Israel	2009	Pig/closed	21[7]

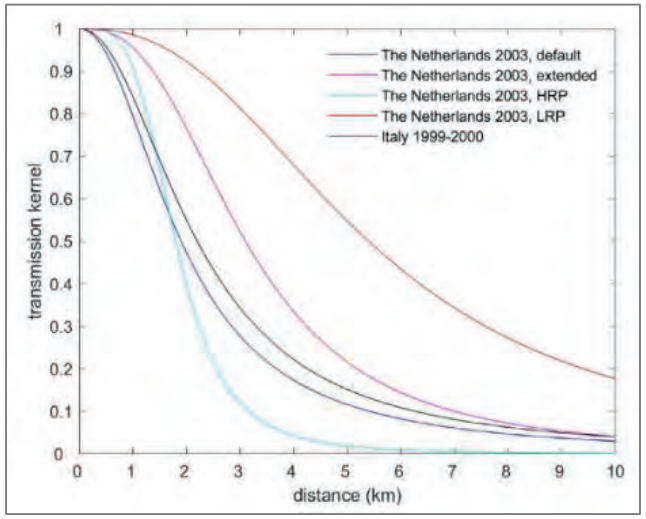
Data used

- Extensive literature reviews
  - Aetiology, Epidemiology, Clinical signs, Diagnosis and Geographical distribution of diseases
  - Average, shortest, and longest period between the earliest point of infection and the time of reporting of a suspicion by the competent authority
  - Transmission kernels from reported outbreaks



The extracted values for (n = 3) (Tables 5 and 6) can be summarised as follows:

1) Average (mean) period = 86 days (median = 90 days).
2) Shortest period = 61 days.
3) Longest period = 108 days.



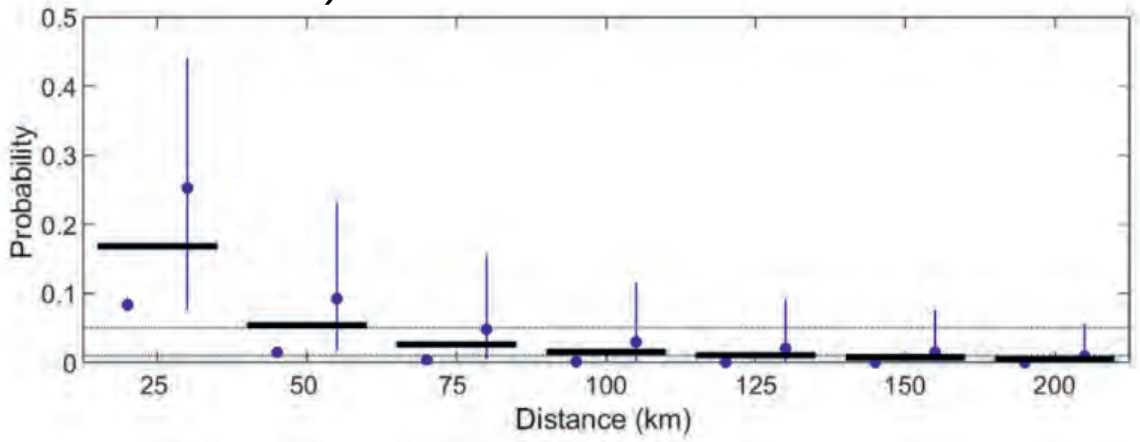
African Horse Sickness

Duration of monitoring period

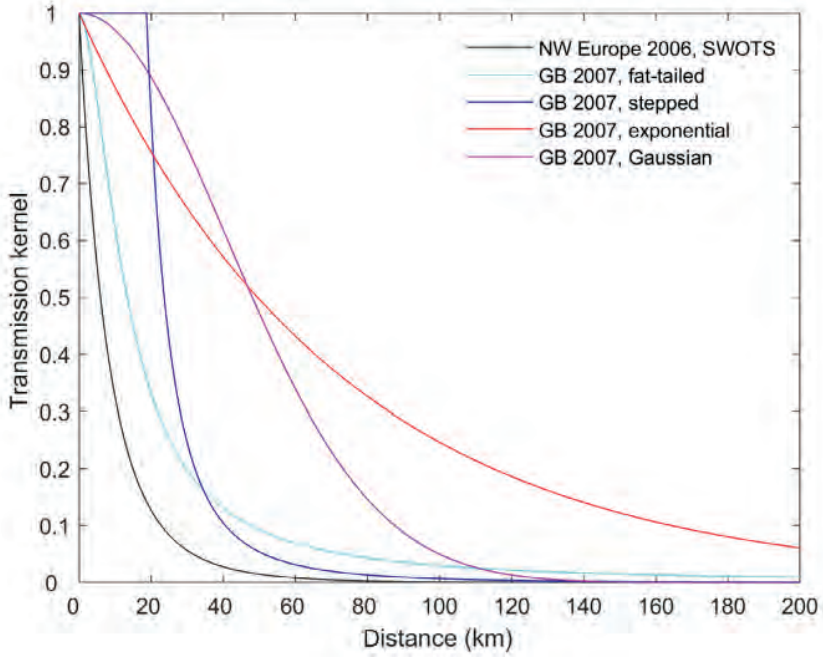
Period (days)	Ref.	n	Median	Mean	Min	Max
First suspicion* and suspicion report	Portas et al. (1999), OIE (2012), Weyer et al. (2012), Grewar et al. (2013), OIE (2020a,c)	5	0	9	0	30
First suspicion* and confirmation	Rodriguez et al. (1992)	1	11	11	11	11
Suspicion report and confirmation	Portas et al. (1999), OIE (2012), Weyer et al. (2012), Grewar et al. (2013), OIE (2020a,b,c)	6	3	4	2	7

*: Based on the first observed clinical signs of AHS or first death.

Probability of transmission beyond a given distance (if transmission were to occur from an infected establishment)



Minimum radius – transmission kernel of BTV by Culicoides



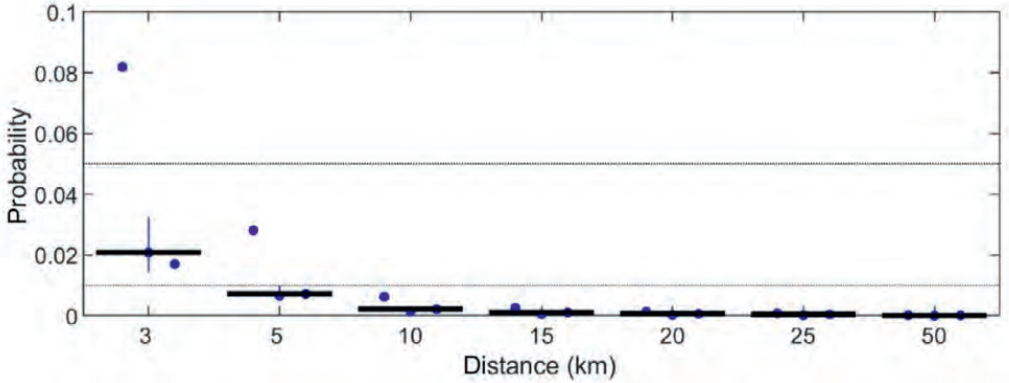
African Swine Fever

Parameters for modelling ASFV transmission (CSFV)

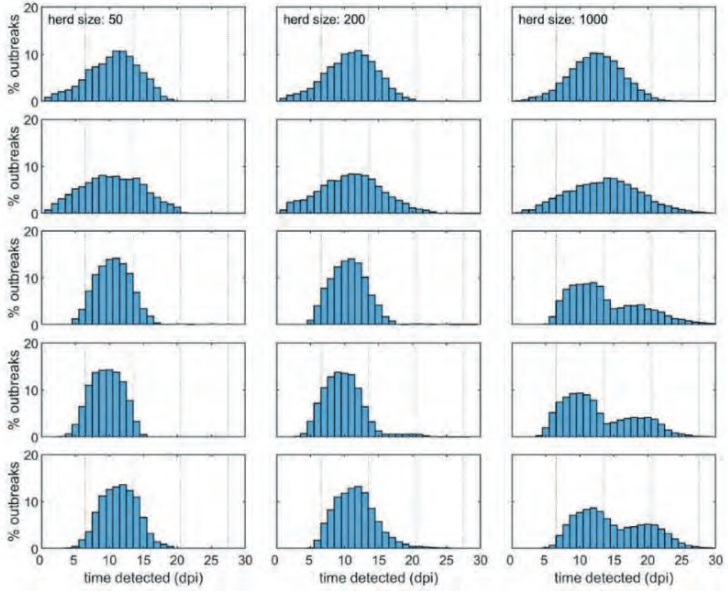
Disease scenario	R_0	β	μ_E	k_E	μ_I	k_I	Case fatality (%)
1. Malta 1978	20.4	2.8	5.0	10†	7.3	10†	25
2. The Netherlands 1986	8.1	0.9	5.0	10†	9.0	20†	50
3. Georgia 2007, low	4.8	0.7	6.1	18	6.9	20	100
4. Georgia 2007, medium	13.2	2.2	9.7	28	6.0	25	100
5. Georgia 2007, high	17.4	2.2	9.0	23	7.9	22	100

†: Assumed values based on ranges reported in de Carvalho Ferreira et al. (2013).
R_0 – reproduction ratio.
β – transmission rate.
μ_E – mean latent period.
k_E – shape parameter for gamma-distributed latent period.
μ_I – mean infectious period.
k_I – shape parameter for gamma-distributed infectious period.

Probability of transmission from an infected establishment beyond a given distance

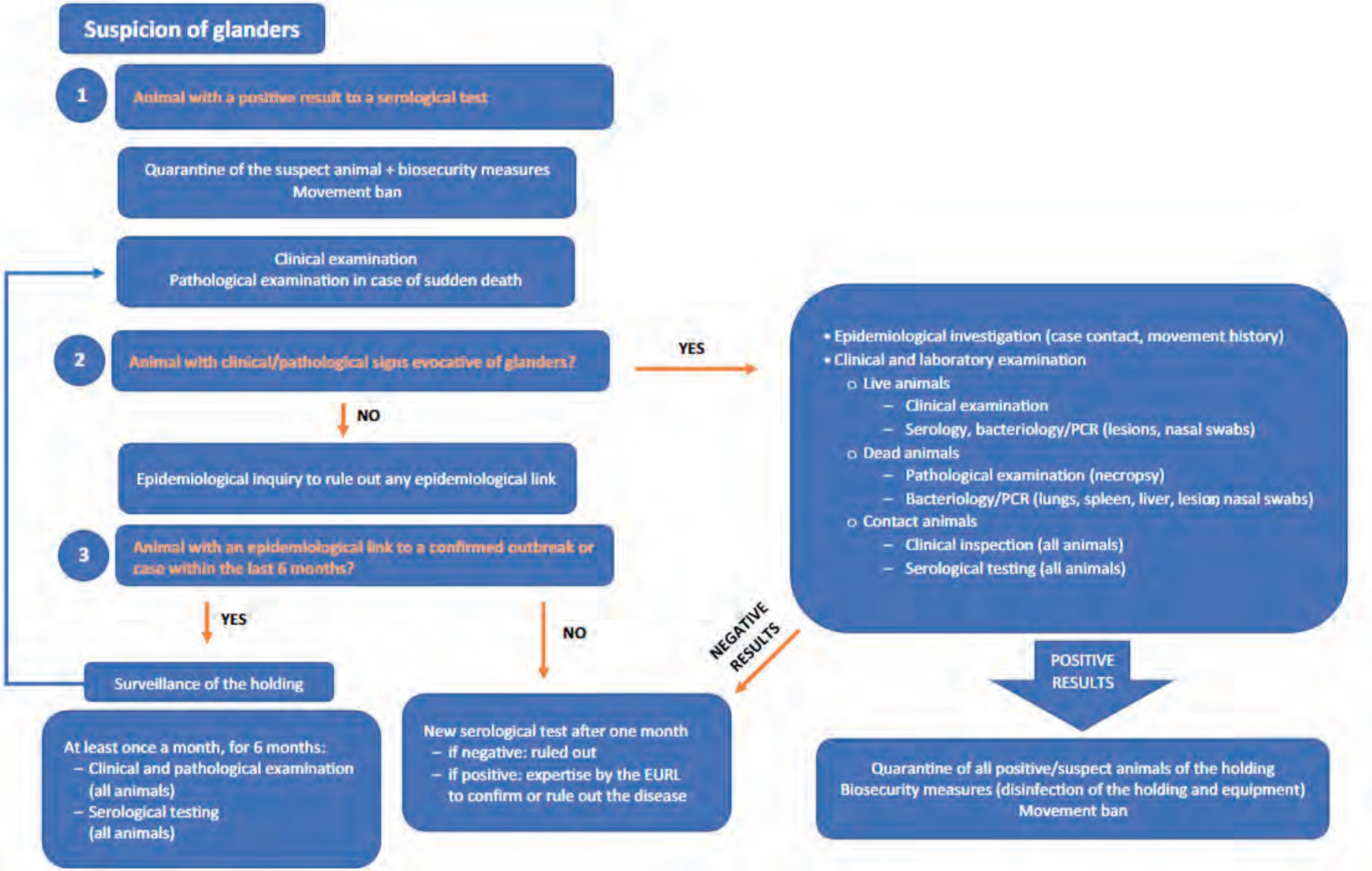


Simulated time-to-detection testing 2 dead pigs/week



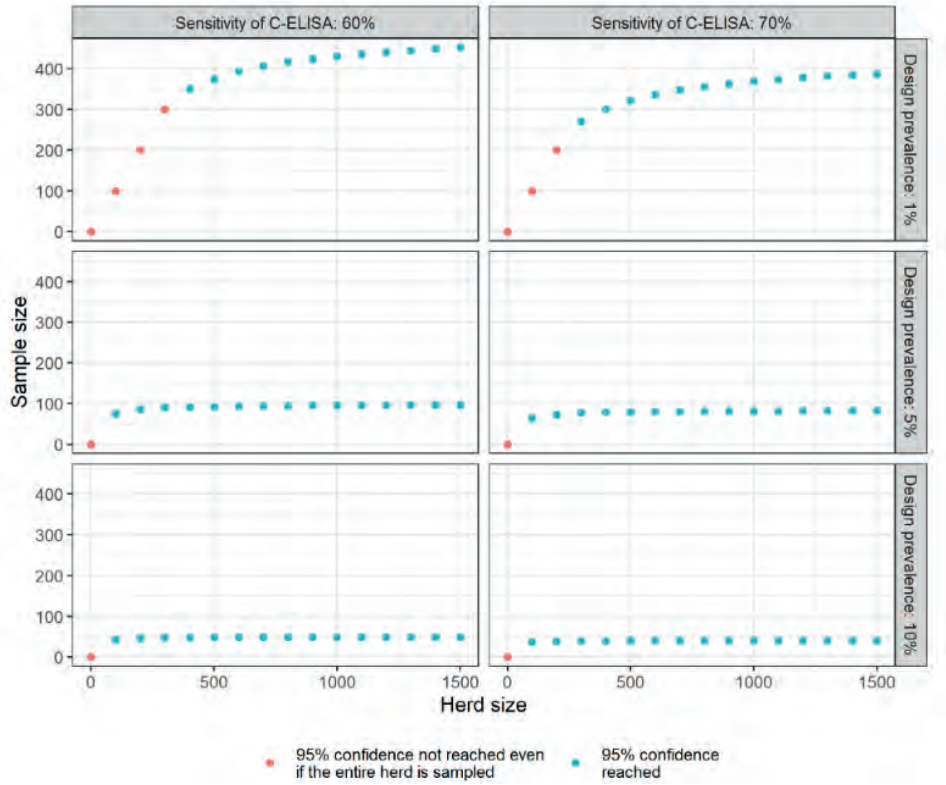
Reference	Country	Outbreak year	Period between earliest point of infection and suspicion report (days)
Animal Health - Regulatory Committee (2014)	Lithuania	2014	18[1]
Nurmoja et al. (2020)	Estonia	2015–2017	11 (7–20)[2]
Animal Health - Regulatory Committee (2016)	Lithuania	2016	3; 9[3]
OIE Standing Group of Experts on African swine fever in Europe (2017)	Romania	2017	5[4]
Lamberga et al. (2020)	Latvia	2017–2018	13; 22[5]
Animal Health - Regulatory Committee (2018)	Romania	2018	5[4]
Zani et al. (2019)	Bulgaria	2018	23[5]
Nielsen et al. (2017)	Denmark	NA	13–19[6]
Andraud et al. (2019)	France	NA	11; 15[6]

Burkholderia mallei / Glanders



Contagious bovine pleuropneumonia

Minimum number of animals needed to be sampled



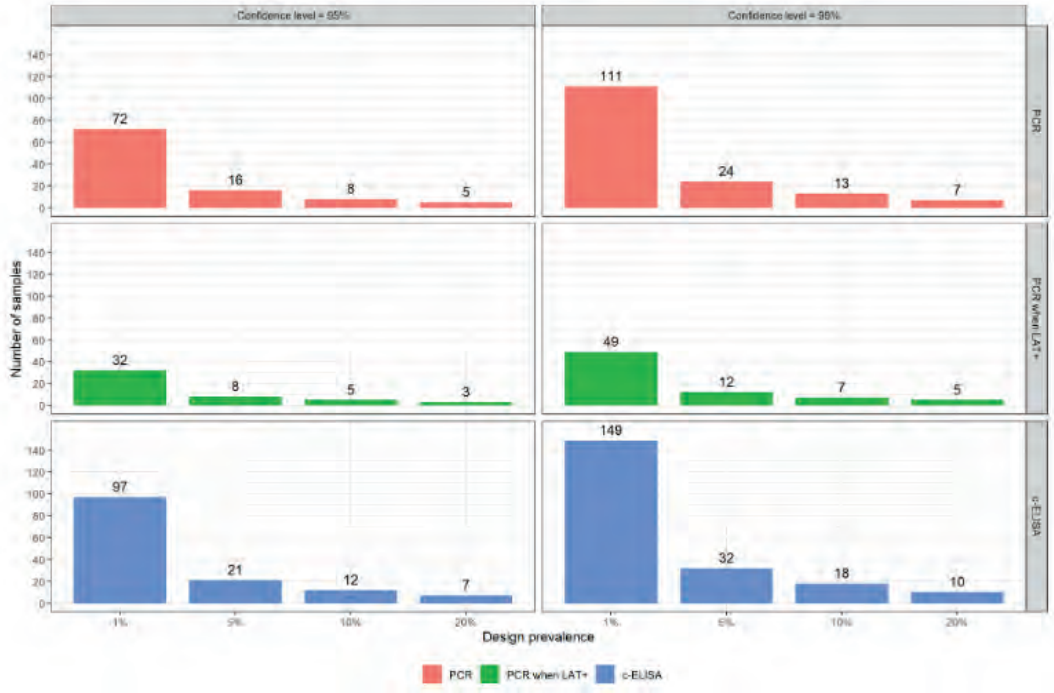
Duration of monitoring period – period between earliest point of infection and suspicion report

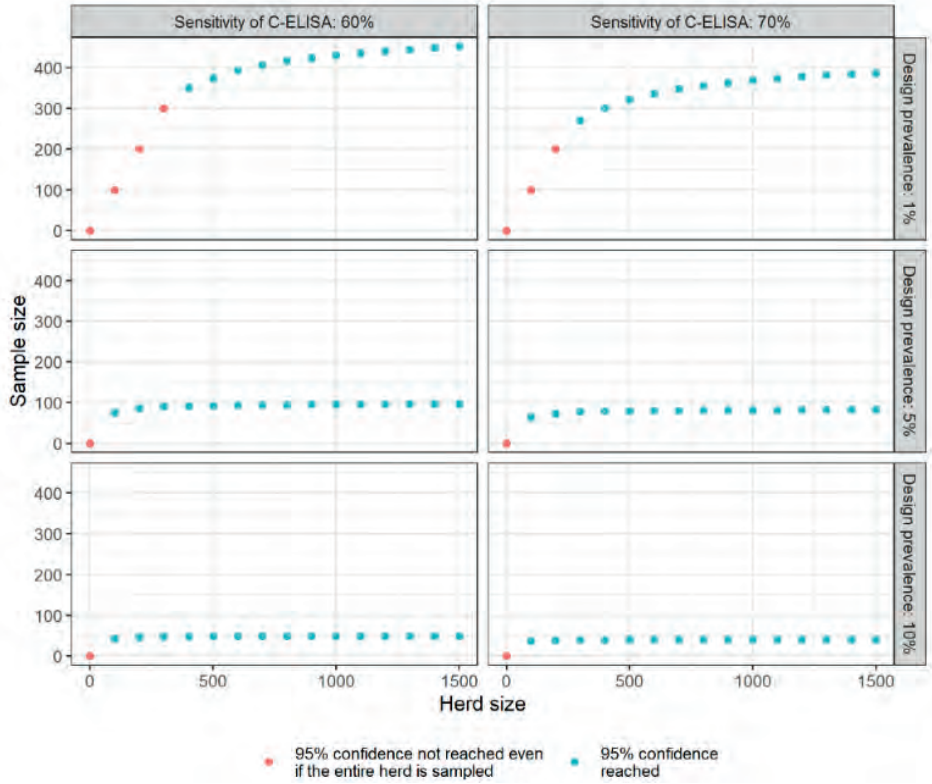
Reference	Country	Year	Host/Breed	Period (days)
ProMED (2003)	Eritrea	2002	Cattle/Raya-Azebo	61(1)
ProMED (2004)	Democratic Republic of Congo	2004	Cattle/Ankole longhorn	108(1)

(1): Primary outbreak.

Contagious caprine pleuropneumonia

Minimum number of animals needed to be sampled



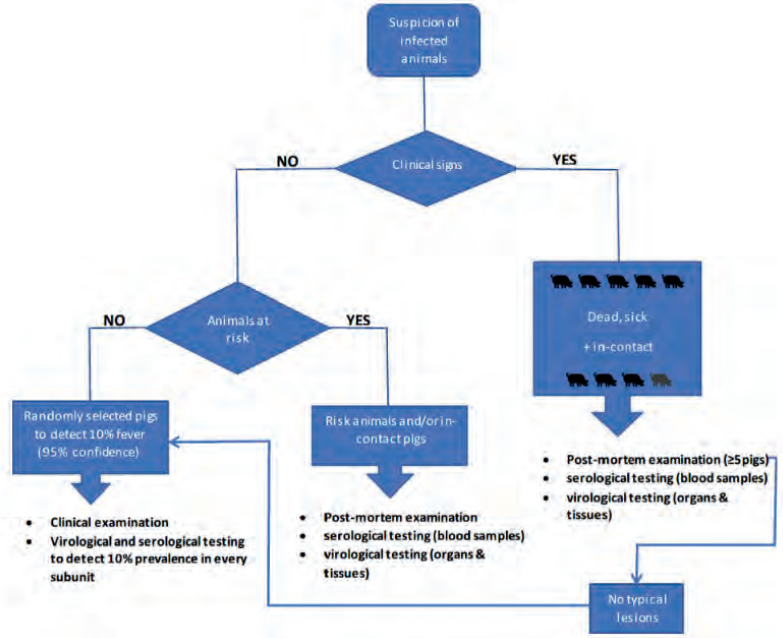


Duration of monitoring period – period between earliest point of infection, suspicion and confirmation

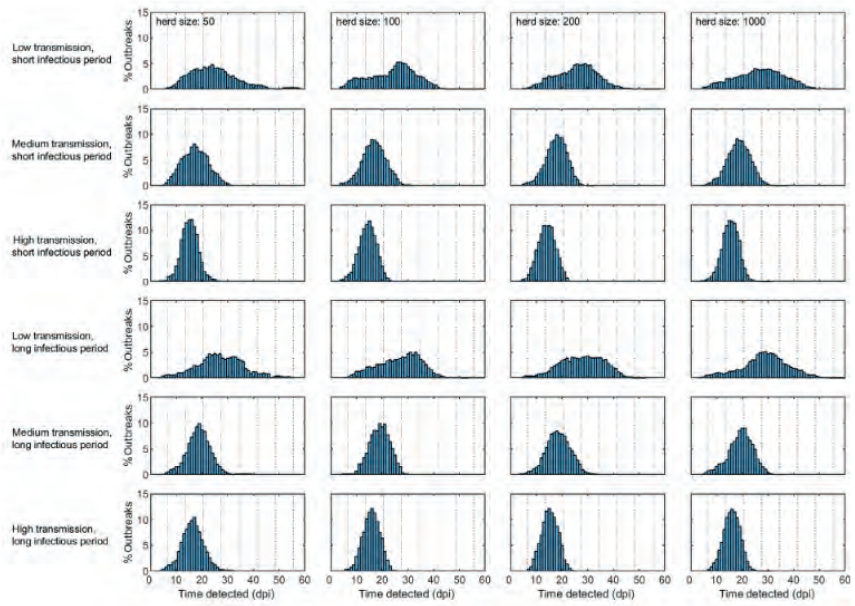
Period (days)	Ref.	Country	Year	Host	Period (days)
Earliest point of infection and first suspicion[(1)]	Kusiluka et al. (2000)	Tanzania	1999	Goat	7[(3)]
First suspicion[(1)] and suspicion report[(2)]	Lignereux et al. (2018)	United Arab Emirates	2013	Captive sand gazelle (*Gazella marica*)	2[(3)]
First suspicion[(1)] and confirmation	(ProMED, 2009)	Mauritius	2009	Goat	90

Classical swine fever

Diagnostic procedure for CSF confirmation



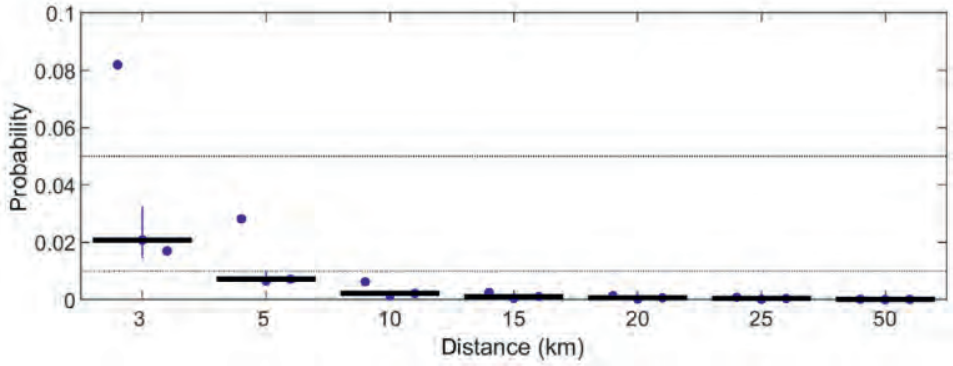
Simulated time-to-detection testing 2 dead pigs/week



Period between earliest point of infection and suspicion report

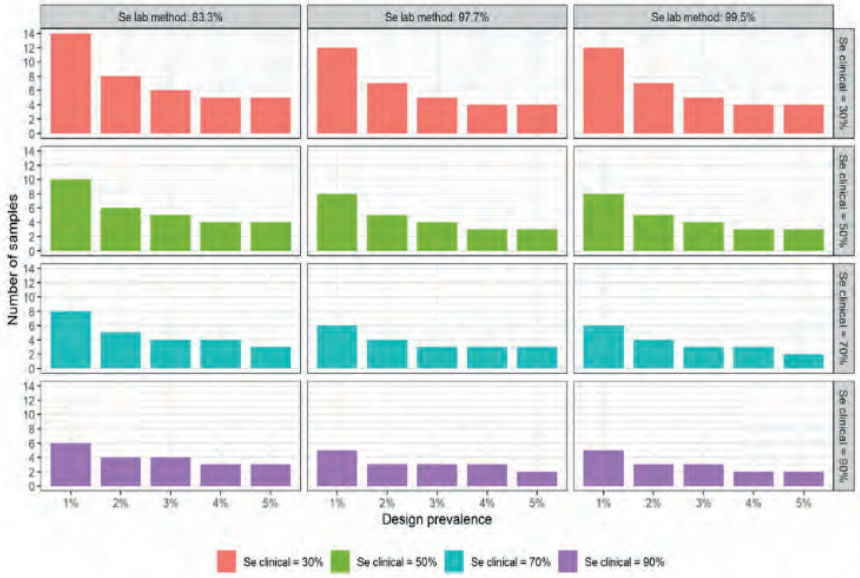
Reference	Country	Year	Species/farm type	Period (days)
Elbers et al. (1999)	Netherlands	1992	Pig/NA	42[1]
Laevens et al. (1998)	Belgium	1993	Pig/fattening	18[2]
Elbers et al. (1999)	Netherlands	1997	Pig/mixed Insemination center	42[3] 30[4]
Elbers et al. (1999)	Germany	1997	Pig/NA	56[1]
Elbers et al. (1999)	Spain	1997	Pig/NA	63[1]
Mintiens et al. (2001)	Belgium	1997	Pig/fattening	19[5]
Moennig et al. (2013)	Germany	2006	Pig/NA	70[6]
David et al. (2011) OIE (2009)	Israel	2009	Pig/closed	21[7]

Probability of transmission from an infected establishment beyond a given distance

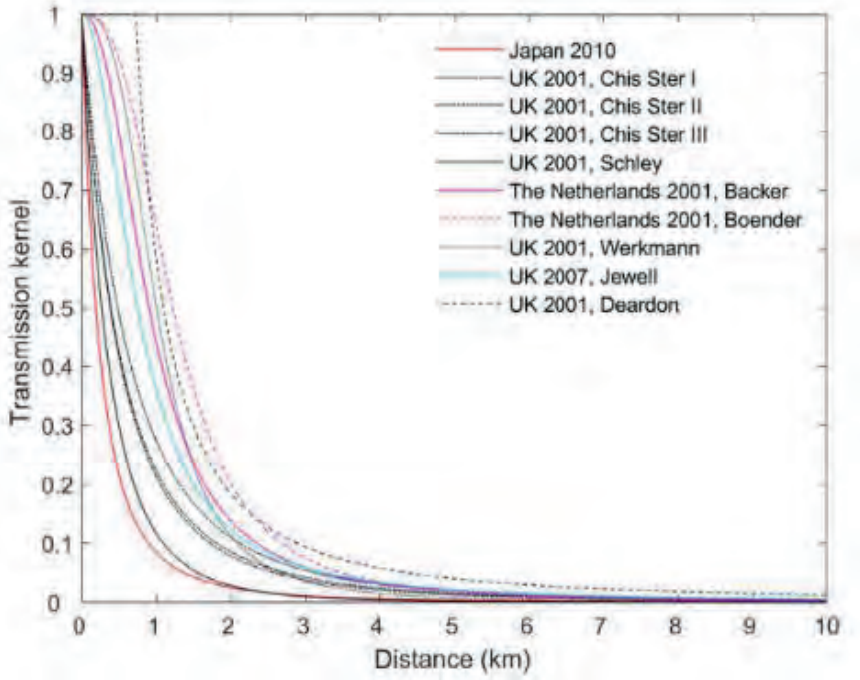


Foot and Mouth Disease

Minimum sample size for detection



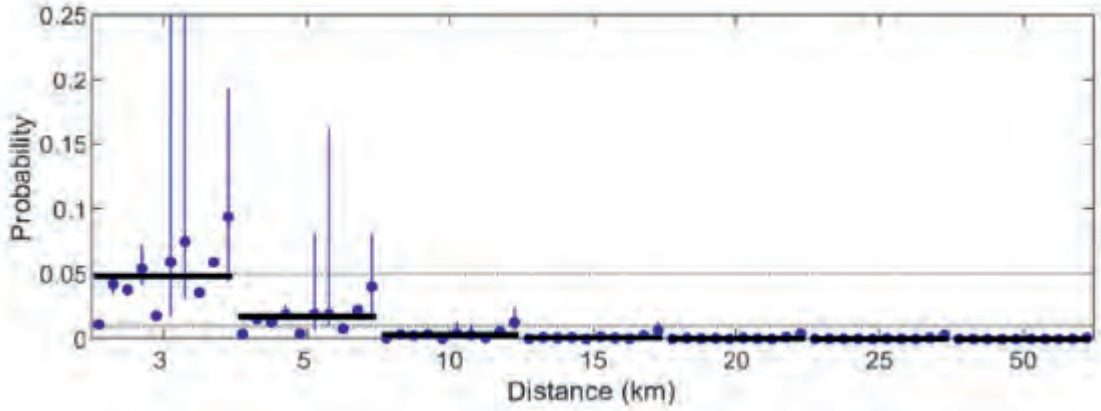
Transmission kernels



Period between earliest point of infection and suspicion report

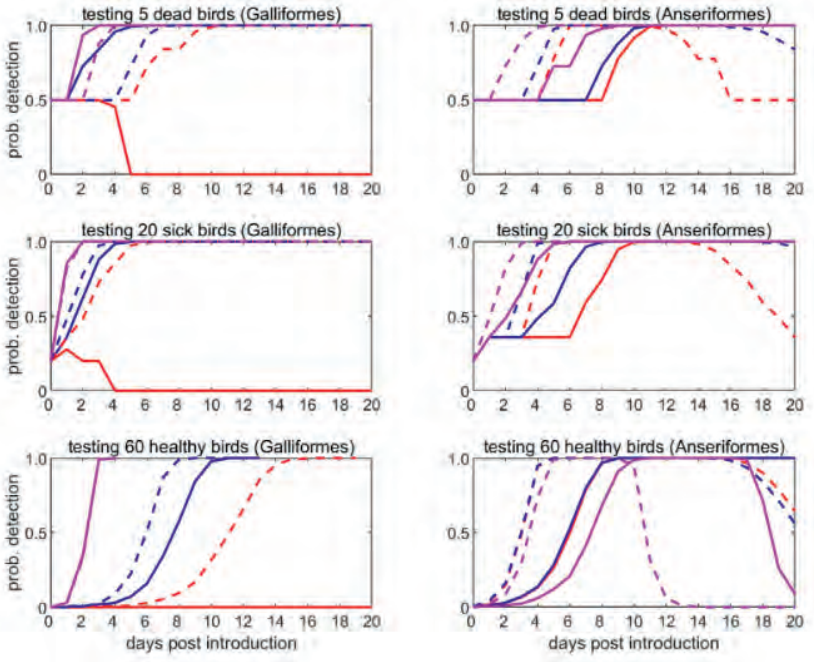
Reference	Country	Outbreak year	Species	Period between earliest point of infection and suspicion report (days)
Gibbens et al. (2001)	United Kingdom	2001	Pig	21[1]
Ferguson et al. (2001)	United Kingdom	2001	Cattle Sheep	8[1] 9.51
Alexandersen et al. (2003a)	United Kingdom	2001	Cattle	6–26[2]
EuFMD (2001)	France	2001	Cattle	14[3]
Bouma et al. (2003)	Netherlands	2001	Goat	19[4]
Ryan et al. (2008)	United Kingdom	2007	Cattle	8–13[5]
DEFRA (2007b)	United Kingdom	2007	Cattle	7–20[2]
DEFRA (2007a)	United Kingdom	2007	Cattle	6–18; 11–23[2]
EFSA AHAW Panel (2012)	Bulgaria	2011	Cattle	6–18[2]
Rautureau et al. (2012)	France	NA	Cattle, pig, sheep and goat	6–14[6]

Probability of transmission from an infected establishment beyond a given distance

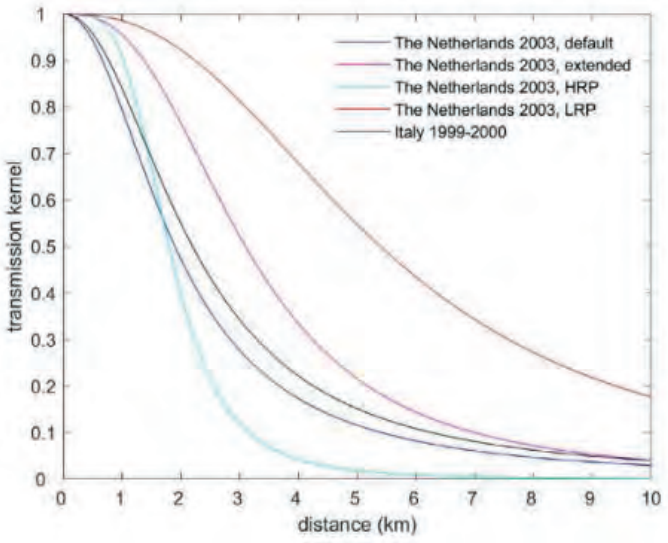


Highly Pathogenic Avian Influenza

Probability of detection



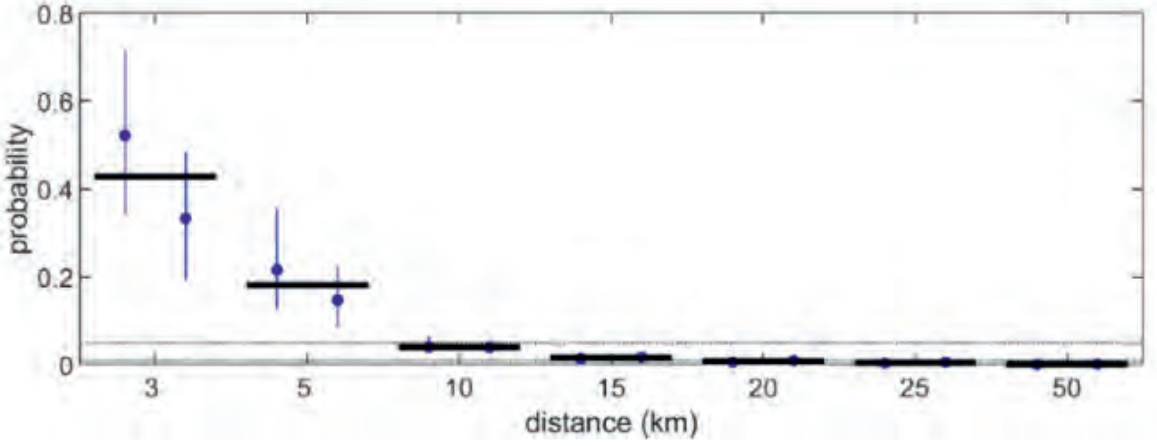
Transmission kernels



Period between earliest point of infection and suspicion report/confirmation

Reference	Country	Outbreak year	Species	Period between earliest point of infection and suspicion report (days)
Bos et al. (2007)	Netherlands	2003	Chickens	12[(1)]
Hobbelen et al. (2020)	Netherlands	2014 2016 2016	Chickens Chickens Ducks	9.8; 11.8; 14.8[(2)] 5.9; 7.4[(2)] 9.5; 14.5; 18.8[(2)]
APHA (Animal & Plant Health Agency) (2015)	United Kingdom	2015	Chickens	11[(3)]

Probability of transmission from an infected establishment beyond a given distance



Lumpy Skin Disease

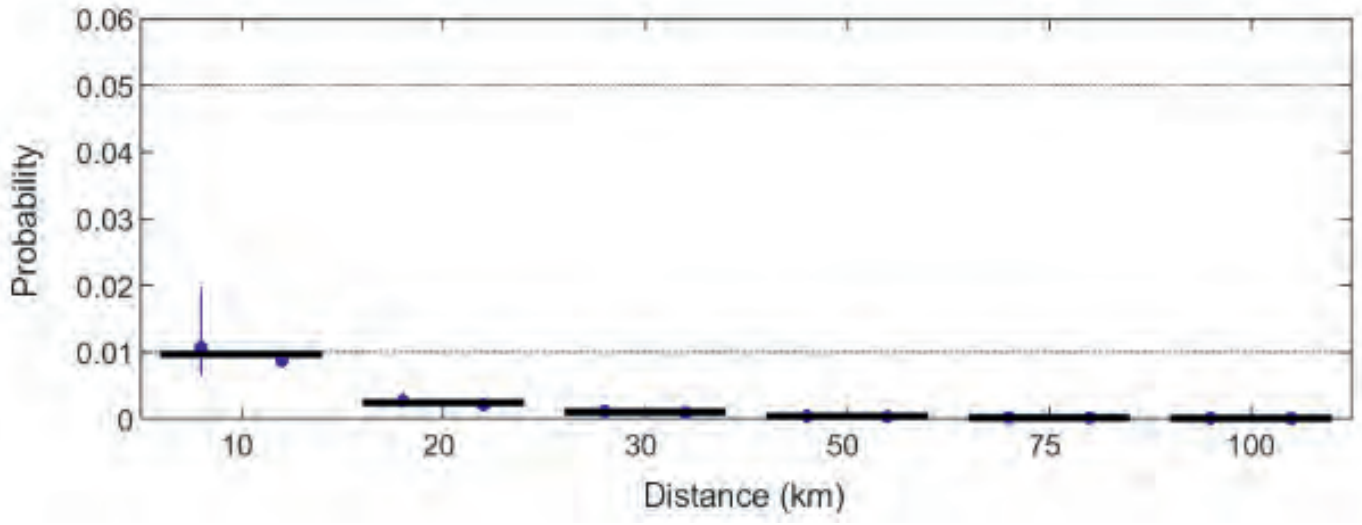
Antibody detection experimental studies

Laboratory method	Type of inoculation	First day of antibody detection*	References
Antibody detection with ID Screen Capripox Double Antigen (DA) ELISA	Vector Feeding	22	EURL for Capripox**
	IVI and IDI	14–28	Moller et al. (2019)
	IVI	17–28	Wolff et al. (2020)
Antibody detection with Virus Neutralization technics (VNT)	Vector Feeding	14	Issimov et al. (2020)
	Vector Feeding	17–31	Sohier et al. (2019)
	IDI	13–19	Sohier et al. (2019); EURL for Capripox**
	IVI and IDI	14	Moller et al. (2019)
	IVI	17–28	Wolff et al. (2020)
	IVI	21	Babiuk et al. (2008)
	IVI	12–18	Irons et al. (2005)
	AI with infected semen	20–27	Annandale et al. (2014)
Antibody detection with IPMA	Vector Feeding	15–29	EURL for Capripox**
	IDI	8–13	EURL for Capripox**
Antibody detection with indirect immunofluorescence test (iIFT)	IVI and IDI	7–14	Moller et al. (2019)

Period between earliest point of infection and suspicion report/confirmation

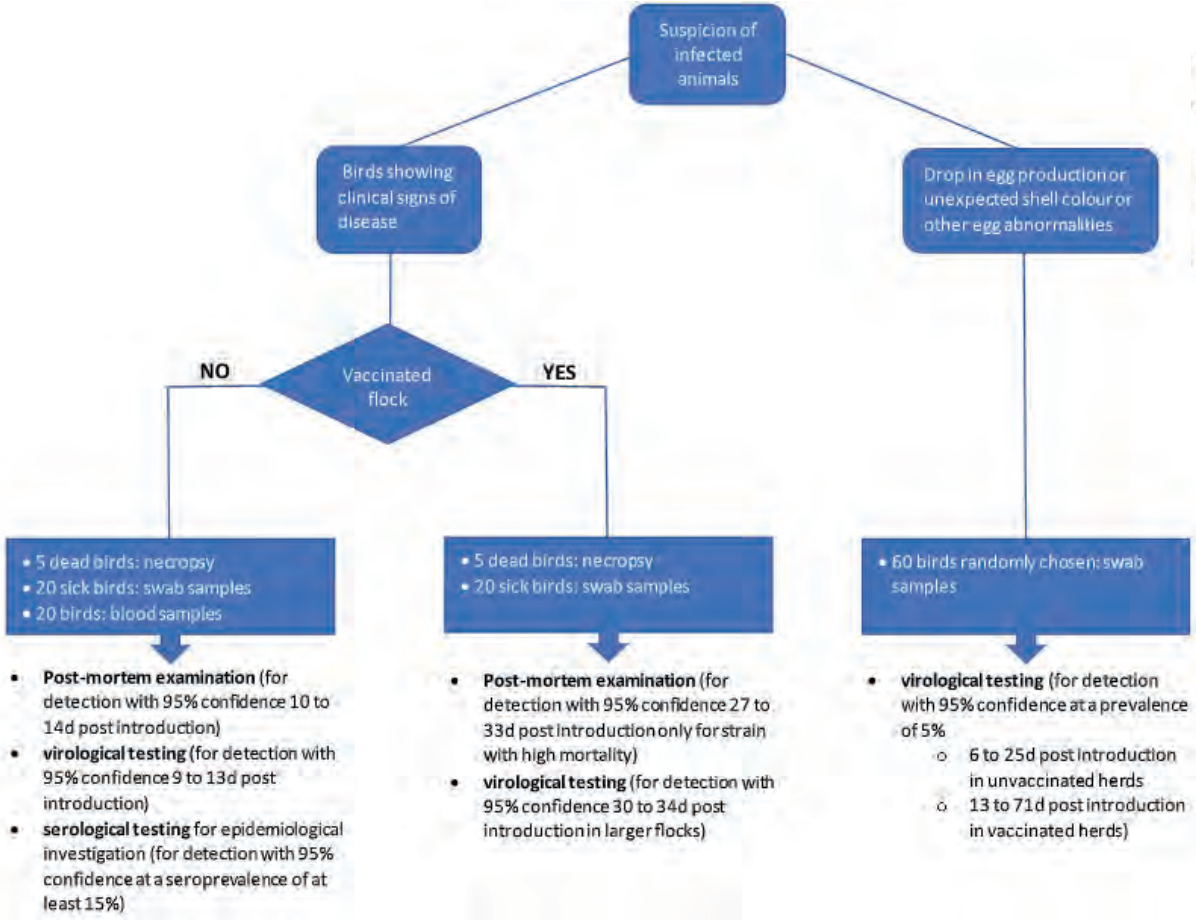
Reference	Country	Outbreak year	Period between earliest point of infection and suspicion report (days)
EFSA (2017)	Turkey	2014	20[1]
EFSA AHAW Panel (2016)	Greece	2015–2016	11[2]
Animal Health - Regulatory Committee (2016c)	Greece	2016	32–42[3]
Animal Health - Regulatory Committee (2016b) and Miteva et al. (2017)	Bulgaria	2016	12–27[4]
Animal Health - Regulatory Committee (2016a)	North Macedonia	2016	14[5]
EFSA AHAW Panel (2015a)	Greece	NA	7–15[6]
EFSA (2018)	Greece and Bulgaria Albania	NA NA	21–22[7] 15–30[7]
Saegerman et al. (2018)	France	NA	30[8]

Probability of transmission from an infected establishment beyond a given distance



Newcastle Disease

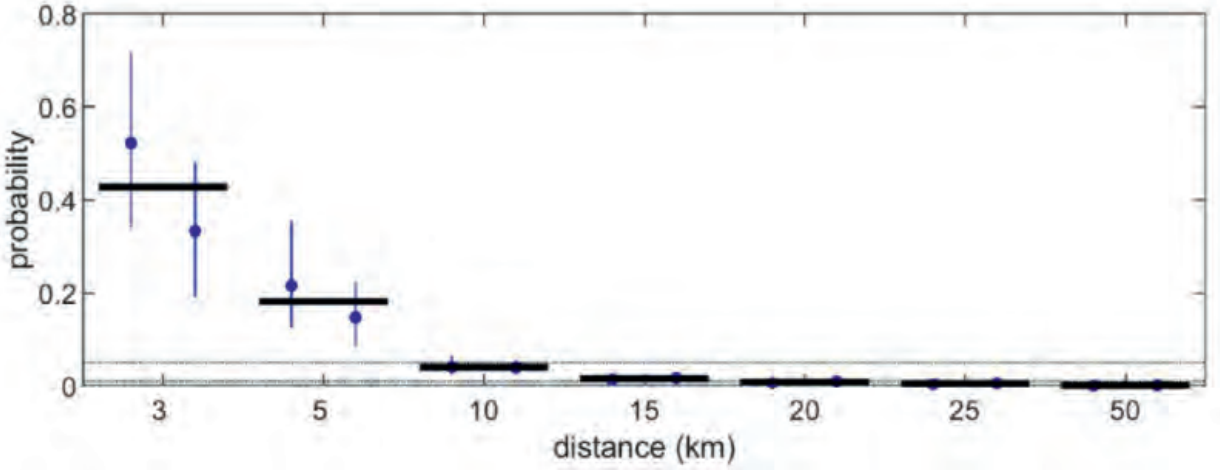
Suggested sampling procedure for ND confirmation



Period between earliest point of infection and suspicion report

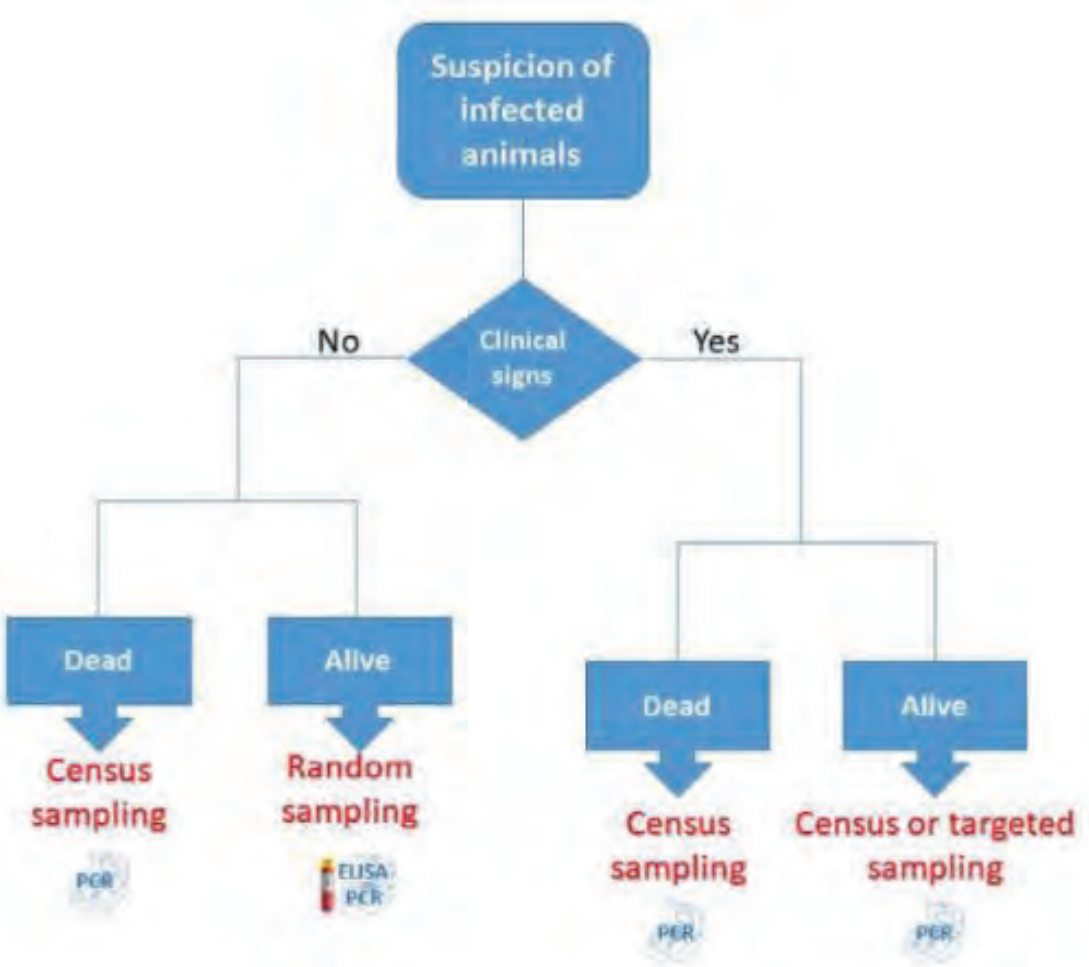
Reference	Country	Year	Species/Farm type	Period (days)
ProMED (2005)	United Kingdom	2005	Pheasant/Game	20(1)
PAFF (2015)	Romania	2015	Chicken/Indoor broiler	23(2)
PAFF (2018)	Belgium	2018	Chicken/Hobby	3(3)
PAFF (2019)	Romania	2019	Chicken/Rearing layer	21(4)

Probability of transmission from an infected establishment beyond a given distance



Peste des Petits Ruminants

Diagnostic procedure for PPR detection



Probability of transmission from an infected establishment beyond a given distance

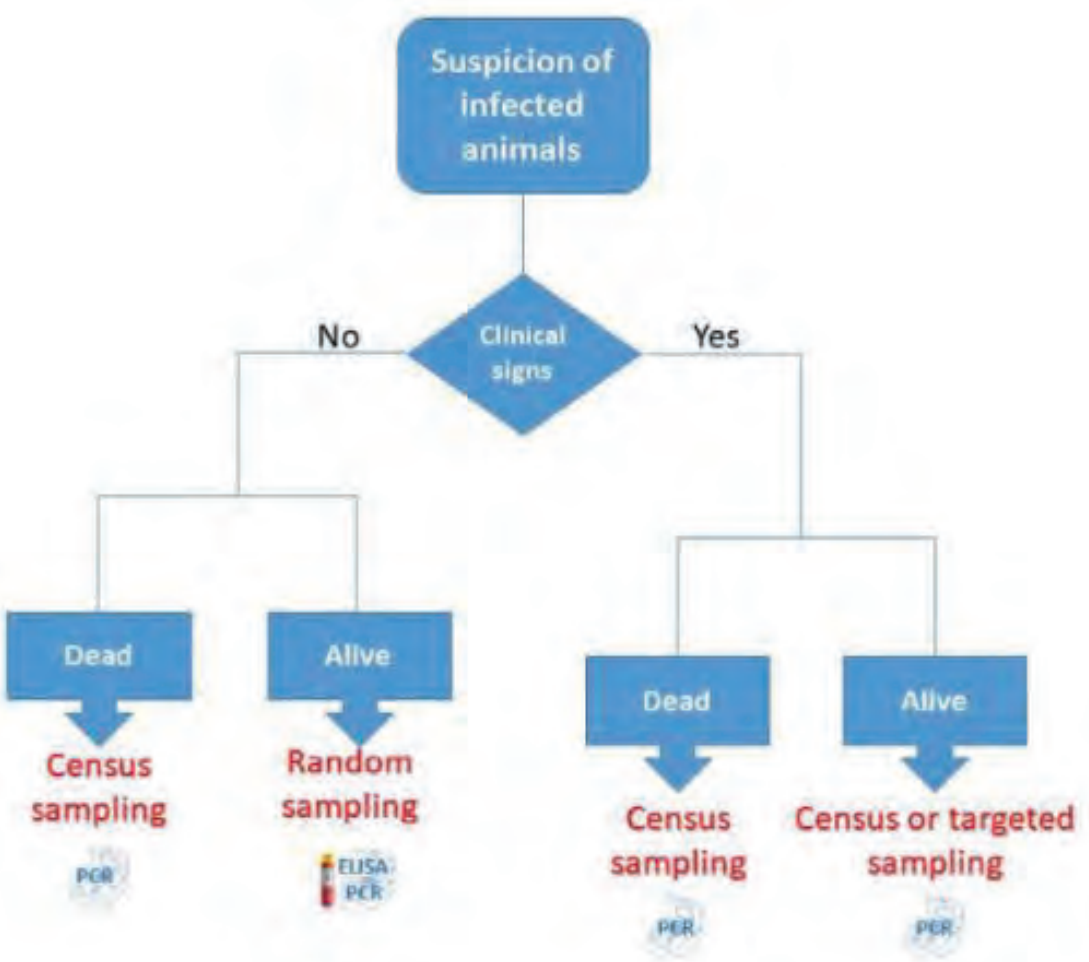
	Distance (km)						
	3	**5**	**10**	**15**	**20**	**25**	**50**
Estimate	0.096	0.054	0.023	0.014	0.010	0.007	0.003
Lower 95% CI	0.031	0.019	0.010	0.007	0.005	0.004	0.002
Upper 95% CI	0.258	0.145	0.055	0.028	0.017	0.011	0.003

Period between first clinical signs and suspicion report

Period (days)	**Reference**	**Country**	**Year of outbreak**	**How duration was calculated**	**Minimum value**	**Maximum value**
From first suspicion* to suspicion report	EFSA AHAW Panel (2015)	China	2014	Date report minus date first clinical signs (days)	23	23
	OIE (2016)	Georgia	2016	Date report minus date first clinical signs (days)	14	
	PAFF (2018)	Bulgaria	2018	NA (Reported as such)	10	15

Rinderpest

Diagnostic procedure for RP detection



Probability of transmission from an infected establishment beyond a given distance

	Distance (km)						
	3	**5**	**10**	**15**	**20**	**25**	**50**
Pakistan 1994	9.9	2.1	0.1	< 0.1	< 0.1	< 0.1	< 0.1

Period between earliest point of infection and suspicion report

Reference	Country	Year	Species/Type	Period (days)
OIE (1996a)	Turkey	1996	*B. taurus*/fattening	4[(a)]
OIE (1996b)	Kenya	1996	*B. taurus*/pastoral	16[(a)]
OIE (1998)	Russia	1998	*B. taurus*/NA	13[(a)]

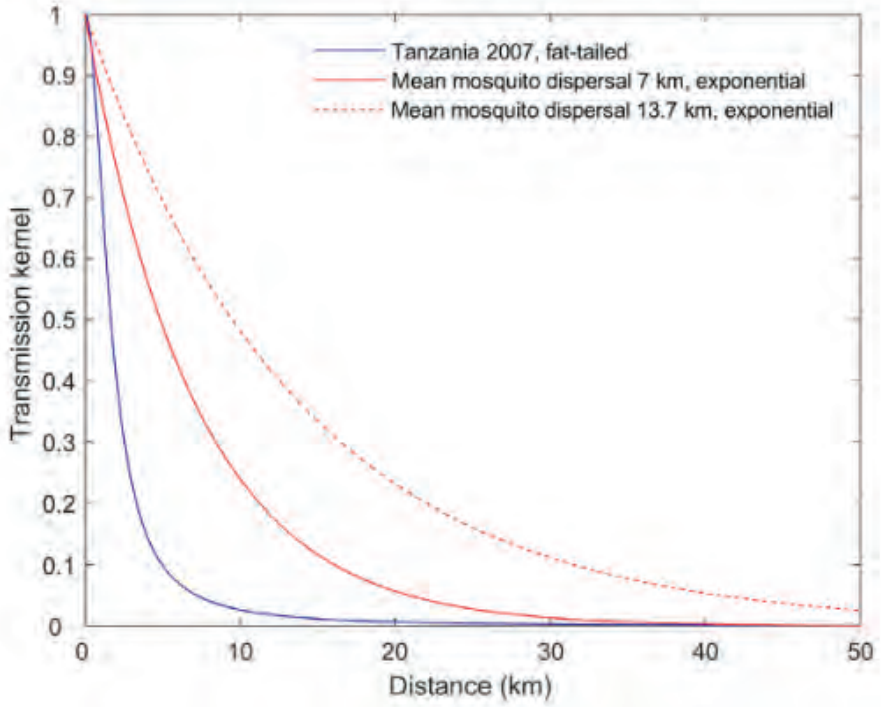
Rift Valley Fever

Period between earliest point of infection and suspicion report – outbreak data

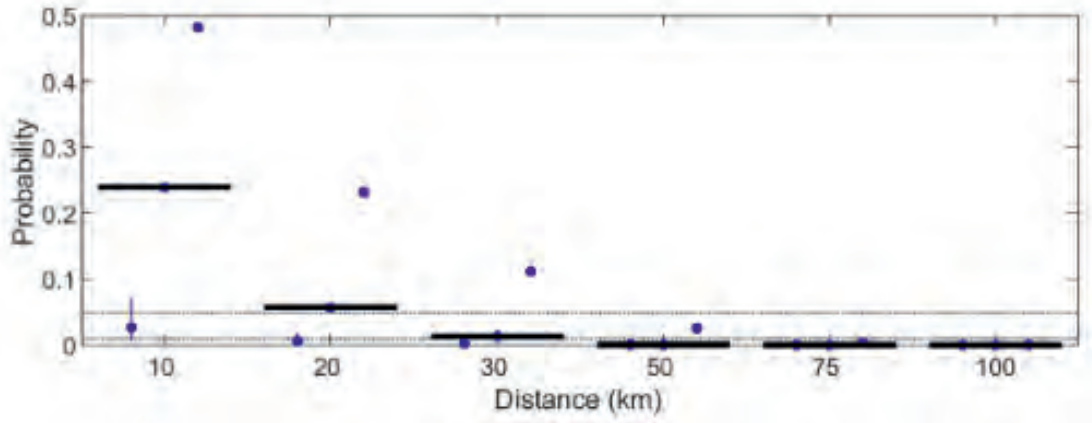
Reference	Country	Year	Host animal/Farm type	Period (days)
Mapaco et al. (2012b)	South Africa	2008	Cattle/dairy	18(1)

Period between earliest point of infection and suspicion report – simulation data

Reference	Country	Year	Species/farm type	Period (days)
(EFSA AHAW Panel et al., 2020b)	EU (Netherlands)	NA	NA	20(1)



Probability of transmission from an infected establishment beyond a given distance



Sheep and goat pox

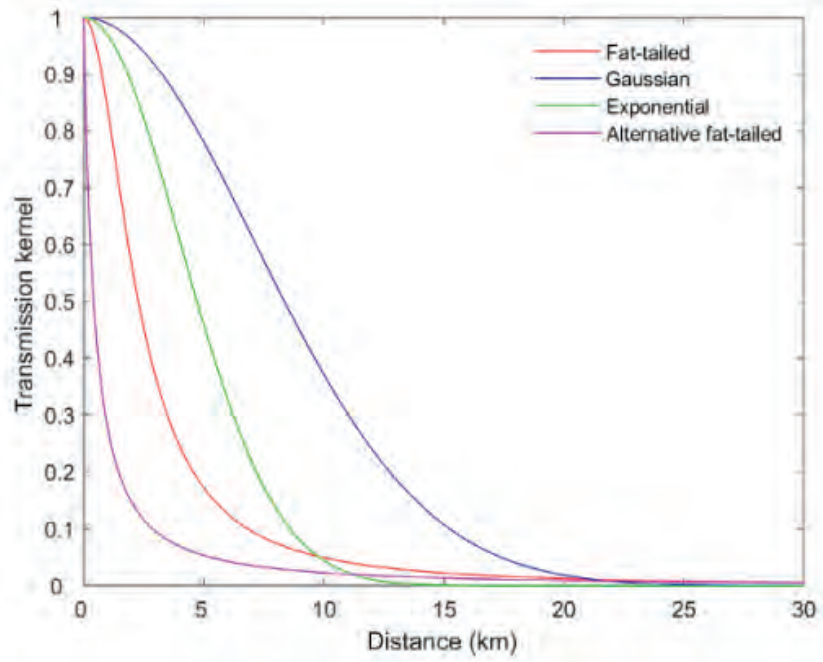
Period between earliest point of infection and suspicion report

Reference	Country	Year	Species	Period (days)
SCoFCAH (2013a,b)	Greece	2013	Sheep	14[1]
SCoFCAH (2014)	Bulgaria	2013	Sheep	2[2]

Probability of transmission from an infected establishment beyond a given distance

	Distance (km)						
	3	5	10	15	20	25	50
Estimate (median)	0.096	0.054	0.023	0.014	0.010	0.007	0.003
Lower 95% CI	0.031	0.019	0.010	0.007	0.005	0.004	0.002
Upper 95% CI	0.258	0.145	0.055	0.028	0.017	0.011	0.003

Transmission kernels



Outputs

- Methodological approach

- African Horse Sickness
- African Swine Fever
- *Burkholderia mallei* (Glanders)
- Contagious Bovine Pleuropneumonia
- Contagious Caprine Pleuropneumonia
- Classical Swine Fever
- Foot and Mouth Disease
- Highly Pathogenic Avian Influenza
- Lumpy Skin Disease
- Newcastle Disease
- Peste des Petits Ruminants
- Rinderpest
- Rift Valley Fever
- Sheep and Goat Pox