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Assessment of the control measures of the category A diseases of Animal Health Law: peste des petits ruminants

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Abstract

EFSA received a mandate from the European Commission to assess the effectiveness of some of the control measures against diseases included in the Category A list according to Regulation (EU) 2016/429 on transmissible animal diseases ('Animal Health Law'). This opinion belongs to a series of opinions where these control measures will be assessed, with this opinion covering the assessment of control measures for peste des petits ruminants (PPR). In this opinion, EFSA and the AHAW Panel of experts review the effectiveness of: (i) clinical and laboratory sampling procedures, (ii) monitoring period and (iii) the minimum radii of the protection and surveillance zones, and the minimum length of time the measures should be applied in these zones. The general methodology used for this series of opinions has been published elsewhere; nonetheless, the transmission kernels used for the assessment of the minimum radii of the protection and surveillance zones are shown. Several scenarios for which these control measures had to be assessed were designed and agreed prior to the start of the assessment. The monitoring period of 21 days was assessed as effective, except for the first affected establishments detected, where 33 days is recommended. It was concluded that beyond the protection (3 km) and the surveillance zones (10 km) only 9.6% (95% CI: 3.1–25.8%) and 2.3% (95% CI: 1–5.5%) of the infections from an affected establishment may occur, respectively. This may be considered sufficient to contain the disease spread (95% probability of containing transmission corresponds to 5.3 km). Recommendations provided for each of the scenarios assessed aim to support the European Commission in the drafting of further pieces of legislation, as well as for plausible ad-hoc requests in relation to PPR.

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Summary

This opinion is part of a series of opinions, in which the three first Terms of Reference (ToR) of a mandate received from the European Commission have been considered. The background and specific details of this mandate can be found in the opinion. The ToRs in this mandate request an assessment of the effectiveness of:

- the clinical and laboratory examination in their capacity to detect disease (or estimate the disease prevalence within an establishment), either in suspect or confirmed animals in a single establishment, or in establishments within restriction zones (ToR 1);
- the effectiveness of the duration of the monitoring period (for different scenarios) in the control of suspected and confirmed outbreaks (ToR 2);
- the size (ToR 3.1) and duration (ToR 3.2) of the restriction zones, in their capacity for mitigating disease spread.

In order to harmonise the approach to these assessments, the methodology used in this series of opinions, covering all Category A diseases, was agreed on, and published in a separate technical report.

Specific clinical and laboratory procedures for peste des petits ruminants (PPR) for each scenario of ToR 1 have been assessed. For assessing the effectiveness of detecting PPR in a herd, a model to study the within herd transmission of PPR was designed. This allowed the calculation of infection and seroprevalence at different points in time from PPR introduction in a herd, so to calculate the sample size needed for early detection of suspected animals in an infected flock.

With a suspicion of PPR in an establishment, the purpose of the clinical examination based on detection of clinical signs related to PPR, is to identify potentially infected animals in order to target the sampling correctly. The confirmation of a clinical suspicion is based on laboratory testing, mainly by confirming the presence of the virus nucleic acids (RT-PCR) or of antibodies (ELISA test).

To answer ToR 2, the assessment of the length of the monitoring period, and to assess the minimum duration of measures to be implemented in the protection and surveillance zones (ToR 3.2), an extensive literature search (ELS) was carried out. This ELS aimed to assess the average, shortest, and longest period between the earliest point of infection of small ruminants with PPR virus (PPRV) and the time of reporting of a suspicion by the competent authority. Twenty-one days as defined in the Delegated Regulation is considered effective for all scenarios mentioned in ToR 2, except for the first affected establishments detected in an area, where a monitoring period of 33 days is recommended.

Based on the assessment, the minimum period of 21 days indicated in the Delegated Regulation for the restriction measures being in place in the protection zone is considered effective to detect infected establishments and to prevent the movement of infected animals from the protection zone. The minimum period of 30 days indicated in the Delegated Regulation for the restriction measures in the surveillance zone should be extended up to 33 days, so to detect infected establishments and to prevent the movement of infected animals from the surveillance zone.

To assess the effectiveness of the minimum radius to be implemented in the protection and surveillance zones (ToR 3.1), transmission kernels were used. Because suitable transmission kernels were not available for PPRV in EU situation, those for sheep and goat pox were used as a proxy. These kernels were estimated using data on outbreaks of sheep pox and goat pox reported in the Evros region of Greece from 2013 to 2014. The estimated probability of transmission beyond the protection zone of 3 km radius (as indicated in the Delegated Regulation) from an infected establishment if transmission occurred is 9.6% (95% CI: 3.1–25.8%) and 2.3% (95% CI: 1–5.5%) for 10 km radius (surveillance zone), which may be considered sufficient to contain the disease spread. The 95% probability of containing transmission would correspond to 5.3 km (CI: 1.8–10.6 km). If the aim is to reduce the probability of transmission beyond the surveillance zone to 1%, the radius of this zone should be increased from 10 km to 19 km (95% CI: 9.8–26.8). This, nonetheless, would on average increase the number of farms in the surveillance zone (affected by movement restrictions) fourfold.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EU) 2016/429 on transmissible animal diseases ('Animal Health Law'), hereinafter referred to as AHL, requires the Commission to lay down detailed rules on the disease control measures against listed diseases as referred to in point (a), (b) and (c) of its Article 9 (category A, B and C diseases). The Commission is empowered to adopt delegated acts supplementing the rules laid down in Part III of Regulation (EU) 2016/429 on transmissible animal diseases (Animal Health Law) on disease control measures for listed diseases as referred to in point (a), (b) and (c) of its Article 9 (category A, B and C diseases). Therefore, the Commission has developed and adopted a Delegated Regulation laying down rules for the prevention and control of certain diseases ('the Delegated Regulation'). The rules laid down in the Delegated Regulation are in respect of terrestrial animals largely replicating the rules currently in force concerning the disease control measures in the event of animal diseases with serious effects on the livestock as they have proven to be effective in preventing the spread of those diseases within the Union. Consequently, many animal disease control measures laid down in existing Directives will be, to the extent that not already done by the Animal Health Law, replaced by the rules provided in the Delegated Regulation. At the same time, these rules have been aligned with the international standards from the World Organisation for Animal Health (OIE), wherever these existed. However, certain disease control measures proposed in the Delegated Regulation, in particular in its Annexes, were considered as outdated i.e. possibly not based on most recent scientific evidence at the time of development. Their review is considered as necessary. Moreover, for those category A diseases for which rules were not established before or were not detailed enough, certain disease control and risk mitigating measures are, due to the lack of scientific basis, extrapolated from other diseases, for which rules existed in the past. Finally, for some other diseases the evidence and scientific knowledge, was not available to the Commission and to the Member States at the time of developing the Delegated Regulation due to the time constraints. The following diseases are examples of the later: infection with Rift Valley fever (RVF), infection with *Mycoplasma mycoides* subsp. *Mycoides* SC (Contagious bovine pleuropneumonia) (CBPP), Contagious caprine pleuropneumonia (CCPP), Sheep pox and goat pox, infection with PPR, African horse sickness (AHS), Glanders. In this regard, the existing rules will cease to apply as from the date of application of the Animal Health Law and its complementing legislation including the Delegated Regulation, i.e. from 21 April 2021. Certain of the proposed measures for the prevention and control of category A diseases of terrestrial animals should therefore be assessed in order to ensure that they are effective and updated based on the latest scientific knowledge in this new set of legislation. This is particularly important in the case of those diseases that are less common or have been never reported in the Union.

1.1.1. ToR 1: sampling of animals and establishments for the detection of category A diseases in terrestrial animals

Based on available scientific information, assess the effectiveness of existing sampling procedures to detect or rule out the presence of each category A disease of terrestrial animals and, in case of absence of effective procedures, develop them, in order to complete the rules provided for in Annex I to the Delegated Regulation. In particular, provide for disease-specific procedures for the sampling of:

ToR 1.1 Animals for clinical examinations to ensure the detection of the relevant category A disease during the performance of official investigations in establishments that are affected or suspected to be affected by category A diseases and visits in establishments located in restricted zones in accordance with Articles 6(2), 13(3)(c), 14(1) and 26(2) of the Delegated Regulation.

ToR 1.2 Animals for laboratory examinations to ensure the detection of the relevant category A disease during the performance of official investigations in establishments that are affected or suspected to be affected by category A diseases and visits in establishments located in restricted zones in accordance with Articles 6(2), 12(3), 13(3)(c), 14(1), 26(2) of the Delegated Regulation.

ToR 1.3 Establishments to ensure the detection of the relevant category A disease for the performance of visits in establishments located in protection zones larger than 3 km and establishments located in the surveillance zone in accordance with Articles 26(5) and 41 of the Delegated Regulation.

ToR 1.4 Animals for clinical and laboratory examinations to ensure the detection of the relevant category A disease for the movement of animals from restricted zones in accordance with Articles 28 (5), 43(5), 56(1)(c) of the Delegated Regulation.

ToR 1.5 Animals for laboratory examinations to ensure the detection of the relevant category A disease before and after being introduced in the affected establishment for repopulation, in accordance with Article 59(2), (3) and (9) of the Delegated Regulation.

1.1.2. ToR 2: monitoring period

ToR 2.1 Assess the effectiveness of the length of the monitoring periods set out in Annex II of the Delegated Regulation for each category A disease of terrestrial animals. In this regard, it is important to take into consideration that the monitoring period was introduced as a management tool, which represents a time frame of reference assigned to each category A disease for the competent authority to apply certain control measures and to carry out investigations in the event of suspicion and confirmation of category A diseases in terrestrial animals.

This assessment should be carried out with respect to the following situations:

- a) the records analysis carried out by the competent authority in the framework of the epidemiological enquiry referred to in Article 57 of Regulation (EU) 2016/429, in the event of suspicion of a category A disease (Article 8(4) of the Delegated Regulation);
- b) the derogation from killing in the event of an outbreak of a category A disease in establishments keeping animals of listed species in two or more epidemiological units (Article 13(1) of the Delegated Regulation);
- c) the tracing carried out by the competent authority to identify establishments and other locations epidemiologically linked to an establishment affected by a category A disease (Article 17(2) of the Delegated Regulation);
- d) the exemption applied to certain products from the prohibitions laid down in Annex VI taking into account the date they were produced (Article 27(3)(c) of the Delegated Regulation);
- e) the specific conditions for authorising movements of semen from approved germinal product establishments in the protection and surveillance zones (Article 32(c) and 48(c) of the Delegated Regulation);
- f) the repopulation of establishments affected by a category A disease (Article 57(1)(b) and 59(4)(b) of the Delegated Regulation).

ToR 2.2 Propose the length of what should be the monitoring period in those diseases for which the time is assessed as not effective.

1.1.3. ToR 3: minimum radius of restricted zones and duration of the disease control measures in restricted zones

ToR 3.1 Assess the effectiveness to control the spread of the disease of the minimum radius of the protection and surveillance zones set out in Annex V of the Delegated Regulation for each category A disease of terrestrial animals.

ToR 3.2 Assess the effectiveness to control the spread of the disease of the minimum periods during which the competent authority should apply the restriction measures in the protection and surveillance zones as set out in Annex X and XI for each category A disease of terrestrial animals.

1.1.4. ToR 4: prohibitions in restricted zones and risk-mitigating treatments for products of animal origin and other materials

ToR 4.1 Assess the effectiveness to control the spread of disease of prohibitions set out in Annex VI of the Delegated Regulation with respect to the risk associated for each category A disease, to the listed activities and commodities.

ToR 4.2 Review the available scientific information on risk-mitigating treatments that are effective to control the presence of category A disease agents in products of animal origin and other relevant materials. Based on this:

- a) provide an opinion on the effectiveness of the risk-mitigating treatments for products of animal origin and other materials produced or processed in the restricted zone set out in Annex VII and VIII, and

- b) if relevant, suggest new treatments or procedures that can be effective to mitigate or to eliminate such risk.

1.2. Interpretation of the Terms of Reference

To address the ToRs of the mandate, EFSA proposed and agreed with the European Commission the following:

- a) The publication of 14 individual opinions, one for each of the diseases included in the list of category A diseases for terrestrial animals, with each of these opinions providing the answer to ToRs 1, 2 and 3. The current manuscript is one of the 14 opinions covering ToRs 1, 2 and 3 for PPR.
- b) The publication of a unique opinion covering ToR 4 for all diseases listed (i.e. ToR 4 is not covered in this opinion).
- c) To address ToR 1 (effectiveness of sampling procedures), EFSA agreed with the European Commission on 21 scenarios (based on different articles of the Delegated Regulation¹) for which the effectiveness of the sampling procedures will be assessed (Annexes B and C). Although these scenarios will be assessed independently, some of these scenarios may be merged if the assessment processes are the same.
- d) To address ToR 2 (effectiveness of the monitoring period), seven scenarios previously agreed with the contractor were defined (Annex D). The assessment of the effectiveness of the monitoring period will be done by assessing its ability to ensure that specific actions can be carried out without posing a risk of disease spread, if the monitoring period is calculated backwards or forwards from a specific date (e.g. a 15-day monitoring period would be considered effective if all the epidemiological links of an affected establishment can be traced by an inspection of the establishment records that go 15 days back from the date of the disease confirmation). If the length of the monitoring period estimated by EFSA is longer than the existing monitoring period, the existing monitoring period will be considered non-effective. If the length of the monitoring period estimated by EFSA is shorter than the existing monitoring period, this existing monitoring period will be considered effective from a disease control point of view. No assessment of the plausible unnecessary economic burden that may be placed on the stakeholders as a result of an excessive length of the monitoring periods will be done by EFSA.
- e) The assessment of the minimum duration and the length of the radii of the protection and surveillance zones (ToR 3) will be done independently. The setting of these two zones (protection and surveillance zones) surrounding an affected establishment and the control measures implemented in each one of the zones are based on the general principle that the probability of disease spread is higher the closer an establishment is to an affected establishment. The validity of this statement will not be assessed in this manuscript; nonetheless the limitations that this assumption may have in the control of certain diseases will, when relevant, be discussed.
- f) The following scenarios of the ToR 1 of the Annex B are not relevant for PPR, and therefore not included in the assessment of the current Opinion:
 - i) scenarios 10, 11, 16 and 17 because they are referring to poultry.
- g) The duration of the monitoring period for PPR as described in Annex II of the Delegated Regulation is 21 days.
- h) The minimum radii of the protection zone (PZ) and surveillance zone (SZ) for PPR as described in Annex V of the Delegated regulation are 3 and 10 km, respectively.
- i) The minimum duration of the measures in the PZ and SZ for PPR as described in Annex X and XI of the Delegated Regulation are 21 and 30 days, respectively.

¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R0687&from=EN>

2. Disease characterisation and geographical distribution of PPR

2.1. Aetiology

PPR is a highly contagious viral disease affecting mostly sheep and goats, but also some other wild species within the order Artiodactyla (see Section 2.2). The causative agent is the PPR virus (PPRV), an enveloped RNA virus with a mono-segmented genome of negative sense, and the species name: *Small ruminant morbillivirus* (Amarasinghe et al., 2019). It belongs to the family *Paramyxoviridae*, genus *Morbillivirus*, which also includes rinderpest, canine distemper and measles viruses. A single serotype is present, but the various strains are grouped into four genetic lineages (lineages I–IV) based on molecular characterisation using a partial sequence of the N gene, with lineages I and II occurring in West Africa, lineage III in East Africa, the Middle East and southern India, and lineage IV in Asia (Kwiatek et al., 2007; Charbonnier et al., 2015; EFSA AHAW Panel, 2015; Dundon et al., 2020). The different lineages and strains may have also different virulence.

2.2. Epidemiology

PPRV infects mostly sheep and goats, with goats being more susceptible than sheep, and in particular dwarf goat species from West Africa (Diop et al., 2005; EFSA AHAW Panel, 2015). PPRV is not considered pathogenic in cattle or wild African buffaloes (*Syncerus caffer*), which develop a solid immune response, but high case fatality rates (96%) have been reported in domestic water buffaloes (*Bubalus bubalis*) in India (Govindarajan et al., 1997; CFSPH, 2015). PPRV was detected in camelids exhibiting respiratory signs, but recent publications suggest they are dead-ends hosts (CFSPH, 2015; Charbonnier et al., 2015; EFSA AHAW Panel, 2015; Schulz et al., 2019). Like cattle, pigs are considered a dead-end host. However, experimental infections of domestic pigs with PPRV have shown that pigs may transmit the virus to in-contact pigs and goats (Schulz et al., 2019). Viral excretion of infected pigs and wild boars suggest that suids should be considered as a possible source of infection (Charbonnier et al., 2015; Schulz et al., 2018).

A large number of species within the order *Artiodactyla*, both wild and captive, are susceptible to PPRV. Spill-over infections from domestic populations have been reported, with clinical disease in several species of gazelles and antelopes and other wild ruminants such as wild goats and wild sheep species, though the epidemiological role of wildlife as a potential reservoir is unknown (CFSPH, 2015; EFSA AHAW Panel, 2015). Natural infections in free-ranging wildlife leading to mass die-offs, such as for the Saiga antelope (*Saiga tatarica*), highlight the threat of PPR to endangered wild species (Pruvot et al., 2020).

The impact of PPR on other endangered wild artiodactyl populations remains unknown (Aguilar et al., 2018). In endemic regions, wildlife does not appear to maintain PPRV infection (Mahapatra et al., 2015). However, due to our still incomplete understanding of PPR in wildlife and considering that wildlife may act as bridge hosts (Caron et al., 2015), the role of wildlife in PPR epidemiology and control cannot be ignored (Wohlsein and Singh, 2015; Fine et al., 2020).

PPRV is transmitted mainly by direct contact with discharges from infected animals. In these animals, the virus is present in excretions and secretions, ocular and nasal discharges, urine, milk and faeces. Infection occurs after breathing viral aerosols but also indirectly after ingestion of material from contaminated fomites (such as water troughs, feed troughs, and bedding) though the virus does not persist more than a few days in the environment especially in hot regions (Charbonnier et al., 2015). The severity of the disease depends on the immune status of the animals and will be more pronounced in naïve populations or in young animals at weaning, when they are no longer protected by colostral antibodies (Charbonnier et al., 2015).

The disease was first described in 1942 in West Africa, and has progressively spread to East and Northern Africa and is now endemic in most African countries (except the southern extreme of the continent), the Near and Middle East, several Asian countries (extending from West Asia to China) and has more recently reached Turkey, and Europe (Georgia and Bulgaria) (EFSA AHAW Panel, 2015; OIE, 2019a). This rapid expansion now threatens more than 80% of the sheep and goat population throughout the world. Factors that have contributed to the spread of PPR include: an increase in livestock movements across countries and regions for commercial and trade purposes (e.g. the massive imports of small ruminants into the Middle East); transhumance and nomadic customs; and extensive farming practices, especially if occurring during breakdown of veterinary services, e.g. in

areas or periods of socio-political instability (EFSA AHAW Panel, 2015). Movements of infected animals through illegal trade are the major route of introduction of the disease into non-endemic areas.

PPR is the fastest growing and potentially the most economically important disease affecting small ruminants. For this reason, a PPR global control and eradication programme and strategy was launched by FAO and OIE in 2015 with the goal of eradicating the disease by 2030, following a four-stage stepwise approach, depending on the epidemiological situation in endemic countries (FAO, 2016). In case of incursion of PPR into free countries, strict control of animal movements and quarantine are necessary; slaughter of infected and exposed animals with a possible use of ring-vaccination is needed. In endemic countries, vaccination with a live-attenuated vaccine is effective, providing long-term (at least 3 years, possibly life-long) immunity, and serological monitoring is used to estimate the disease seroprevalence and/or vaccination coverage (OIE, 2020).

2.3. Clinical Signs and Diagnosis

The incubation period is typically 4–6 days (range 3–10 days). In a review of experimental infections, the median incubation period was 4 days and the minimum was 1 day in goats and 3 days in sheep (Dórea et al., 2021). The severity of the disease depends on the PPRV strain, host species, breed, health status, immune status.

Goats are generally more severely affected than sheep. The morbidity in a susceptible population can reach 90–100% and the case fatality up to 50–100% (OIE, 2020). In endemic areas these rates can be much lower for both morbidity and mortality (10–20%) and the disease usually occurs with seasonal outbreaks affecting mostly young non-immune animals aged 4–24 months (CFSPH, 2015).

In the acute form, the most common, infected animals develop a sudden and high fever (40–41°C), which can last 3–5 days, anorexia, depression, dry muzzle, conjunctivitis followed by serous nasal and ocular discharge becoming later on mucopurulent with the presence of crusts around the nostrils, which can become obstructed. Within a few days, gums become hyperaemic and erosions and necrosis appear in the mouth (gums, dental pad, lips, tongue) causing pain and hypersalivation and a typical foul smell. Similar lesions are also seen on the vulva and vagina in females. Later on, a profuse and watery diarrhoea, sometimes bloody, will appear causing dehydration and weakness. Associated bronchopneumonia with dyspnoea and cough is common and often complicated by bacterial infections (pasteurellosis). Death occurs within 5–10 days after the onset of the symptoms and surviving animals recover after 1–2 weeks. Abortion of pregnant animals is frequent. In the peracute form, with general signs of major infections and mostly observed in naïve young animals, the course of the disease is shorter and more severe and the animal progresses to sudden death (100% case fatality in 5–6 days), while in the subacute form, fever and other symptoms are less pronounced, sometimes limited to ocular and nasal discharge. Asymptomatic form can be observed in endemic areas, especially in sheep (FAO, 1999; Diallo, 2003; CFSPH, 2015; Charbonnier et al., 2015; EFSA AHAW Panel, 2015; OIE, 2020).

The virus shedding goes on for a long period from the beginning of the incubation period to the end of the diarrhoea phase. Detection of PPRV during this period can be made from swabs of ocular and nasal discharge or from unclotted blood samples. It is routinely performed with antigen capture enzyme linked immunosorbent assays (ELISAs), reverse transcription polymerase chain reaction (RT-PCR), real-time RT-PCR or reverse transcription-loop mediated isothermal amplification technique (RT-LAMP), the latter being able to perform the test within 1 h in the field. Real-time RT-PCR assays have 100% sensitivity in sheep and goats, according to a literature review done by EFSA (Dórea et al., 2021) and presented in Table I.1 in Annex I. Other antigen detection tests are commercial lateral flow device (LFD), counter-immuno-electrophoresis and agar gel diffusion (AGID), the latter being less sensitive. Virus isolation is performed for genetic characterisation of the PPRV strain (OIE, 2019a, 2020).

Animals recovering from PPRV infection are protected for life against any other PPRV infections, whatever the lineage involved. Competitive antibody ELISA (c-ELISA) for antibody detection is the method of choice, as it is well adapted to large-scale studies. C-ELISA shows a high degree of correlation to the virus neutralisation test (VNT), the gold standard assay (Se: 100%, see Annex I) that, nevertheless, is laborious and requires 7–14 days for completion. The average sensitivity of the c-ELISA applied to cattle, sheep and goats, is 94.5% according to the average value from a recent literature review (Dórea et al., 2021) and presented in Table I.1 in Annex I. Currently, these tests cannot differentiate infected from vaccinated animals. Antibody ELISAs are used either for seroprevalence studies or estimation of vaccination coverage (Charbonnier et al., 2015; OIE, 2019a).

PPR can be easily confused with other diseases with similar respiratory signs such as bluetongue, contagious caprine pleuropneumonia (CCPP) and pasteurellosis, a secondary complication of PPR.

2.4. Geographical distribution of PPR

PPR is present mainly in Africa and Asia. In Figure 1, the number of years with reported outbreaks of PPR between 2004 and 2020 is shown, while in Figure 2 the countries with the OIE official free status for PPR are displayed.

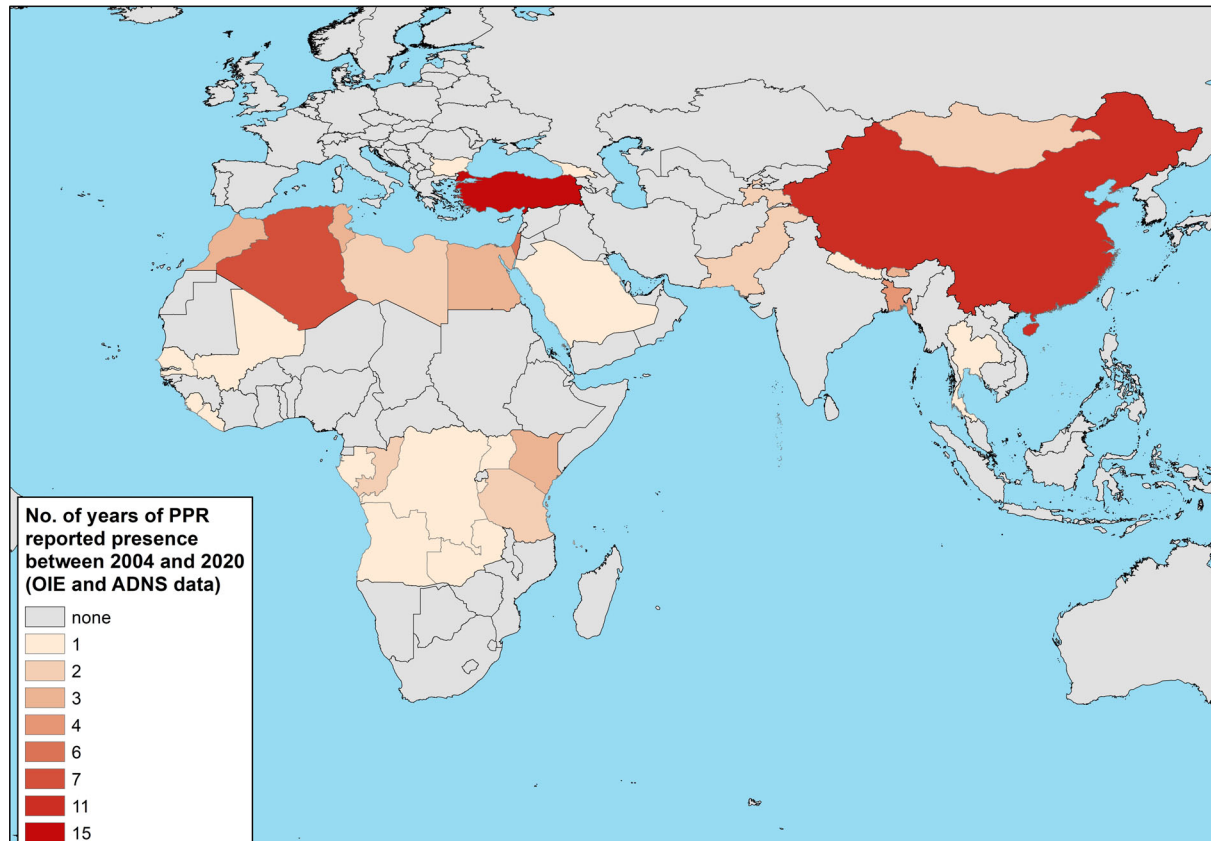


Figure 1: Map of countries with number of years of reported outbreaks of PPR in small ruminants between 2004 and 2020 (Data sources: ADNS and OIE)

OIE Members' official peste des petits ruminants status map

Last update May 2020

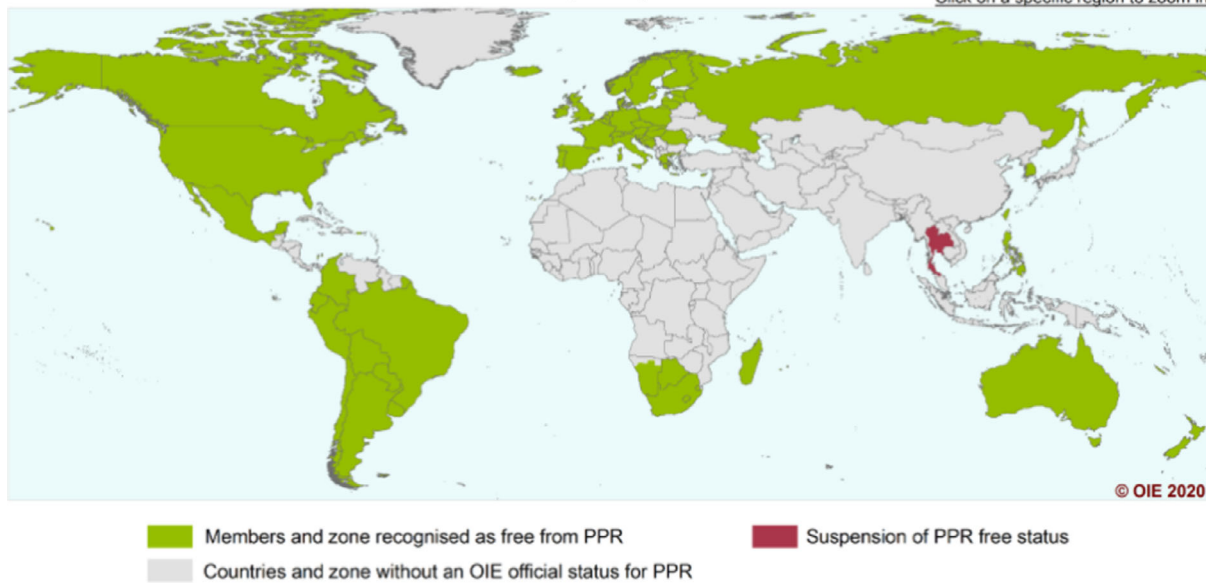
[Click on a specific region to zoom in](#)


Figure 2: Map of countries with the OIE official free status for PPR, 2020 (Source: OIE; © OIE)

2.5. Vaccination

Vaccination is the most important and effective control tool against PPR and the OIE together with the FAO developed the Global Control and Eradication Strategy of PPR under the Global Framework for the progressive control of Transboundary Animal Diseases (GF-TADs). The strategy is based on a stepwise approach to control the disease through extensive vaccination campaigns, with the ultimate goal of the global eradication of PPR by 2030. So far only live attenuated vaccines are available, with high safety and efficacy, and protecting against all known strains of PPRV (EFSA AHAW Panel, 2015). No PPR vaccines are licensed in the EU. The most common vaccine strain, Nigeria 75/1, has been used extensively in Africa and the Middle East to suppress outbreaks (EFSA AHAW Panel, 2015). The available PPR vaccines do not support the Differentiating Infected from Vaccinated Animals (DIVA) principle. Possible DIVA vaccines based on recombinant techniques are promising but are still at the experimental stage. Inactivated vaccines are not available and, owing to the immunological response to PPRV, would not be fully effective. The lessons learned from the PPR epidemics show that PPR can be controlled in areas, such as Northern Africa, through mass vaccination campaigns implemented at the national level, provided that adequate means are available and correctly implemented (EFSA AHAW Panel, 2015).

3. Data and methodologies

3.1. Methodology used in ToR 1

Although the general methodology applied to all opinions covering the assessment of control measures for the Category A diseases produced under this mandate has been published elsewhere (EFSA, 2020), specific details of the methodology related to the PPR opinion are presented below.

3.1.1. Mathematical model for within-herd dynamics of PPR and transmission scenarios considered

3.1.1.1. Model description

The within-herd dynamics of PPRV in small ruminants were modelled using a stochastic SEIR epidemic model (Keeling and Rohani, 2011). The small ruminant population was divided into four classes: susceptible (i.e. uninfected), S; exposed (i.e. infected, but not yet infectious), E; infectious, I; and recovered, R. No distinction was made between sheep and goats.

The force of infection is given by,

$$\gamma(t) = \beta \frac{I(t)}{N(t)},$$

where β is the transmission rate, $I(t)$ is the number of infectious animals at time t and $N(t)$ is the total number of animals at time t . This formulation assumes homogeneous mixing (i.e. individuals uniformly and randomly contact each other) and frequency-dependent transmission (i.e. the number of contacts is independent of the population size) (Keeling and Rohani, 2011). The durations of the latent and infectious periods were assumed to follow gamma distributions with means μ_E and μ_I and shape parameters k_E and k_I , respectively (i.e. with variances μ_E^2/k_E and μ_I^2/k_I). This was incorporated in the model by subdividing the latent and infectious classes into k_E and k_I stages each of mean duration μ_E/k_E and μ_I/k_I , respectively (Anderson and Watson, 1980). Disease-associated mortality was assumed to occur at a constant rate during the infectious period.

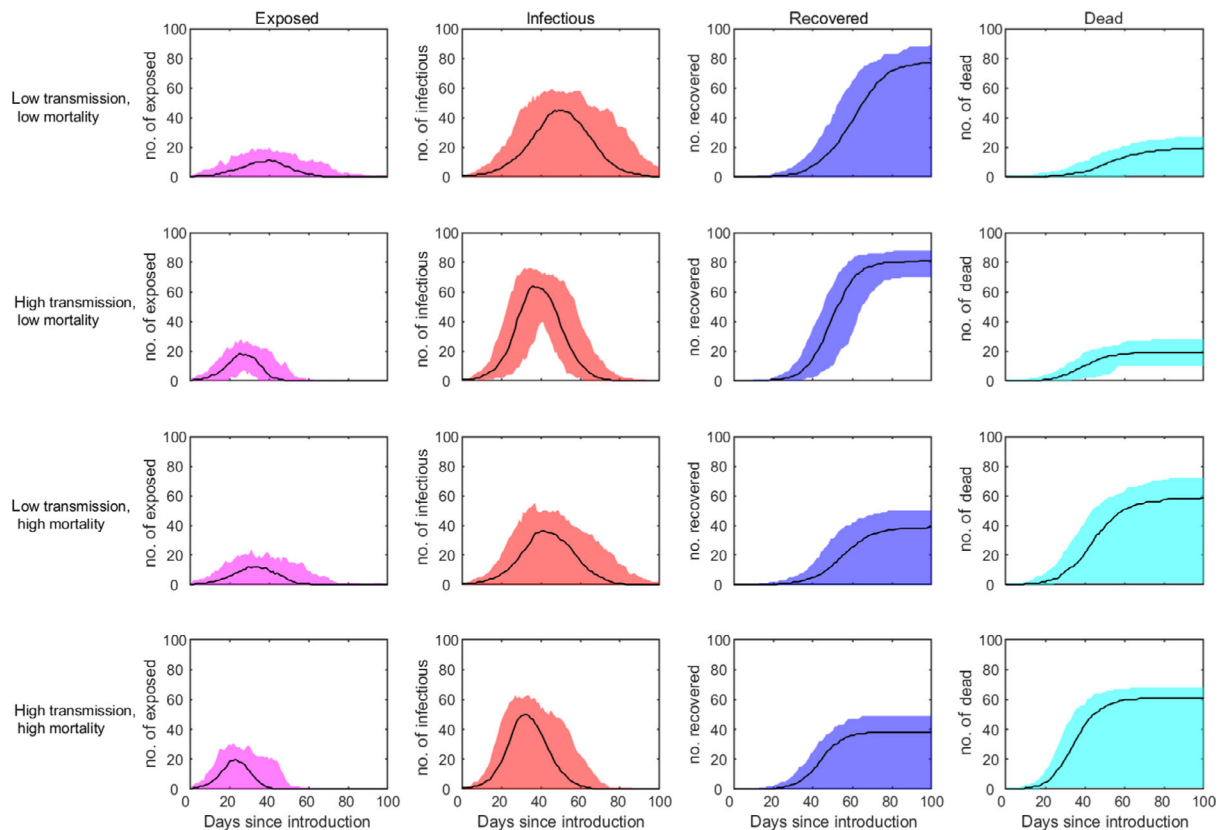
The number of animals in each class takes an integer value, while transitions between classes are stochastic processes. The number of transitions of each type during a small time interval δt was drawn from a binomial distribution with number of animals in the class, n , and transition probability, q , (the appropriate per capita rate multiplied by δt) as parameters.

The initial herd size was assumed to be 50, 100, 500 or 1,000 small ruminants. Transmission rates and mortality were extracted from published analyses of outbreaks (Zahur et al., 2009; Kivaria et al., 2013; Fournié et al., 2018). From these, two scenarios were identified for the transmission rate (low and high) and two for mortality (low and high) (Table 1). Accordingly, four scenarios were considered in total (Figure 3). Latent and infectious periods were estimated from challenge experiments (Couacy-Hymann et al., 2007; Liu et al., 2013; Wernike et al., 2014; Parida et al., 2019; Halecker et al., 2020) and were the same in all scenarios (latent period: mean, $\mu_E = 4$ days; shape, $k_E = 10$; infectious period: mean, $\mu_I = 21$ days; shape, $k_I = 10$).

Table 1: Parameters in the model for the transmission of PPR virus

| Scenario | | Basic reproduction number (R_0) | Transmission rate [†] (β) | Case fatality (%) |
|----------------|-------------------|-------------------------------------|--|-------------------|
| Low mortality | Low transmission | 4.2 | 0.23 | 20 |
| | High transmission | 6.8 | 0.37 | 20 |
| High mortality | Low transmission | 4.2 | 0.32 | 60 |
| | High transmission | 6.8 | 0.52 | 60 |

†: The transmission rate was calculated so that R_0 was the same in the two case fatality scenarios (20% and 60%).



The plots show the median (solid black line) and 95% prediction interval (coloured shading) for the number of exposed animals (first column; magenta), infectious animals (second column; red), recovered animals (third column; blue) and cumulative number of dead animals (fourth column; cyan) for four scenarios which differ in transmission rate and mortality (rows; see Table 1 for details).

Figure 3: Results of a simulation model showing within-herd dynamics of PPRV in a herd of 100 small ruminants

3.1.1.2. Detection of PPR virus

Sampling sick or dead sheep and goats

Only infectious animals were assumed to show clinical signs of PPR. The proportion of animals showing clinical signs was assumed to be 40% in the low mortality scenarios and 80% in the high mortality scenarios (cf. Kivaria et al., 2013). The number of animals showing clinical signs each day was drawn from a binomial distribution with number of trials given by the number of infectious animals and the probability of success given by the proportion of animals showing clinical signs. The number of sheep or goats dying of PPR is a direct output of the model.

The time to five sheep or goats showing clinical signs of PPR and dying of PPR in each scenario is shown in Tables K.1 and K.2 in Annex K, respectively.

Sampling asymptomatic sheep and goats

The prevalence of virus-positive sheep and goats was assumed to correspond to the prevalence of infectious animals. Based on a time to seroconversion (i.e. time between infection and when antibodies are first detectable) of around 8 days (see Section 4.2.1.2 and other studies (Wernike et al., 2014; Liu et al. 2013; Halecker et al., 2020)), which is also in line with what is presented in Section 4.2.1.2) 97% of infectious animals and all recovered animals were assumed to be seropositive.

The prevalence is the proportion of sheep and goats either infected or seropositive, with the denominator in the calculations being the initial herd size minus the cumulative number of animals that have died of PPRV.

The time to reach 5% and 10% infection and seroprevalence in herds containing 50, 100, 500, or 1,000 animals, respectively, is calculated and displayed in Tables K.3–K.6 in Annex K, respectively.

The infection prevalence and seroprevalence of PPR reached at 7, 14, 21, 28 days post-introduction is displayed in Tables K.7–K.14 in Annex K, respectively. This is useful to calculate the sample size needed for detection of suspected animals in an infected flock (see Section 4.1.1.1).

3.2. Methodology used in ToR 2

3.2.1. Time lag between infection and reporting

To estimate the time lag between infection and reporting of a PPR suspicion (ToR 2), an extensive literature search (ELS) was outsourced by EFSA (OC/EFSA/ALPHA/2020/02 – LOT 2). The aim of this ELS was to answer the epidemiological question of: 'what is the average, shortest and longest period of time for an outbreak of PPR to be reported (measured as the number of days from the earliest point of infection with PPR, to the time of declaration of a suspicion by the competent authority after the clinical investigation by an official veterinarian)?'. To answer this question, an ELS on case reports, papers describing outbreaks or epidemics of PPR, and any other relevant grey literature or data was carried out (details are provided in Annex J). For inclusion in the ELS, the earliest point of infection had to be estimated by carrying out an epidemiological investigation. Papers and other sources of data, where the earliest point of infection was determined purely by subtracting a known incubation period from the date of the suspicion of the outbreak, were excluded. The ELS was initially restricted to studies conducted in Europe or describing results obtained in Europe, although, because of the small number of references retrieved for European countries ($n = 2$), the selection was extended to the rest of the world. If fewer than six articles were retrieved in the first search, the search was extended to the rest of the world. A ELS protocol similar to that shown in Annex 5 of the Methodology report (EFSA, 2020) was followed.

3.2.2. Seroconversion period

Considering scenario 5 of the 2nd ToR, 'the earliest day of the seroconversion after the infection, detected by different serological methods in different animal species is necessary to be identified for each disease of concern. In addition, the time interval between the earliest day of antibodies detection and the latest day of antibodies detection by different laboratory methods would be useful', a scientific literature review on the earliest day of seroconversion and the latest day of antibody detection after PPR infection and the relevant target population (listed species) of the disease, was conducted to successfully address this scenario.

The objectives of the literature review were to identify:

- i) the earliest day/or range of days of seroconversion (earliest day when antibodies have been detected) after infection/inoculation for each serological test used, for different animals' species,
- ii) the duration of serological positivity after infection/inoculation for each serological test used, per each animal species,
- iii) the target population (*listed species*) for the diseases.

The methodology used to perform the literature search is described in Annex G.

3.3. Methodology used in ToR 3

3.3.1. Methodology for assessing the effectiveness of the minimum radius of the protection and surveillance zones

The assessment of radius size of restricted zones (ToR 3), to prevent further disease spread at a given probability, was performed by using disease transmission kernels (EFSA, 2020) and presented in Section 4.3. Details about the methodology are shown in Annex H.

3.3.2. Methodology for assessing the effectiveness of the duration of the protection and surveillance zones

To estimate the duration of measures in the protection and surveillance zones, the outputs obtained from the ELS described in Section 3.2 were used. Further details can be found in the Methodology report (EFSA, 2020).

3.4. Uncertainty

A description of the methodology used to deal with uncertainty is provided in a Methodology report published by EFSA (EFSA, 2020).

4. Assessment

4.1. Assessment of sampling procedures (ToR 1)

4.1.1. Assessment of sampling procedures in the event of suspicion or confirmation of PPR

4.1.1.1. In the event of a suspicion of PPR in an establishment where animals of the listed species are kept

The purpose of this section is to assess the effectiveness of disease-specific sampling procedures of animals of listed species in a suspected establishment, based on clinical examination (ToR 1.1) and laboratory examination (ToR 1.2), in their ability to detect PPRV infection in kept animals if the disease is present in that establishment, or to rule it out if not present (Art. 6 (2)). For further details, see Annexes B and C.

- **1st Scenario of sampling procedures**
- ToR 1.1 and ToR 1.2 in accordance with Mandate
- Article 6(2) of the Delegated Regulation
- Commission Implemented Regulation 2018/1882 on listed species

The following elements of the scenario were taken into consideration for the assessment:

- 1) It concerns an event of suspicion of PPR in an establishment with kept animals of the listed species;
- 2) The listed species for PPR as provided in Commission Implemented Regulation 2018/1882 are those belonging to the species *Ovis* and *Capra* ssp., and the families Camelidae, and Cervidae;
- 3) Subsequent to the suspicion, the competent authority shall immediately conduct an investigation to confirm or rule out the presence of the disease;
- 4) The official veterinarian must perform a clinical examination and collect samples for further laboratory examination (see Annex C for details on guidelines on how the clinical and laboratory examination must be carried out).

Summary of sampling procedures

No specific guidelines on sampling procedures for clinical or laboratory examination in the event of a suspicion of PPR are available in the EU legislation.

Guidelines for sampling procedures in case of PPR suspicion are reported in other available documents, particularly in relation to the number of samples to be taken from clinically affected or dead animals.

The manual by ILRI (Wieland et al., 2020) suggests to collect samples from 1 to 5 animals for the PPRV rapid diagnostic test. In case of recently dead sheep or goats (within 24 h), then a post-mortem examination is recommended with the collection of tissue samples collected for laboratory submission.

The field guide by the Department of Agriculture and CSIRO (2019), suggests to collect serum, from at least 10 animals (if possible) towards the end of the acute phase or from recovered animals, and EDTA blood, from live, clinically affected animals (7–10 mL/animal) during the acute phase (preferably from pyretic animals).

The Manual for samples collection in case of PPR by the SADC PPR working group (SADC PPR WG, 2013) suggests a more structured procedure for sample collection, including a random sample of clinically healthy animals, stratified according to the age, and to sample at least 4 animals with lesions or clinical signs compatible with PPR.

Assessment

In the scenario of a suspicion of PPR in an establishment, the purpose of the clinical examination² based on detection of clinical signs such as fever, diarrhoea, respiratory signs (including both the initial visual inspection of the herd and the individual examination of the animals), is to identify potentially infected animals in order to target the sampling correctly.

The confirmation of clinical suspicion is based on laboratory test, mainly by confirming the presence of the virus nucleic acids (RT-PCR) or of antibodies (ELISA test).

The collection of samples for RT-PCR testing can be performed either on dead or alive animals. In the latter, samples should be collected in the acute phase of the disease, when clinical signs are apparent, to maximise the probability of detecting the viral genome. The recommended samples from live animals are swabs of conjunctival discharges, nasal secretions, buccal and rectal mucosae, and anticoagulant-treated blood.

In dead or euthanised animals, the best samples for RT-PCR examination are mediastinal and mesenteric lymph nodes, lungs and spleen. Considering the rapid inactivation of the virus after the death of the animal, samples must be collected few hours after the death. Therefore, in field conditions, samples from sick but live animals are preferred. All samples must be refrigerated and quickly dispatched to the laboratory, within 24 h (CIRAD, 2019).

Detection of antibodies for PPR confirmation in a PPR-free country, with no vaccinated animals, can complement the RT-PCR testing, taking into account that only from 10 to 14 days after the infection the antibodies are detectable by ELISA assays. The confirmation based on serology alone requires the collection of two blood samples, 3 weeks apart, from the same animals, which is not always feasible in the field. Serological surveys are useful to determine the presence or absence of infection in a defined country or zone and its extent in a population.

Development of new procedures

In Figure 4, a schematic decision tree showing the diagnostic procedure for PPR confirmation is reported.

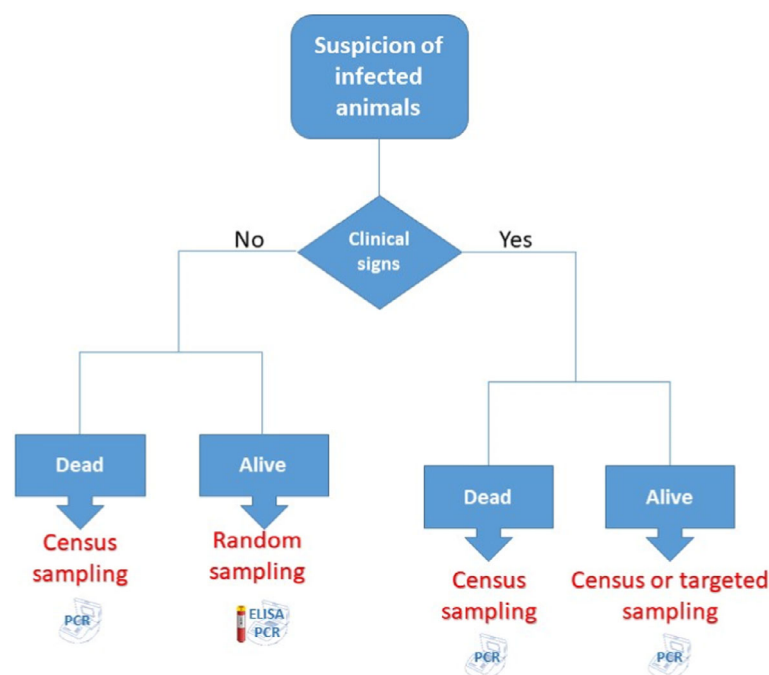


Figure 4: Decision tree of the diagnostic procedure for PPR confirmation

² Definition of the term 'clinical examination' is provided in the article 3 of the Delegated Regulation: the clinical examination comprises: (i) an initial general evaluation of the animal health status of the establishment which comprises all the animals of listed species kept in the establishment; and (ii) an individual examination of the animals included in the sample referred to in point (a). The sampling of animals for clinical examination is carried out in accordance with point A.1 of Annex I for terrestrial animals.

For sampling purposes, in case of clinical signs being present, even generic signs such as fever, lethargy, lost appetite, nasal/oral discharge and/or changes in the individual animal behaviour and/or in the feed intake, animals should be targeted and PCR should be the test of choice, since animals with clinical signs of PPR are expected to be viraemic. Post-mortem examination will be carried out on euthanised or recently dead susceptible animals for the collection of organs and tissues on which virological tests will be performed.

In case of sick animals, therefore, these should be the preferred targets for sample collection. Ideally, all euthanised and sick animals should be sampled, to maximise the probability of detecting the virus or its genome. However, in case of large numbers of animals showing clinical signs, those showing fever and other signs typical of the acute phase of the disease should be preferred. The cachectic or pre-agonic animals, in the final stages of the disease, are not the best option for PPRV detection.

It must be considered that, according to the model simulation as displayed in Table 2, in a period between 13 and 27 days after disease introduction (d.p.in., depending on the herd size) at least five animals are expected to be clinically affected. Given this, considering the high sensitivity of RT-PCR (100%, see Section 2.3 and Annex I), the probability of not detecting the infection after testing five affected animals is almost nil.

If clinical signs are not evident in the herd, the sampling of randomly selected asymptomatic animals can be performed.

Given the variability of PPR spread and mortality, the sample size (based on random sampling) needed is based on the median values of infection and serological prevalence predicted in four scenarios as presented in Section 3.1.1, combining low and high transmission ($R_0 = 4.2$ and 6.8 , respectively) and low and high case fatality (20% and 60%), at different point in time after introduction of the virus into the herd and for different herd sizes, i.e. 50, 100, 500 and 1,000 animals, respectively (Tables 2 and 3). The mortality is considered occurring continuously during the whole outbreak period, not only in the end of infectious period.

If clinical signs are absent (suspicion because of contact, import, etc.), then ELISA should be also performed (sensitivity and specificity of c-ELISA is 94.5% and 98.6%, respectively, with Se ranging from 93.4% to 96.7% and Sp ranging from 98.1% to 99.2%), based on literature review, Dórea et al., 2021), since the exact time of exposure is unknown, and the animals may have a high level of antibodies. In the case of serology, however, the scenarios for calculation of sample size needed to reveal positive animals should not consider the 7 d.p.in. (Table 2), since at that point in time detectable levels of antibodies cannot be found in infected animals yet.

Table 2: Sample size for random sampling to detect PPR infection with 95% confidence based on different values of infection prevalence (median values, as from Tables 8–11) at 7, 14, 21 and 28 days after PPRV introduction into the herd for testing by PCR (Se and Sp: 100%, Annex I) for four different scenarios of transmission and mortality and of herd size

| Scenario: sample size at 7 d.p.in. into the herd (median value) for PCR testing | Herd size | | | |
|---|-----------|-----|-----|-------|
| | 50 | 100 | 500 | 1,000 |
| Low transmission, low mortality | 48 | 96 | 476 | 951 |
| High transmission, low mortality | 39 | 78 | 388 | 777 |
| Low transmission, high mortality | 48 | 96 | 476 | 951 |
| High transmission, high mortality | 39 | 78 | 388 | 777 |
| 14 d.p.in. | | | | |
| Low transmission, low mortality | 32 | 63 | 316 | 632 |
| High transmission, low mortality | 22 | 39 | 196 | 393 |
| Low transmission, high mortality | 26 | 53 | 264 | 632 |
| High transmission, high mortality | 17 | 39 | 174 | 393 |
| 21 d.p.in. | | | | |
| Low transmission, low mortality | 17 | 35 | 196 | 312 |
| High transmission, low mortality | 9 | 17 | 76 | 145 |
| Low transmission, high mortality | 15 | 31 | 156 | 283 |
| High transmission, high mortality | 7 | 12 | 52 | 92 |

| Scenario: sample size at 7 d.p.in. into the herd (median value) for PCR testing | Herd size | | | |
|---|-----------|-----|-----|-------|
| | 50 | 100 | 500 | 1,000 |
| 28 d.p.in. | | | | |
| Low transmission, low mortality | 11 | 19 | 90 | 170 |
| High transmission, low mortality | 5 | 6 | 27 | 47 |
| Low transmission, high mortality | 9 | 15 | 69 | 122 |
| High transmission, high mortality | 4 | 5 | 16 | 25 |

Table 3: Sample size for random sampling to detect PPR serological positivity with 95% confidence based on different values of seroprevalence (median values, as from Table 13–15 at 14, 21 and 28 days after PPRV introduction into the herd for testing by ELISA (Se: 94.5%, Sp: 98.6%), for four different scenarios of transmission and mortality and of herd size

| | Herd size | | | |
|-----------------------------------|-----------|-----|-----|-------|
| | 50 | 100 | 500 | 1,000 |
| 14 d.p.in. | | | | |
| Low transmission, low mortality | 33 | 67 | 334 | 668 |
| High transmission, low mortality | 24 | 42 | 208 | 416 |
| Low transmission, high mortality | 28 | 56 | 279 | 668 |
| High transmission, high mortality | 18 | 41 | 184 | 330 |
| 21 d.p.in. | | | | |
| Low transmission, low mortality | 18 | 33 | 184 | 330 |
| High transmission, low mortality | 9 | 17 | 77 | 154 |
| Low transmission, high mortality | 18 | 30 | 165 | 299 |
| High transmission, high mortality | 7 | 13 | 57 | 97 |
| 28 d.p.in. | | | | |
| Low transmission, low mortality | 10 | 18 | 85 | 171 |
| High transmission, low mortality | 4 | 7 | 28 | 49 |
| Low transmission, high mortality | 9 | 15 | 70 | 124 |
| High transmission, high mortality | 4 | 5 | 17 | 27 |

4.1.1.2. For the purposes of the epidemiological enquiry as referred to Article 57 of Regulation (EU)2016/429 in an establishment affected and officially confirmed with PPR

The purpose of this section is to assess the effectiveness of disease-specific sampling procedures, based on laboratory examination (ToR 1.2), in their ability to detect the disease in the event of preventive killing, and in their ability to support 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. For further details, see Annexes B and C.

- **2nd Scenario of sampling procedures.**
- ToR 1.2 in accordance with Mandate.
- Article 12(3) and the Art. 7 (4) (Preventive killing) of the Delegated Regulation.
- Article 57 of the Regulation (EU) 2016/429.

The following elements of the scenario were taken into consideration for the assessment:

- 1) It concerns an affected establishment officially confirmed;
- 2) Kept animals of listed species found dead or before/when they are killed are sampled;

- 3) Competent authority collects samples for laboratory examination;
- 4) The purposes of the sampling are:
 - a) supporting the epidemiological enquiry to:
 - i) identify the likely origin of the disease;
 - ii) calculate the likely length of time that the disease is present;
 - iii) 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; and
 - iv) 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.

Summary of sampling procedures

There are no sampling procedures defined for the purposes of the epidemiological enquiry in an establishment affected and officially confirmed with PPR.

Assessment

Length of infection

For PPR, it is not possible to derive or estimate the length of infection (the time of exposure) by the lesions, which are not disease-specific and may greatly vary. In addition, it is not possible to estimate the time of infection using laboratory results. Antibodies are detectable 10–14 days (see Section 4.2.1.2) after infection and they probably remain for the whole productive life of the animals. Consequently, detection of antibodies suggests that infection occurred > 10 days prior to detection of antibodies, but no other inferences can be made upon the time of exposure on the basis of serological results. No commercial tests are available for the detection of IgM and other more transient antibody classes.

Origin of infection

Genomic information of PPRV can be useful for determining the geographical area of origin of the PPRV of concern. PPRV can be divided into 4 genetically distinct lineages based on the nucleocapsid (N) gene, with different and distinct geographical patterns (see Section 2.1).

4.1.1.3. For granting a specific derogation from killing animals of the categories described in article 13.2 of the Delegated Regulation in a PPR affected establishment

The purpose of this section is to assess the effectiveness of disease-specific sampling procedures based on clinical (ToR 1.1) and laboratory (ToR 1.2) 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. For further details, see Annexes B and C.

- **3rd Scenario of sampling procedure.**
- ToR 1.1 and ToR 1.2 in accordance with Mandate.
- Article 13(3)c of the Delegated Regulation.

The following elements of the scenario were taken into consideration during for the assessment:

- 1) It concerns an affected establishment where infection is officially confirmed;
- 2) In the establishment where there are kept animals of listed species of the following 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.

- 3) the competent authority may grant specific derogation from killing all the animals of listed species belonging to any of the above categories in an affected establishment, provided that specific conditions are fulfilled;
- 4) The animals should be subjected to clinical surveillance, including laboratory examinations;
- 5) Sampling procedures should ensure that the animals do not pose a risk of transmission of the category A disease if left alive.

Summary of sampling procedures

There are no sampling procedures to grant a derogation from killing of animals in an affected establishment.

Assessment

Animals in an affected establishment and for which a specific derogation from killing has been granted should be subjected to clinical and laboratory examination. Sampling procedures should ensure that the animals do not pose a risk of transmission if left alive.

Animals of the holding that are negative for antibodies and virus do not pose a risk of transmission of PPR. Recovered animals with antibody positive results only do not pose a risk of transmission.

Development of new procedures

General evaluation of the health status of all the animals in the establishment should be carried out, preferably every day, to detect early the onset of clinical signs, for a period of at least the existing monitoring period of 21 days calculated forwards from the day of confirmation of the latest case.

All the animals intended derogation from killing should be subjected to thorough individual clinical examination at two weeks intervals to identify those animals with clinical signs in order to take samples for virological testing (see Section 4.1.1.1 for details).

Sampling all the animals for derogation for laboratory examination (both for virus detection and antibodies), as soon as the derogation from killing is granted and irrespectively of the presence of clinical signs, will enable to identify also infected animals without clinical signs, estimate the prevalence of PPR in the establishment and evaluate the risk. Sampling for laboratory examination can be repeated at any time, but the last sampling should be carried out not earlier than 21 days calculated forwards from the day of confirmation of the latest case.

Sampling procedures for laboratory examinations in order to detect or rule out the presence of PPR virus should follow the procedures described in the Section 4.1.1.1.

4.1.1.4. For the animals of non-listed species kept in an affected establishment by PPR

The purpose of this section is to assess the effectiveness of disease-specific sampling procedures, based on clinical (ToR 1.1) and laboratory (ToR 1.2) examinations of the animals of non-listed species kept in an affected establishment, in their ability to ensure the detection of the virus if the virus is present in these species. For further details, see Annex B.

- **4th scenario of sampling procedures.**
- ToR 1.1 and ToR 1.2 in accordance with Article 14(1) of the Delegated Regulation.
- Article 57 of the Regulation (EU) 2016/429.
- Commission Implemented Regulation 2018/1882 on listed species.

The following elements of the scenario should be taken into consideration during for the assessment:

- 1) It concerns an affected establishment officially confirmed;
- 2) In the affected establishment there are kept animals of non-listed species of epidemiological relevance for the control of the disease;
- 3) Animals of non-listed species are those animals that are not listed in Commission Implementing Regulation (EU) 2018/1882 for each of the category A diseases;
- 4) The animal species acting purely as mechanical carriers of the virus will not be covered;
- 5) The competent authority is not obliged to carry out the sampling of non-listed species, but they may establish it in addition to other measures;
- 6) The purpose of the sampling procedures is to ensure detection of the virus in these species.

Summary of sampling procedures

There are no sampling procedures defined for of non-listed species kept in an affected establishment by PPR.

Assessment

The listed species for PPR according to Commission Implementing Regulation (EU) 2018/1882³ are *Ovis* spp., *Capra* spp., Camelidae and Cervidae.

Where other susceptible domestic animals are also kept, these should also be sampled. Those should be tested for both the presence of virus by PCR and/or viral isolation as well as for serology. Although there is no evidence from literature or other reports (Fine et al., 2020) suggesting that PPRV could naturally spread by intraspecies transmission between pigs and wild boar, suids should be considered as possible source of infection as suggested by experimental infections and possible facilitators for the introduction and spread of PPRV into the European Union (see Section 2.2.). Schulz et al. (2018) showed that domestic pigs and wild boars infected with PPRV may excrete the virus and transmit the disease to in-contact pigs and goats. In the late 1970s, a contact transmission of a PPRV lineage II, known to be mild, had shown the passage of the virus from goat to contact pigs. Pigs in trials showed subclinical to only mild clinical signs. Regarding rinderpest, a virus closely related to PPRV, common warthog (*Phacochoerus africanus*) was reported to be highly susceptible (Plowright, 1968, 1987). However, for PPRV, there is no evidence to suggest that this is the case.

Therefore pigs, if kept in an affected establishment affected by PPR, should be also tested for PPR.

4.1.1.5. For wild animals of the listed species within the PPR affected establishment and its surroundings

The purpose of this section is to assess the effectiveness of disease-specific sampling procedures, based on clinical (ToR 1.1) and laboratory (ToR 1.2) examinations of the wild animals of listed species within the affected establishment and in its surroundings. The purpose of the sampling procedures is to ensure the detection of the virus, if the virus is present in these wild species. For further details, see Annex B.

- **5th scenario of sampling procedures.**
- ToR 1.1 and ToR 1.2 in accordance with Article 14(1) of the Delegated Regulation.
- Article 57 of the Regulation (EU) 2016/429.
- Commission Implemented Regulation 2018/1882 on listed species.

The following elements of the scenario were taken into consideration for the assessment:

- 1) It concerns an affected by PPR establishment officially confirmed.
- 2) They may exist wild animals of listed species within the establishment and in the surroundings of the establishment.
- 3) As listed in Commission Implementing Regulation (EU) 2018/1882 for PPR; the wild animals of listed species animals are Cervidae.
- 4) The competent authority may establish these sampling procedures in addition to other measures.
- 5) The purpose of the sampling procedures in wild animals of listed species is to ensure the detection of the virus, if the virus is present in these wild species.

Summary of sampling procedures

There are no sampling procedures defined for wild animals of the listed species within the PPR affected establishment and its surroundings.

Assessment

In the scenario where wild cervids (e.g. roe deer, red deer, fallow deer) or wild bovids (e.g. muflon, chamois, ibex, etc.) are kept or living in the surrounding area of the affected establishment, these may acquire the infection by direct or indirect contact with affected animals, if no or low biosecurity measures are in place to keep animal species separated.

³ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R1882&from=EN>

Development of new procedures

The surveillance of wildlife around the affected establishment may include the visual inspection of these animals from distance and the testing of fallen stock and hunted animals both by PCR and serology (the latter not validated in wild species for PPR). Unexpected mortality events in susceptible wildlife should be investigated.

Samples from animals with clinical signs from dead or hunted animals should be collected for laboratory analysis, following the procedures of the Section 4.1.1.1. Wildlife population health experts would be able to provide additional advice in these circumstances.

4.1.1.6. For animals of listed species in the non-affected establishments located in a protection zone

The purpose of this section is to assess the effectiveness of disease-specific sampling procedures based on clinical (ToR 1.1) and laboratory (ToR 1.2) examinations of the animals of listed species in establishments located in the protection zone. The purpose of the sampling procedures is to ensure the detection of the virus, if the virus is present in these animals. For further details, see Annexes B and C.

- **6th Scenario of sampling procedures.**
- ToR 1.1 and ToR 1.2 in accordance with Mandate.
- Article 26(2) of the Delegated Regulation.

The following elements of the scenario should be taken into consideration during for the assessment:

- 1) It concerns the protection zone with radius up to 3 km;
- 2) Official veterinarians must visit at least once all the non-affected establishments with kept animals of listed species located in the protection zone;
- 3) Among others, they must perform a clinical examination of kept animals of listed species and if necessary, collection of samples for laboratory examination;
- 4) The purpose of sampling procedures is to confirm or rule out the presence of a category A disease.

Summary of sampling procedures

There are no sampling procedures defined for animals of listed species in the non-affected establishments located in a protection zone for PPR.

Assessment

All establishments located in the protection zone should be visited and the animals should be subjected to clinical surveillance (for details, see Section 4.1.1.1), including a laboratory examination to ensure the detection of the virus, if the virus is present in these animals.

Development of new procedures

For the purpose of this scenario, the guidelines provided in Section 4.1.1.1 can be followed based on whether clinical signs are observed or not at the clinical examination.

Active surveillance via serological or virological testing of randomly selected animals (i.e. in the absence of clinical signs) should be conducted only if this could be considered necessary due to epidemiological considerations such as spread of a low virulent strain of the virus with none or very little clinical signs.

4.1.1.7. For non-affected establishments located in a protection zone with a radius larger than 3 km

This scenario is not applicable, since for PPR it is not proposed for a protection zone larger than 3 km.

4.1.1.8. For non-affected establishments located in a surveillance zone

The purpose of this section is to assess the effectiveness of disease-specific sampling procedures, based on clinical (ToR 1.1) and laboratory (ToR 1.2) examinations of the animals of listed species, for the sampling of the establishments located within the surveillance zone. The purpose of the sampling

procedure is to ensure disease detection if the virus is present in establishments within the surveillance zone. For further details, see Annex B.

- **8th scenario of sampling procedures:**
- ToR 1.3 in accordance with Article 41 of the Delegated Regulation.

The following elements of the scenario were taken into consideration for the assessment:

- 1) It concerns the surveillance zone;
- 2) Sample of the establishments of kept animals of listed species in the surveillance zone;
- 3) Official veterinarians carry out visits to a sample of the establishments among others perform clinical examination of kept animals of listed species and if necessary, collection of samples for laboratory examination;
- 4) The purpose of sampling procedure is to ensure the detection of the disease if the disease is present in any of the establishments.

Summary of sampling procedures

There are no sampling procedures defined for animals of listed species in the non-affected establishments located in a protection zone for PPR.

Assessment

It is extremely unlikely (1–5%) (EFSA Scientific Committee, 2018) that establishments in this zone, not epidemiologically linked to an outbreak, will become infected with PPRV without having additional outbreaks in the protection zone.

Consequently, for the surveillance zone, it is recommended that the efforts will be allocated to enhance passive surveillance by increasing awareness in all establishments, industry and public.

Development of new procedures

Any establishment where generic signs of disease such as fever, lethargy, lost appetite, nasal/oral discharge and even changes in the individual animal behaviour and /or in the feed intake are reported should be visited, the animals should be clinically examined and samples should be collected following the procedures described in Section 4.1.1.1.

Establishments in the surveillance zone epidemiologically linked to an affected establishment or to any other establishment in the protection zone, should be also visited; the animals should be clinically examined, and samples should be collected in case a suspicion is raised following the procedures described in Section 4.1.1.1.

4.1.2. Assessment of sampling procedures to grant derogations for animal movements

4.1.2.1. From non-affected establishments located in the protection zone to slaughterhouses located within the protection zone or in the surveillance zone or outside the restricted zone

- **9th Scenario of sampling procedures.**
- ToR 1.4 in accordance with Article 28(5) of the Delegated Regulation.
- Article 29 of the Delegated Regulation.

The following elements of the scenario were taken into consideration for the assessment:

- 1) It concerns the protection zone;
- 2) Grant derogation for movement of kept animals of listed species from a non-affected establishment in the protection zone;
- 3) Animals to be moved to a slaughterhouse located within the protection zone or in the surveillance zone or outside the restricted zone;
- 4) Clinical examinations and laboratory examination of animals kept in the establishment, including those animals to be moved.

The purpose of this section is to assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations of the animals of an establishment in a protection zone, in order to grant a derogation from prohibitions in the movement of animals, and allow for the animals to be moved to a slaughterhouse located within the protection zone or in the surveillance zone or outside the restricted zone (Art. 29). For further details, see Annex B.

Summary of sampling procedures

No sampling procedures are defined for PPR for this scenario.

Assessment

As noted above, clinical examination of listed species is not sensitive enough to confirm PPR when outside the diagnostic window. There is then a risk of undiagnosed infected animals spreading the disease during movement. Sending the animals to slaughter undoubtedly reduces this risk. This scenario applies to listed animals that are moved: (a) from the protection zone to a slaughterhouse in the protection zone; (b) from the protection zone to a slaughterhouse in the surveillance zone; and (c) from the protection zone to a slaughterhouse outside the restriction zones. The risk of spreading the disease from undiagnosed animals increases from (a) to (c).

In the event animals to be moved would be found ill whether in a subunit or in contact with all the other animals, laboratory samples must be collected and the assessment remains as per Section 4.1.1.1. In addition, post-mortem examination of these animals, for collection of different organ samples such as lung, spleen or lymph nodes for virological tests must be taken at slaughter and processed according to scenario 4.1.1.1.

Development of new procedures

Clinical examinations must be carried out in each subunit of the establishment in which the kept listed species are to be moved following the procedures described in the Section 4.1.1.1.

If one or more animals exhibit clinical signs consistent with PPR, the establishment is considered suspected and confirmation follows the procedures described in the Section 4.1.1.1 for appropriate laboratory investigation.

If individual clinical examination of all the animals is not feasible, in that case the plan is to examine the number of animals indicated by the sample size calculations, with at least 95% confidence as described in the Section 4.1.1.1.

If listed animals are moved from the protection zone to a slaughterhouse outside the restriction zones, as described in (c), clinical examination and sample collection for laboratory investigation for should be performed as described in the Section 4.1.1.1.

4.1.2.2. From non-affected establishments located in the protection zone to a plant approved for processing or disposal of animal by-products in which the animals are immediately killed

The purpose of this section is to assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations of the animals of an establishment in a protection zone, in order to grant derogation from prohibitions in the movement of these animals to a plant approved for processing or disposal of animal by-products in which the kept animals are immediately killed (Art. 37). For further details, see Annexes B and C.

- **12th Scenario of sampling procedures.**
- ToR 1.4 in accordance with Mandate.
- Article 28(5) and article 37 of the Delegated Regulation.

The following elements of the scenario were taken into consideration for the assessment:

- 1) It concerns the protection zone;
- 2) To grant derogation for movement of kept animals of listed species from a non-affected establishment in the protection zone;
- 3) The animals to be moved to a plant approved for processing or disposal of animal by-products in which the kept animals are immediately killed;
- 4) Clinical examinations and laboratory examinations of animals kept in the establishment, including those animals to be moved.

Summary of sampling procedures

No specific guidelines on sampling procedures for clinical or laboratory examination were found for the 12th Scenario in EU legislation.

Assessment

This scenario is very similar to the scenario of the Section 4.1.2.1 and therefore the assessment is the same.

Development of new procedures

This scenario is very similar to the 9th scenario of the Section 4.1.2.1; therefore, the same new procedures are suggested.

4.1.2.3. From an establishment in a surveillance zone to a slaughterhouse located within or outside the restricted zone and from an establishment outside the surveillance zone to a slaughterhouse situated in the surveillance zone

The purpose of this section is to assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations of the animals of listed species in order to grant derogation from prohibitions and allow for these animals to be moved: (a) from an establishment in a surveillance zone to a slaughterhouse located within or outside the restricted zone, (b) from an establishment outside the surveillance zone to a slaughterhouse situated in the surveillance zone. For further details, see Annexes B and C.

- **13th Scenario of sampling procedures.**
- ToR 1.4 in accordance with Mandate.
- Article 43(5) and article 44 of the Delegated Regulation.

The following elements of the scenario were taken into consideration for the:

- 1) It concerns kept animals of listed species of the establishments in the surveillance zone;
- 2) To grant derogation for movement from an establishment in the surveillance zone to be moved to a slaughterhouse within the restricted zone or outside the restricted zone;
- 3) To grant derogation for movement from an establishment outside the surveillance zone to a slaughterhouse situated in the surveillance zone;
- 4) Clinical examinations and laboratory examination of animals kept in the establishment, including those animals to be moved.

Summary of sampling procedures

No sampling procedures are defined for PPR for this scenario.

Assessment

This scenario is very similar to the scenario of the Section 4.1.2.1 and therefore the assessment is the same.

Development of new procedures

To grant derogations for animal movements from an establishment in a surveillance zone to a slaughterhouse located outside the restricted zone, clinical examination and sample collection for laboratory investigation for should be performed as described in the Section 4.1.1.1.

For animals intended to be moved from an establishment located outside the surveillance zone to a slaughterhouse situated in the surveillance zone, there is no need for laboratory examination, if there are no other reasons based on the national risk assessment to recommended it (e.g. epidemiological link with affected establishment or with affected or high-risk area). Only clinical examination as described above would be enough.

4.1.2.4. From an establishment in a surveillance zone to pastures situated within the surveillance zone

The purpose of this section is to assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations of kept ungulates of listed species in order to grant a

derogation and allow for the animals to be moved from an establishment in the surveillance zone to pastures situated within the surveillance zone. For further details, see Annex B.

Summary of sampling procedures

No sampling procedures are defined for PPR for this scenario.

Assessment

Animals in a surveillance zone, for which a specific derogation has been granted to be moved to pastures, should be subjected to clinical surveillance, including laboratory examinations.

Sampling procedures for laboratory examination should ensure, with a confidence level of 95%, that the animals do not pose a risk of transmission.

Animals of the holding that are negative at the clinical examination and are negative according to procedures described in the Section 4.1.1.1 do pose negligible risk of transmission of PPR.

- **14th scenario of sampling procedures.**

- ToR 1.4 in accordance with article 43(5) and article 45(1) of the Delegated Regulation.

The following elements of the scenario were taken into consideration for the assessment:

- 1) It concerns kept animals of listed species from establishments located in the surveillance zone;
- 2) To grant derogation for movement from the surveillance zone;
- 3) To be moved to pastures situated within the surveillance zone;
- 4) Clinical examinations and laboratory examination of animals kept in the establishment, including those animals to be moved.

4.1.2.5. From an establishment in a surveillance zone to an establishment belonging to the same supply chain, located in or outside the surveillance zone

The purpose of this section is to assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations of kept ungulates of listed species in order to grant derogation and allow to be moved from an establishment in the surveillance zone to an establishment belonging to the same supply chain, located in or outside the surveillance zone, in order to complete the production cycle before slaughter. For further details, see Annex B.

- **15th scenario of sampling procedures.**

- ToR 1.4 in accordance with article 43(5) and article 45(2) of the Delegated Regulation.

The following elements of the scenario were taken into consideration for the assessment:

- 1) It concerns the surveillance zone;
- 2) Grant derogation for movement of kept animals of listed species;
- 3) from the surveillance zone;
- 4) To be moved to an establishment belonging to the same supply chain, located in or outside the surveillance zone, to complete the production cycle before slaughter;
- 5) Clinical examinations and laboratory examination of animals kept in the establishment, including those animals to be moved.

Summary of sampling procedures

No specific guidelines on sampling procedures for clinical or laboratory examinations were found for the 15th Scenario in EU legislation.

Assessment

Animals in a surveillance zone, for which a specific derogation has been granted to be moved to an establishment of the same supply chain located in or outside the surveillance zone, should be subjected to clinical examination, including laboratory examinations.

Sampling procedures for laboratory examination should ensure, with a confidence level of 95%, that the animals do not pose a risk of transmission.

Moving animals from a non-affected establishment found negative at the clinical examination and negative to virus and antibodies in laboratory examination, according to procedures described in the Section 4.1.1.1 minimise the risk of PPRV transmission.

Development of new procedures

All the animals in the establishment of origin should be clinically examined before their movement to an establishment belonging to the same supply chain, following the procedures described in the Section 4.1.1.1. Visual inspection of the herd would be helpful to identify animals with signs compatible to PPR.

In an establishment where the number of animals is large, the individual clinical examination of all the animals may not be feasible; in this case, a minimum sample of animals (including all animals to be moved) should be clinically examined to detect or rule out the presence of animals with clinical signs with at least 95% confidence, as described in the Section 4.1.1.1.

In case clinical signs compatible to PPR are identified, the establishment is considered suspected and the procedures for the laboratory confirmation as described in the Section 4.1.1.1 should be followed, and movement prohibited until confirmation of being negative. The dispatch of animals of the listed species to an establishment belonging to the same supply chain should be done after sampling for laboratory examination, following the procedures described in the Section 4.1.1.1, in order to exclude infected but subclinical animals with a confidence level of 95%.

4.1.2.6. From an establishment located in the restricted zone to move within the restricted zone when restriction measures are maintained beyond the period set out in Annex XI of the Delegated Regulation

The purpose of this section is to assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations of the animals of an establishment located in the restricted zone of an outbreak in order to allow their move within the restricted zone, when restriction measures are maintained beyond the period set out in Annex XI of the Delegated Regulation. For further details, see Annex B.

- **18th scenario of sampling procedures.**
- ToR 1.4 in accordance with article 56(1) of the Delegated Regulation.

The following elements of the scenario were taken into consideration for the assessment:

- 1) It concerns the restricted zone when restriction measures are maintained beyond the period set out in Annex XI;
- 2) To grant derogation for movement of kept animals of listed species from an establishment within the restricted zone;
- 3) Clinical examinations and laboratory examination of animals kept in the establishment, including those animals to be moved.

Summary of sampling procedures as described in the diagnostic manual

No specific guidelines on sampling procedures for clinical or laboratory examination were found for the 18th Scenario.

Assessment

Animals in the restricted zone, for which a specific derogation has been granted for movement within the restricted zone, should be subjected to clinical examination; if they are not immediately slaughtered, they should also be sampled for laboratory examinations.

Sampling procedures for laboratory examination should ensure, with a confidence level of 95%, that the animals do not pose a risk of transmission.

Moving animals from non-affected establishments that are negative at the clinical examination and negative at laboratory examination, according to the procedures described in the Sections 4.1.1.1 and 4.1.1.2 minimise the risk of PPRV transmission.

Development of new procedures

Sampling procedures should be implemented as described in Sections [4.1.2.1](#), [4.1.2.3](#), [4.1.2.4](#) and [4.1.2.5](#).

4.1.3. Assessment of sampling procedures for repopulation purposes

4.1.3.1. For the animals that are kept for the repopulation prior to their introduction

The purpose of this section is to assess the effectiveness of disease-specific sampling procedures based on laboratory examinations of the animals that are kept for the repopulation prior to their introduction to rule out the presence of the disease. For further details, see Annex [B](#).

- **19th scenario of sampling procedures.**
- ToR 1.5 in accordance with article 59(2) of the Delegated Regulation.

The following elements of the scenario were taken into consideration for the assessment:

- 1) It concerns the repopulation of a previous affected establishment;
- 2) Animals intended to repopulation shall be sampled prior to their introduction into the establishment of destination;
- 3) The samples shall be collected from a representative number of animals to be introduced of each consignment from each establishment or from a representative number of animals of each consignment (if animals are all to be introduced at different times or from different establishments of origin);
- 4) Laboratory examinations;
- 5) The purpose sampling procedures is to rule out the presence of the disease.

Summary of sampling procedures as described in the diagnostic manual

No specific guidelines on sampling procedures for laboratory examination were found for the 19th scenario.

Assessment

For animals kept for repopulation, clinical examination and sampling should be used as standard procedures to ensure that the animals do not pose a risk of PPR transmission. For animals that are introduced from disease free areas outside the restricted zone, sampling can be omitted because they have not been exposed to virus before entry and, consequently, can only produce a negative test result.

Animals that are negative at the clinical examination and are negative according to laboratory procedures described in the Section [4.1.1.1](#) do pose very low risk of transmission of PPRV.

Development of new procedures

Animals intended for repopulation should be subjected to clinical examinations.

In an establishment where the number of animals is large, the individual clinical examination of all the animals may not be feasible; in this case a minimum sample of animals (including all animals to be moved) should be clinically examined to detect or rule out the presence of animals with clinical signs with at least 95% confidence, as described in the Section [4.1.1.1](#).

In case clinical signs compatible to PPR are identified, the establishment is considered suspected and the procedures for the laboratory confirmation as described in the Section [4.1.1.1](#) should be followed. The animals intended for the repopulation, even if clinically healthy, should not be dispatched.

If animals are sourced from restricted areas, all the animals in the establishment of origin should be sampled. Sampling procedures for laboratory examination should ensure, with a confidence level of 95%, that the animals do not pose a risk of transmission. Laboratory examinations should be in accordance with the procedures described in the Section [4.1.1.1](#).

In case the animals originate from establishments located in free areas, there is no need for laboratory examination if there are no other reasons based on the authorities' risk assessment to

recommend it (e.g. epidemiological link with an affected establishment or with an affected or high risk area). Clinical examination as described above would be enough.

4.1.3.2. In the event of unusual mortalities or clinical signs being notified during the repopulation

The purpose of this section is to assess the effectiveness of disease-specific sampling procedures based on laboratory examinations of the animals that have been repopulated, in the event of unusual mortalities or clinical signs being notified during the repopulation; to rule out the presence of the disease. For further details, see Annex B.

- **20th scenario of sampling procedures.**
- ToR 1.5 in accordance with article 59(9) of the Delegated Regulation.

The following elements of the scenario were taken into consideration for the assessment:

- 1) It concerns the repopulated establishment;
- 2) Unusual mortalities or clinical signs during the repopulation;
- 3) The official veterinarians shall without delay collect samples for laboratory examination;
- 4) The purpose of sampling procedures is to rule out the presence of the disease.

Summary of sampling procedures as described in the diagnostic manual

No specific guidelines on sampling procedures for laboratory examination were found for the 20th scenario.

Assessment

In the case of unusual mortalities or clinical signs compatible with PPR notified during the repopulation, it is important to rule out the presence of the disease.

Development of new procedures

In the event of animals with clinical signs compatible with PPR, as they have been described in Section 4.1.1.1, are notified during the repopulation, the establishment is considered suspected. The repopulation should be stopped and the procedures for the laboratory confirmation as described in the Section 4.1.1.1 should be followed.

In addition, the establishments from where the suspected animals are coming from, should be considered as suspected; the procedures described in the Section 4.1.1.1 should be followed as well.

4.1.3.3. For animals that have been repopulated

The purpose of this section is to assess the effectiveness of disease-specific sampling procedures based on laboratory examinations of the animals that have been repopulated, on the last day of the monitoring period calculated forward from the date on which the animals were placed in the repopulated establishment. In case the repopulation takes place in several days, the monitoring period will be calculated forward from the last day in which the last animal is introduced in the establishment. For further details, see Annex B.

- **21st scenario of sampling procedures.**
- ToR 1.5 in accordance with article 59(5) of the Delegated Regulation.

The following elements of the scenario were taken into consideration for the assessment:

- 1) It concerns the repopulated establishment;
- 2) Animals that have been used for repopulation;
- 3) Laboratory examinations;
- 4) Sampling procedures to rule out the presence of the disease.

Summary of sampling procedures as described in the diagnostic manual

No specific guidelines on sampling procedures for laboratory examination were found for the 21st scenario.

Assessment

During the repopulation of an establishment previously affected by PPR, there is still a risk of re-introduction of the disease with the new animals being infected either at the establishment of origin or during their transport, and a risk of re-emergence of the disease if the new animals are infected after their arrival at the establishment of destination. The animals that have been used for the repopulation should be submitted to thorough clinical and, if showing signs, laboratory examination in order to rule out the presence of the disease.

Development of new procedures

Animals must be subjected to clinical inspection at least every three days for the first 14 days following the introduction, and weekly from 15 to at least 21 days (monitoring period as defined in the Commission Delegated Regulation (EU) 2020/687) after re-introduction. The last day of the monitoring period following the latest day of animals' introduction, all the animals should be subjected to thorough clinical examination as described in Section 4.1.1.1. and should be sampled for laboratory examination in accordance with the procedures described there.

In an establishment where the number of animals is large, the individual clinical examination of all the animals may not be feasible; in this case a minimum sample of animals (including all animals to be moved) should be clinically examined, to detect or rule out the presence of animals with clinical signs with at least 95% confidence, as described in the Section 4.1.1.1.

If clinical signs are identified, then the procedures for the laboratory confirmation that are described in the Section 4.1.1.1 should be followed.

4.2. Assessment of the length of the monitoring period

The concept of the monitoring period was introduced as a management tool for the investigation and control of suspected and confirmed outbreaks of Category A diseases in terrestrial animals. This tool aimed to standardise the methodology by which relevant authorities responded to suspected and confirmed cases of these diseases. In this regard, a disease-specific monitoring period was set for each of the 14 diseases included in the Category A list. Throughout the EU legislation, the monitoring period is used as an aid in the control of these diseases, although the specific purpose in which the monitoring period is used varies depending on the articles of the legislation.

The length of the monitoring period for each disease is set out in Annex II of the Commission Delegated Regulation (EU) 2020/687 supplementing the rules laid down in Part III of Regulation (EU) 2016/429 (Animal Health Law).

The table in Annex D in this manuscript describes the seven scenarios for which an assessment of the length of the monitoring period for PPR had been requested.

4.2.1. Results

4.2.1.1. Period between the earliest point of infection and suspicion report

The details of the review protocol are in Annex J. A search was carried out identifying 277 references published after 1/1/2000 (because of the small number of references retrieved for European countries ($n = 2$), the selection was extended to the rest of the world). Among the 277 references, 10 were selected to be included in the qualitative review. The full selection process is displayed in Figure 5.

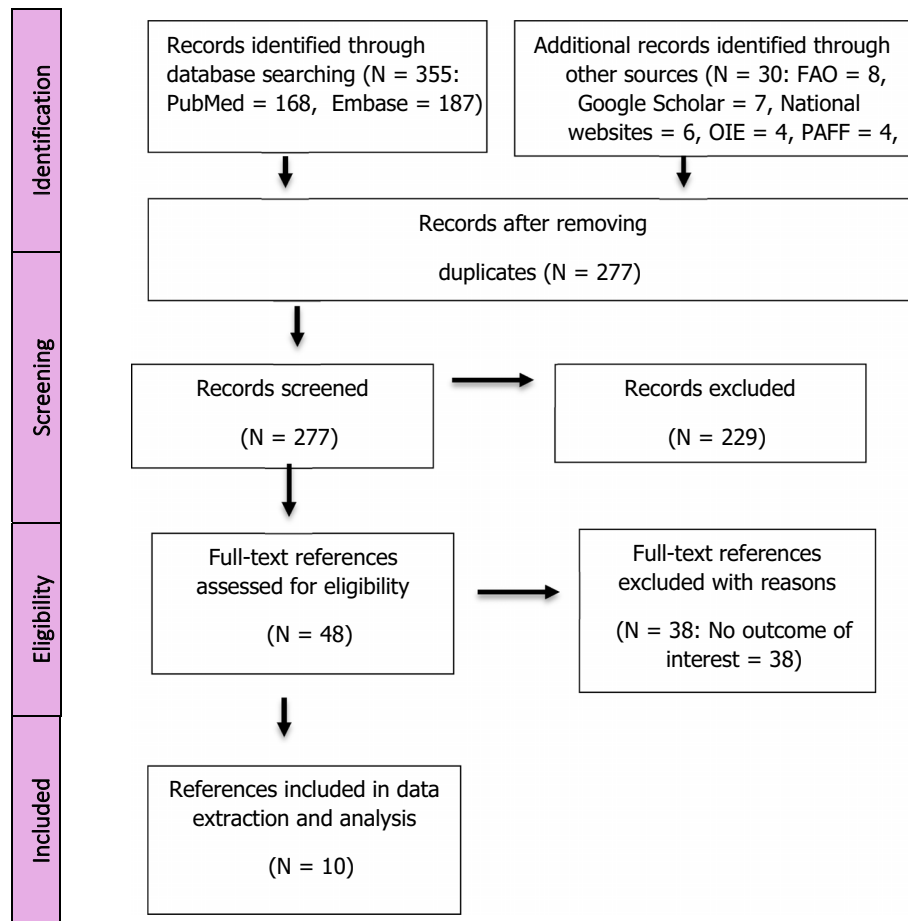


Figure 5: PRISMA diagram PPR Monitoring period ELS

Half of the references reported dates instead of periods; these dates were used to calculate the periods of interest. Information on the main outcome of interest, the period between the earliest point of infection and the suspicion report, was only retrieved from three references (Table 4), two of which were not considered relevant for the scope of this exercise.

Based on worldwide experience, it is expected that in case of an introduction of PPR in Europe, goats would show more severe signs than sheep. Therefore, we may assume that an outbreak in a goat flock would be detected more easily and earlier than in sheep (EFSA AHAW Panel, 2015).

Thus, because only three references with information on the main outcome of interest were extracted, two of which were not considered representative for the European context, data were also extracted for other period of interest i.e. the period between first suspicion and the suspicion report. These data are summarised in Table 4.

Table 4: Summary of the period of interest (days) in the outbreak reporting process

| 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 |

*: Based on first observed clinical signs of PPR.

For the purpose of this assessment, the period between the earliest point of infection and the suspicion report was then reconstructed by adding the length of the incubation period as obtained in the literature, to the period between first suspicion and the suspicion report as presented in Table 4. Three references were extracted where this period had been calculated.

According to the OIE, the incubation period can range from 3 to 10 days (mean = 7 days). To reconstruct the period between the earliest point of infection and the suspicion report, the mean of the incubation period (7 days) can be added to the median of the period between suspicion and the suspicion report (14 days), resulting in an estimate of 21 days (14 + 7). In a similar manner, the maximum period between the earliest point of infection and the suspicion report can be reconstructed as 33 days, by adding the maximum incubation period (10 days) to the maximum period between first suspicion and suspicion report (23 days).

4.2.1.2. Seroconversion in animals

The results regarding the range of days for seroconversion and the latest detected day of antibody presence in listed species of PPR after experimental infection with PPRV is presented in Table 5.

Species *Capra* spp. and *Ovis* spp.

According to the available scientific literature reviewed, the seroconversion date for *Capra* spp. ranged between 6 and 13 days post infection (dpi)⁴ and for *Ovis* spp. ranged between 5 and 11 dpi. Differences among studies regarding the ELISA tests used, the methods of infection (route of infection, TCID₅₀ per animal) and the lineages used, did not yield major differences in the range of seroconversion. The use of VNT for antibodies detection seemed to give positive results only after the first week post infection; the small number of studies and the different blood sampling intervals after infection among studies warrant caution for the interpretation of this finding. The latest day of antibody detection coincided with the duration of the experimental study after the infection of the animals. In most studies, animals were euthanized or slaughtered soon after the severity of PPR signs worsened, usually between first and second week post infection. In studies where antibodies were monitored after the second week post infection, animals remained seropositive until the end of the study: Liu et al. (2013) reported that goats remained seropositive until 240 dpi.

Schulz et al. (2018) infected pigs and wild boars with PPRV and added 2 contact control goats 2 days later. Goats seroconverted at 15–24 dpi. Of those, one was euthanized at 18 dpi and the second at 30 dpi; both remained seropositive until then.

⁴ This means that in the experiments considered the earliest animals seroconverted at 6 while the latest animals seroconverted at 13 dpi.

Table 5: Range of days for seroconversion and latest detected day of antibody presence in listed species after experimental inoculation with PPR virus

| Species | Animals in the study | Laboratory method | Range of days for seroconversion (days post infection, dpi ¹) | | Latest day of antibodies detection/end of experiment [Ref. ID] | Total number of references | Reference ID | |
|-------------------|---|-------------------|--|--|--|----------------------------|---|--------------------------|
| | | | Earliest day of seroconversion start [Ref. ID] | Latest day of seroconversion start [Ref. ID] | | | | |
| Capra spp. | Goats | C- ELISA | 6 ^{a,b} (Wernike et al., 2014) | 12 ^a (Pope et al., 2013) 13 ^b (Wani et al., 2018) | 21 ^a (Pope et al., 2013) 240 ^b (Liu et al., 2013) | 16 | (Couacy-Hymann et al., 2007; El Harrak et al., 2012; Pope et al., 2013; Truong et al., 2014; Wernike et al., 2014; Muniraju et al., 2015; Holzer et al., 2016; Schulz et al., 2018; Wani et al., 2018; Bamouh et al., 2019; Enchery et al., 2019; Begum et al., 2020; Mahapatra et al., 2020) | |
| | | | 15 ^e | 24 | | | | 28 |
| | | H-ELISA | 7 ^a | – | N/S | 1 | | (El Harrak et al., 2012) |
| | | | 9 ^b | – | N/S | | | |
| | | bELISA | 9 ^a | – | 10 | 1 | | (Bamouh et al., 2019) |
| | | Indirect Ab ELISA | 8 ^{a+b} | – | 21 | 1 | | (Truong et al., 2014) |
| VNT | 11 ^{a+b} (Truong et al., 2014) 14 ^b (Liu et al., 2013) | – | 240 ^b (Liu et al., 2013) | 3 | (Liu et al., 2013; Truong et al., 2014; Li et al., 2018) | | | |
| Ovis spp. | Sheep | C-ELISA | 5 ^c (Rojas et al., 2014) 6 ^b (Wernike et al., 2014) | – | 13 ^c (Rojas et al., 2014) 21 ^b (Schulz et al., 2018; Wani et al., 2018) | 4 | (Rojas et al., 2014; Wernike et al., 2014; Schulz et al., 2018; Wani et al., 2018) | |
| | | | 8 ^{a+b} | – | | | | 21 |
| | | VNT | 11 ^{a+b} | – | 21 | 1 | | (Truong et al., 2014) |
| Camelidae | Dromedary camels | VNT | 14 ^c | 28 | 42 | 1 | (Fakri et al., 2019) | |
| Cervidae | White-tailed deer | CF, SN | 21 ^d | 21 | 21 | 1 | (Hamdy and Dardiri, 1976) | |

N/S: not specified; VNT: virus neutralising titre; SN: serum neutralisation; CF: complement fixation; C-ELISA: competitive ELISA; H-ELISA: haemagglutinin ELISA; bELISA: blocking ELISA; indirect Ab ELISA: indirect antibody ELISA.

a: Intranasal infection; b: subcutaneous infection; c: intravenous infection; a + b: Intranasal infection + subcutaneous infection in the same animal; d: intramuscular infection; e: in contact with infected animals.

Camelidae

One study with PPRV challenge of dromedary camels fulfilled the inclusion criteria. Animals were blood sampled in 7 days intervals post-infection. Serum antibodies were detected with VNT. The range of days for seroconversion was 14–28 dpi, while the latest day of antibodies detection was 42 dpi (end of study).

Cervidae

One study with PPRV challenge of white-tailed deer (*Odocoileus virginianus*) fulfilled the inclusion criteria. Blood sampling was performed at 14 and 21 dpi. Serum antibodies were detected with complement fixation and serum neutralisation tests. PPRV antibodies were detected at 21 dpi.

Cattle (*Bos taurus*)

Two studies with PPRV challenge of cattle fulfilled the inclusion criteria: one with adult cattle and another one with calves. The range of days for seroconversion was 9–15 dpi for adult animals and 21 dpi for calves. Again, the latest day of antibody detection depended only the duration of the experimental study after the infection of the animals. Adult cattle remained seropositive by 30 dpi (end of study), while infected calves remained seropositive by 397 dpi.

Pig (*Sus scrofa*)

Only one study with PPRV challenge of domestic pigs and wild boars fulfilled the inclusion criteria. Antibodies were detected with C-ELISA (N-protein end). The range of days until seroconversion was 7–10 dpi, while the latest day of antibody detection was 30 dpi (end of study).

Assessment

Considering the results presented above, an assessment of the effectiveness of the current monitoring period for PPR, depending on the purpose of that period in the different scenarios shown in Annex C, was carried out. For PPR, the length of the monitoring period as defined in Annex II of the Delegated Regulation is 21 days.

Scenarios 1, 2 and 3

- 1st scenario of monitoring period.
- ToR 2 in accordance with article 8 and Annex II of the Delegated Regulation.
- Article 57 of the Regulation (EU) 2016/429.
- Aim: 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 of a PPR outbreak.

- 2nd scenario of monitoring period.
- ToR 2 in accordance with article 17(2) and Annex II of the Delegated Regulation.
- Article 57 of the Regulation (EU) 2016/429.
- Aim: 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 a PPR outbreak.

- 3rd scenario of monitoring period.
- ToR 2 in accordance with article 13(b) and Annex II of the Delegated Regulation.
- Aim: to assess the effectiveness of the length of the Monitoring Period, as the time period calculated backwards from the date of confirmation of a PPR outbreak in an epidemiological unit in which the disease has not been confirmed, in order to provide derogations from killing the animals in this unit, if this unit has been completely separated, and handled by different personnel during this monitoring period.

For the first three scenarios, the main purpose of the use of the monitoring period is to be able to carry out a full epidemiological investigation (i.e. in Scenarios 1 and 2, at the time of the suspicion and confirmation, respectively), or part of the epidemiological investigation (i.e. Scenario 3, where the aim is to identify any possible epidemiological links between the affected establishment and any separated non-affected epidemiological units).

The length of the monitoring period should then dictate how far backward or forward the activities related to tracing (and other activities needed during an epidemiological investigation) should go (checks for production records, animal movement records, etc.). This monitoring period is the time, where the infection could have been present unknowingly in an establishment, and due to the regular activities carried out in this establishment, could have spread to other epidemiological units.

In the case of Scenario 3, if no epidemiological links between the establishment that has been confirmed positive and the other epidemiological units are found during the investigation (and only if other conditions described in the legislation are met), a derogation from killing the animals in the separated non-affected epidemiological units could be granted.

The period of time the disease could have been present, unknowingly, in an establishment, equates then to the time period between the entry of PPR into the establishment, and the reporting of the suspicion. Once the suspicion has been officially reported, control measures are implemented, and further spread should in this way be prevented.

Based on the ELS carried out and presented above, the length of the time between the earliest point of infection and the suspicion report, reconstructed as described above, was estimated at between 13 and 33 days, with an average of 21 days. The monitoring period as defined in Annex II of the Delegated Regulation of 21 days falls within this range and could thus be considered effective.

However, it is important to take into account that when the disease is first introduced in an area, detection may be delayed. This should be taken into account when carrying out an epidemiological investigation in the index case (first affected establishments) in an area. For that purpose, the maximum period estimated as 33 days could be considered.

The length of the monitoring period of 21 days as defined in the Delegated Regulation is therefore considered effective, except for the first affected establishments detected in an area, where a monitoring period of 33 days, (the longest reconstructed period found in the ELS) is recommended.

- Scenario 4th scenario of monitoring period.
- ToR 2 in accordance with article 27(3)c and Annex II of the Delegated Regulation.
- Aim: 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 the PPR outbreak in the protection zone. Products or other materials likely to spread the disease, must have been obtained or produced, before this time period in order to be exempted from prohibitions of movements.

The main purpose of the monitoring period in Scenario 4 is to ensure that certain products or materials, likely to spread the disease, that have been produced in a non-affected establishment located in the protection zone of an affected establishment, can be moved safely and without posing a risk of disease spread. In this scenario, and in contrast with the previous three scenarios, the establishment of concern is neither a suspected nor an affected establishment. For the assessment of this scenario, we assume that the earliest plausible point of infection of these products or materials in the establishment of concern would be the earliest plausible point of infection of the establishment that originated the protection zone. If these products have been obtained or produced before the earliest point of infection of the affected establishment, then they could be exempted from prohibitions to be moved, as long as other conditions specified in the legislation are met (e.g. the products must have been clearly separated during the production process, storage and transport, from products not eligible for dispatch outside the restricted zone).

As the disease has already been detected in the area, and high awareness is expected, the average length estimated above, i.e. 21 days, is considered effective in this scenario.

Scenario 5

- 5th scenario of monitoring period.
- ToR 2 in accordance with article 32 (c), article 48(c) and Annex II of the Delegated Regulation.
- The purpose of this section is to assess the effectiveness of the length of the Monitoring Period, as the time period calculated forwards from the date of semen collection from animals of listed species kept in approved germinal product establishments in the protection or in the surveillance zone, to prove that the donor animal has tested favourable on a sample taken not earlier than 7 days after the monitoring period.

The aim of the monitoring period in this scenario is to ensure that semen from animals in a non-affected establishment (located in a protection or surveillance zone) that has been collected and frozen after the earliest time of infection of the affected establishment that originated the protection zone, is safe to be moved without posing a risk of disease spread. In this scenario, EFSA is requested to assess the length of time, after the semen was taken, when the animal should be tested in order to allow that semen to be moved. Here, it is assumed that the earliest point of infection of the animal would be on, or after the earliest point of infection of the affected establishment that originated the protection zone, and the latest date the semen could have become contaminated would be the date the semen was collected.

In the case of a PPR outbreak, based on the existing legislation, the animals would have to be tested not earlier than the time in days of the monitoring period plus seven days ($21 + 7 = 28$ days) counted after the semen was taken.

There is, however, uncertainty regarding detection of PPRV in semen; no studies have been found documenting this. Despite this, and assuming that missing an infected establishment as described above would be plausible, below we summarise the assessment in the case that sheep or goats need to be sampled via serology in order to assess the infection status of the animal at the time the semen was taken (indicating whether the semen was infected or not). A negative serological test, if carried out at the right time, would indicate that the animal has never been exposed to the agent, and therefore it will indicate that the semen is free of the agent too.

Based on the results presented in Section 4.2.1 in relation to the seroconversion (in non-vaccinated), naïve animals, the latest date of seroconversion was identified as 11 days for sheep and 13 days for goats.

Consequently, and based on the results of the publications, sampling the animals at least 28 ($21 + 7$) days after semen collection for antibody testing, as it is foreseen in the Delegated Regulation, and with negative results, is considered effective to ensure that semen is safe to be moved without posing a risk of disease spread.

Scenarios 6 and 7

- 6th scenario of monitoring period
- ToR 2 in accordance with article 57 (1) and Annex II of the Delegated Regulation
- Aim: to assess the effectiveness of the length of the Monitoring Period, as the time period calculated forward from the date of the final cleaning and disinfection in an affected establishment, after which the repopulation of the establishment may be allowed by the competent authority (assuming relevant control of insects and rodents was carried out).

- 7th scenario of monitoring period
- ToR 2 in accordance with article 59 (4) and Annex II of the Delegated Regulation
- Aim: to assess the effectiveness of the length of the Monitoring Period, as the time period calculated forward from the date the first animal was introduced for the purpose of repopulation, during this monitoring period, all animals of the listed species intended for repopulation should be introduced.

In Scenarios 6 and 7, the monitoring period is used in the context of repopulation. In Scenario 6, the monitoring period is used to ensure that the repopulation process is not put at risk due to the disease still being present unknowingly in establishments within the surrounding area of the establishment to be repopulated (if an establishment tested positive to PPR virus within a distance

equal or lower to the radius of the surveillance zone, the repopulation process could not take place). Repopulation can only take place after a number of days equal to the monitoring period has elapsed since the final cleaning and disinfection of the affected establishment.

In this regard the number of days of the monitoring period for PPR, counted from the day of the final cleaning and disinfection must ensure enough time for any potentially infected surrounding establishment to be reported as a suspicion. Considering the results presented above, the monitoring period as defined in Annex II of the Delegated Regulation of 21 days is considered effective for this scenario.

In Scenario 7, the monitoring period must be counted forwards from the date in which the first animal is introduced into the establishment to be repopulated, with all the animals intended for repopulation of this establishment being introduced within the length of time of this monitoring period.

The aim of the monitoring period in this scenario is to ensure the early detection of any potentially recently infected animal intended for repopulation once they have been moved into the repopulated establishment. Although the preferred option is that all animals are introduced into the establishment to be repopulated at the same time, this is not always feasible. The first clinical and laboratory sampling of the repopulated animals takes place once all the animals are *in situ*. By restricting the period of time during which animals may be introduced into the establishment, the period of time during which the disease could be unknowingly spreading within the establishment is reduced. Assuming that the latest point of infection of the first animal or batch of animals introduced into the repopulated establishment is the day when the animals are moved, clinically ill animals would be observed at the first visit, if this visit is carried out a number of days equal to the incubation period. For PPR the incubation period is typically 4–6 days (range 3–10 days). The EFSA AHAW Panel thus considers the existing length of the monitoring period as defined in Annex II of the Delegated Regulation (21 days) effective as it would allow for early detection of potentially infected animals at the first visit following re-stocking.

4.3. Assessment of the minimum radius and time periods of the protection and surveillance zones set in place subsequent to a disease outbreak

4.3.1. Assessment of the minimum radius

The purpose of this section, related to the question posed by ToR 3 of the mandate, is to assess the effectiveness to control the spread of PPR by implementing a protection and surveillance zones of a minimum radius, as set out in Annex V of the Delegated Regulation, surrounding the establishment where the disease has been confirmed. Based on this regulation, the minimum radii of the protection and surveillance zones for PPR should be of 3 and 10 km respectively (Annex E).

To assess this, transmission kernels have been used to estimate the minimum radius for PPR spread, under the assumption of excluding the spread due to animal movements. Since no kernels were available in the literature, these were derived from PPR outbreak data. According to OIE, in the last 20 years, PPR has been reported in more than 30 countries in Africa and Asia, with more than 3,000 outbreaks. Outbreaks occurred in EU would give results better fitting to EU situation, but in the EU PPR was reported only once in Bulgaria in 2018 (ADNS), with only seven outbreaks, which provides too little information to estimate a kernel. The closer country to the EU where PPR was reported in sufficient number of outbreaks is Turkey, where the disease is considered endemic at least since 2005, despite the vaccination program in place since at least 2010 (EFSA AHAW Panel, 2015) (Figure 6). The epidemiological trend of PPR in Turkey (many outbreaks reported every year continuously in the last 15 years at least) suggest that the control measures in place, in particular ban on animal movements, may have not been completely and/or successfully implemented, thus creating a situation that would neither fit the above-mentioned assumption (i.e. exclusion of disease spread due to animal movement) nor the EU situation in case of PPR outbreaks (e.g. the quick containment of PPR outbreak in Bulgaria in 2018).

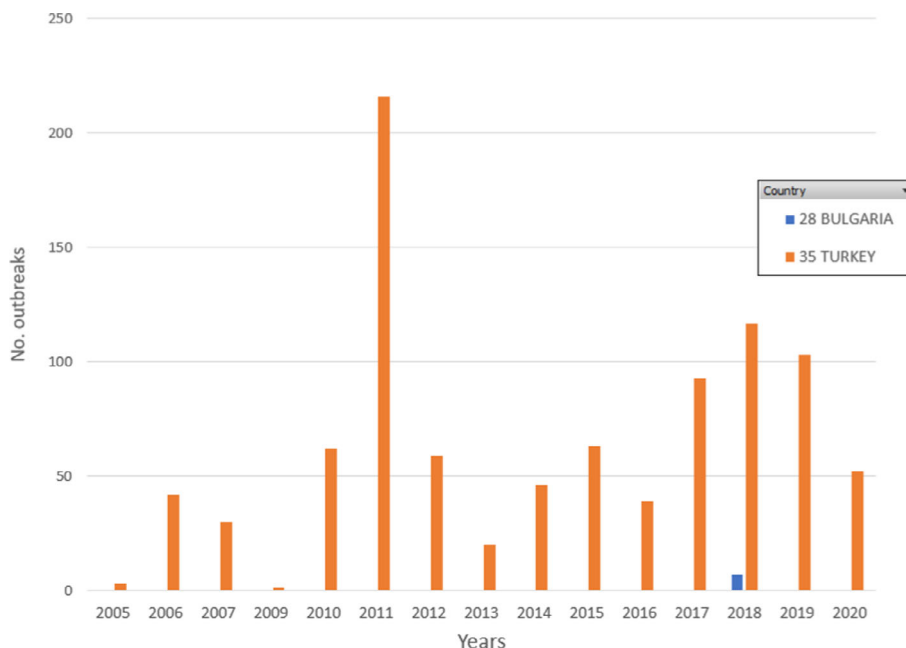


Figure 6: Number of outbreaks of PPR reported in Turkey and Bulgaria since 2005 (Source: ADNS)

Given this, an alternative method has to be used for assessing the PPR minimum radius of spread. In particular a parallel assessment can be done with sheep and goat pox (SGP), which has the same hosts and similar epidemiology in term of transmission routes (EFSA AHAW Panel, 2015) and which spread in EU (Greece and Bulgaria) in 2013–2014 (EFSA AHAW Panel, 2014). The main differences and similarities between PPRV and SGPV are:

- PPRV is an enveloped negative single-stranded RNA virus, which is considered much more fragile in the environment than SGPV, an enveloped, double-stranded DNA virus that may persist in the environment for prolonged periods. PPRV like rinderpest virus, is inactivated by ultraviolet light and desiccation within 3-4 days or less (depending on the specific environment), and normally survives for very short periods in carcasses, while SGPV is susceptible to sunlight, but remain viable in wool/hair/fleece and dry scabs on skin for up to 3 months. Thus, fomites such as water, feed troughs and bedding can probably transmit PPRV for a short time, while fomites and animal products can spread SGPV for at least 3 months.
- The incubation period for PPR can range from 2 to 10 days while for SGP from 4 to 21 days, but is usually one or two weeks. For OIE, the maximum incubation period is 21 days for both diseases. However, shedding begins for PPRV early in the incubation period and for SGPV animals are most contagious during the first week after the onset of clinical signs (infected experientially infectious for one to two months).
- Given the above, SGP are known to be extremely difficult to control using only total or modified stamping out, animal movement restrictions and quarantine (Tuppurainen et al., 2017).
- Other differences that may be a source of bias: so far no evidence of sheep pox and goat pox (SPGP) virus in wild ruminants exists, while PPRV affects a broad range of wildlife species. The global distribution of SGP virus is wider than PPRV, but overlapping on the whole extent of PPR distribution

Whereas similarities between these diseases can be underlined:

- Both PPR and SGP are highly contagious and transmission occurring through aerosols, needing direct or close indirect contact, e.g. through fresh contaminated materials) with infected sheep and goats shedding virus in oral, nasal and ocular secretions;
- Both diseases follow non-vector transmission pathways; the role of insect vectors in the field remains unclear;
- Infection results in robust and long-lasting immunity more than 3 years for PPRV, 22 months for SGP (Kitching, 2003);
- Animals affected by PPRV and SGPV usually clear the infection and do not become carriers.

This would account for a similar behaviour in transmission routes in the European context, and given the main difference of SPGP virus, i.e. the persistence in the environment that may lead to recurrent outbreaks in the same place, using sheep pox as epidemiological proxy for PPR may lead to a slightly worse scenario.

Because suitable transmission kernels were not available for PPRV in EU situation, those for sheep and goat pox were used as a proxy. These kernels were estimated using data on outbreaks of SPGP reported in the Evros region of Greece from 2013 to 2014 (extracted from ADNS) (EFSA AHAW Panel, 2014). Four functional forms were fitted to the data (Table 6 and Figure 7), with the alternative fat-tailed kernel yielding the best fit to the data.

Table 6: Kernels for the transmission of sheep and goat pox, used as a proxy for PPRV

| Epidemic | Kernel | Function | Parameters* | |
|--------------------------------|------------------------|---|---------------------|-------------------|
| | | | d_0 (km) | α |
| Evros region, Greece 2013–2015 | Fat-tailed | $k(d) = \left(1 + \left(\frac{d}{d_0}\right)^2\right)^{-1}$ | 2.28 (1.40, 5.05) | – |
| | Gaussian | $k(d) = \exp\left(-\left(\frac{d}{d_0}\right)^2\right)$ | 10.04 (7.23, 14.49) | – |
| | Exponential | $k(d) = \exp\left(-\frac{d}{d_0}\right)$ | 5.67 (3.36, 10.05) | – |
| | Alternative fat-tailed | $k(d) = \left(1 + \frac{d}{d_0}\right)^{-\alpha}$ | 0.61 (0.08, 3.26) | 1.32 (0.98, 2.07) |

*: Maximum likelihood estimate (95% confidence interval).

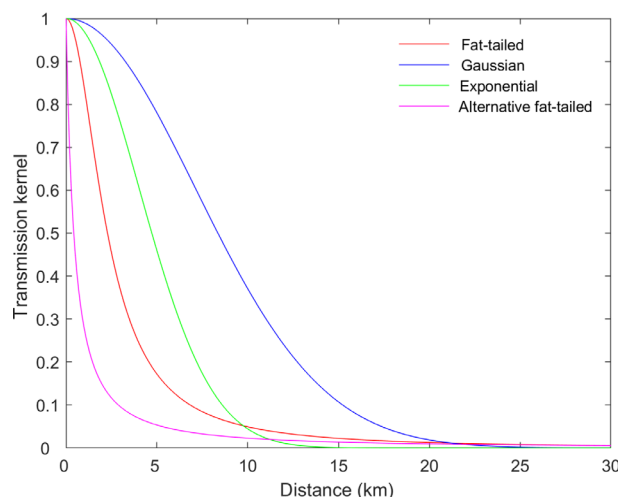


Figure 7: Kernels for the probability of transmission of sheep and goat pox at increasing distances if transmission occurred from an affected establishment, used as a proxy for PPRV when assessing the minimum size of the protection and surveillance zones

The reason why only the outbreaks reported in Evros region were used for the analysis lies on the fact that outbreaks that occurred outside this region were most likely linked to animal movements, which would be in contrast with the assumption made above, i.e. exclusion of the spread due to animal movements. In fact, in that epidemic most outbreaks (82) were reported in eastern Greece (Evros regional unit) at the border with Turkey, but some of them also in the regional units of Rodopi and Xanthi on the west of Evros, and even in Thessaloniki at almost 300 km of distance from Evros. According to the Greek veterinary authorities, the two possible scenarios included the (i) spread from

Evros to Thessaloniki due to the owner of the first infected farm in Thessaloniki who was a truck driver, frequently travelled to Evros; (ii) spread to other Greek regional units more on the West due to uncontrolled movements of sheep and goat transported by animal traders from Greece's Muslim communities of Thrace: in all the outbreaks in the prefecture of Xanthi, the origin of which was considered to be Turkey, as their onset coincided with visits of traders in search of animals for the Islamic festival of Kurban Bayramı (when a large number of small ruminants is required for domestic slaughter), which in 2013 took place on 14 October. This means that animal movement or transport of infected fomites could not be excluded, thus leading to somehow overestimation of the probability of spread.

For the alternative fat-tailed kernel in Table 7 (i.e. the best-fitting one), the probability of transmission beyond given distances (if transmission were to occur from an infected establishment) was computed using the estimates, lower 95% confidence limits and upper 95% confidence limits, including beyond the proposed radius for the protection and surveillance zones (3 km and 10 km, respectively) (Table 7). In addition, the distances at which a threshold probability of transmission beyond that distance is reached were also calculated for each kernel using the estimates, lower 95% confidence limits and upper 95% confidence limits (Table 8).

Table 7: Probability of transmission of PPRV beyond different distances, assuming the same transmission kernels as for sheep and goat pox

| | 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 |

Table 8: Distances (km) at which the probability of transmission of PPRV beyond that distance reaches a threshold level, assuming the same transmission kernels as for sheep and goat pox

| | Threshold probability of transmission | | | | | | |
|--------------|---------------------------------------|-------|------|------|-----|-----|-----|
| | 0.001 | 0.005 | 0.01 | 0.05 | 0.1 | 0.2 | 0.5 |
| Estimate | 103.5 | 33.2 | 19.4 | 5.3 | 2.9 | 1.5 | 0.4 |
| Lower 95% CI | 88.2 | 20.0 | 9.8 | 1.8 | 0.9 | 0.4 | 0.1 |
| Upper 95% CI | 113.7 | 38.8 | 26.8 | 10.6 | 6.6 | 3.8 | 1.3 |

From Table 7, the estimate value of probability of transmission beyond protection zone of 3 km radius if transmission occurred is 9.6% (95% CI: 3.1–25.8%) and 2.3% (95% CI 1–5.5%) for 10 km radius (Table 7), which may be considered sufficient to contain the disease spread (95% probability of containing transmission corresponds to 5.3 km, Table 8).

If the aim is to reduce the probability of transmission beyond the surveillance zone of 10 km to 1% (and not 2.3% as assumed above), the radius should be increased to 19 km (95% CI 9.8–26.8). This, nonetheless, would on average increase the number of farms in the surveillance zone (affected by movement restrictions) fourfold.

4.3.2. Assessment of the minimum period

The purpose of this section is to assess the effectiveness to control the spread of PPR of the minimum periods during which the competent authority should apply the restriction measures in the protection and surveillance zones. The length of the minimum period of duration of measures in protection zone is 21 days, while for the surveillance zone is 30 days (Annex X of the Delegated Regulation).

To assess the minimum length of time the protection and the surveillance zones should be kept in place, the average (for the protection zones) and the longest (for the surveillance zones) period between the earliest point of infection and the notification of a suspicion will be used (EFSA AHAW Panel, 2020).

Based on the results of the ELS as presented in the Table 4 in Section 4.2.1, it follows that the average time between infection and notification of the suspicion is 21 days. This coincides with the minimum period of 21 days indicated in the Delegated Regulation for the restriction measures in the protection zone, therefore the latter is considered effective to detect infected establishments and to prevent the movement of infected animals from the protection zone.

In addition, the maximum period between the earliest point of infection and the suspicion report has been reconstructed as 33 days, by adding the maximum incubation period (10 days) to the maximum period between first suspicion and suspicion report (23 days). Consequently, the minimum period of 30 days indicated in the Delegated Regulation for the restriction measures in the surveillance zone should be extended up to 33 days, so to detect infected establishments and to prevent the movement of infected animals from the surveillance zone.

4.3.3. Uncertainty analysis

Although several sources of uncertainty were identified during the scientific assessment (see Annex F), their impact on the outputs of the assessment could not be quantified.

5. Conclusions and recommendations

| Sampling procedure | Laboratory guidelines based on Council Directive 2003/85/EC if not stated otherwise | Conclusions | Recommendations |
|---|---|---|--|
| ToR 1: In the event of suspicion or confirmation | | | |
| 1st scenario 4.1.1.1 In the event of a suspicion of PPR in an establishment where animals of the listed species are kept | No specific guidelines on sampling procedures for clinical or laboratory examination in the event of a suspicion of PPR are available in the EU legislation | <p>The suspicion of PPR is raised by detection of PPR-related clinical signs. The confirmation of clinical suspicion is based on laboratory test, mainly by confirming the presence of the virus nucleic acids (RT-PCR) or of antibodies (ELISA test). The collection of specimens for RT-PCR testing can be performed either on dead or alive animals. In the latter, samples should be collected in the acute phase of the disease, when clinical signs are apparent, to maximize the probability of detecting the viral genome. If samples are collected from dead animals, these should be few hours from death, since the virus may rapidly inactivate.</p> <p>In case of large numbers of animals showing clinical signs, at least five animals among those showing fever and other signs typical of the acute phase of the disease should be preferred for sampling. If clinical signs are not evident in the herd, the sampling of randomly selected asymptomatic animals can be performed and ELISA should be also performed.</p> <p>Detection of antibodies for PPR confirmation in a PPR free country, with no vaccinated animals, can complement the RT-PCR testing, taking into account that only from 10 to 14 days after the infection the antibodies are detectable by ELISA assays. The confirmation based on serology alone requires the collection of two blood samples, three weeks apart, from the same animals, which is not always feasible in the field.</p> <p>Serological surveys are useful to determine the presence or absence of infection in a defined country or zone and its extent in a population.</p> | |
| 2nd scenario 4.1.1.2. For the purposes of the epidemiological enquiry as referred to Article 57 of Regulation (EU)2016/429 in an PPR officially confirmed establishment | There are no sampling procedures defined for the purposes of the epidemiological enquiry in an establishment affected and officially confirmed with PPR. | For PPR, it is not possible to derive or estimate the time of exposure by the lesions, which are not disease-specific and may greatly vary. In addition, it is not possible to use the laboratory results. Antibodies are detectable after 10–14 days from the infection and they remain probably for the whole productive life of the animals. Consequently, detection of antibodies suggests that infection occurred > 10 days prior to detection of antibodies, but no other inferences can be made upon the time of exposure on the basis of serological results. No commercial tests are available for the detection of IgM and other more transient antibody classes. | |
| 3rd scenario 4.1.1.3. For granting | There are no sampling procedures to grant a | Animals in an affected establishment and for which a specific derogation from killing has been granted should be subjected to clinical and laboratory examination. Sampling | All the animals intended for derogation from killing |

| Sampling procedure | Laboratory guidelines based on Council Directive 2003/85/EC if not stated otherwise | Conclusions | Recommendations |
|---|--|--|---|
| a specific derogation from killing animals of the categories of article 13.2 of the Delegated Regulation in an PPR affected establishment | derogation from killing of animals in an affected establishment | <p>procedures should ensure that the animals do not pose a risk of transmission if left alive.</p> <p>Animals of the holding that are negative for antibodies and virus do not pose a risk of transmission of PPR. Recovered animals with antibody positive results only, do not pose a risk of transmission.</p> <p>General evaluation of the animal health status of the establishment should be carried out, preferably every day, to detect early the onset of clinical signs, for a period of at least the existing monitoring period of 21 days calculated forwards from the day of confirmation of the latest case.</p> | should be subjected to thorough individual clinical examination twice at two weeks intervals to identify those animals with clinical signs in order to take samples for virological testing. |
| 4th scenario 4.1.1.4. For the animals of non-listed species kept in an PPR affected establishment. | There are no sampling procedures defined for non-listed species kept in an affected establishment by PPR | <p>The listed species for PPR according to Commission Implementing Regulation (EU) 2018/1882³ are <i>Ovis</i> spp., <i>Capra</i> spp., Camelidae, Cervidae.</p> <p>Where other susceptible domestic animals are also kept, these should also be sampled. Those should be tested for both the presence of virus by PCR and/or viral isolation as well as for serology. Although there is no evidence from literature or other reports (Fine et al., 2020) suggesting that PPRV could naturally spread by intraspecies transmission between pigs and wild boar, suids should be considered as possible source of infection as suggested by experimental infections.</p> | |
| 5th scenario 4.1.1.5. For wild animals of the listed species within the PPR affected establishment and its surroundings. | There are no sampling procedures defined for wild animals of the listed species within the PPR affected establishment and its surroundings | In the scenario where wild cervids (e.g. roe deer, red deer, fallow deer) or wild bovinds (e.g. muflon, chamois, ibex, etc.) are kept or living in the surrounding area of the affected establishment, these may acquire the infection by direct or indirect contact with affected animals, if no or low biosecurity measures are in place to keep animal species separated. | The surveillance of wildlife around the affected establishment should include the visual inspection of these animals from distance and the testing of fallen stock and hunted animals both by PCR and serology. Unexpected mortality events in susceptible wildlife should be investigated. |
| 6th scenario 4.1.1.6. For animals of listed species in the non-affected establishments located in a protection zone | There are no sampling procedures defined for animals of listed species in the non-affected establishments located in a protection zone for PPR | <p>All establishments located in the protection zone should be visited and the animals should be subjected to clinical surveillance, including a laboratory examination to ensure the detection of the virus, if the virus is present in these animals.</p> <p>Active surveillance via serological or virological testing of randomly selected animals (i.e. in the absence of clinical signs) should be conducted only if this could be considered necessary due to epidemiological considerations such as spread of a low virulent strain of the virus with none or very little clinical signs.</p> | |

| Sampling procedure | Laboratory guidelines based on Council Directive 2003/85/EC if not stated otherwise | Conclusions | Recommendations |
|--|--|---|--|
| 7th scenario 4.1.1.7 For non-affected establishments located in a protection zone with a radius larger than 3 km | | This scenario is not applicable, since it is not proposed for a protection zone larger than 3 km. | |
| 8th scenario 4.1.1.8. For non-affected establishments located in a surveillance zone | There are no sampling procedures defined for animals of listed species in the non-affected establishments located in a protection zone for PPR | It is extremely unlikely (1–5%) that establishments in this zone, not epidemiologically linked to an outbreak, will become infected with PPRV without having additional outbreaks in the protection zone. For the surveillance zone, it is recommended that the efforts will be allocated to enhance passive surveillance by increasing awareness in all establishments, industry and public. Any establishment where more generic signs of disease are reported, should be visited, the animals should be clinically examined and samples should be collected (see 1st scenario for sample scheme). | |
| ToR 1: To grant derogations for animal movements | | | |
| 9th scenario Section: 4.1.2.1. From non-affected establishments located in the protection zone to slaughterhouses located within the protection zone or in the surveillance zone or outside the restricted zone | No sampling procedures are defined for PPR for this scenario | Clinical examinations must be carried out in each subunit of the establishment in which the kept listed species are to be moved following the procedures described in the Section 4.1.1.1. If individual clinical examination of all the animals is not feasible, the number of animals indicated by the sample size calculations as in Section 4.1.1.1 is to be examined. If animals are moved from the protection zone to a slaughterhouse outside the restriction zones, clinical examination and sample collection for laboratory investigation for should be performed as described in the Section 4.1.1.1. | In case of clinical suspicion, the procedures described in the Section 4.1.1.1 for suspected establishment should be followed. |
| 12th scenario 4.1.2.2 From non-affected establishments located in the | No sampling procedures are defined for PPR for this scenario | This scenario is similar to 9th scenario (Section 4.1.2.1) thus same conclusions are valid. | |

| Sampling procedure | Laboratory guidelines based on Council Directive 2003/85/EC if not stated otherwise | Conclusions | Recommendations |
|---|---|---|---|
| protection zone to a plant approved for processing or disposal of animal by-products in which the animals are immediately killed | | | |
| <p>13th scenario 4.1.2.3. From an establishment in a surveillance zone to a slaughterhouse located within or outside the restricted zone and from an establishment outside the surveillance zone to a slaughterhouse situated in the surveillance zone</p> | No sampling procedures are defined for PPR for this scenario | <p>This scenario is very similar to 9th scenario (Section 4.1.2.1); thus the same conclusions are valid.</p> <p>For animals intended to be moved from an establishment located outside the surveillance zone to a slaughterhouse situated in the surveillance zone, there is no need for laboratory examination, if there are no other reasons based on the national risk assessment to recommend it (e.g. epidemiological link with affected establishment or with affected or high-risk area). Only clinical examination as described above would be enough.</p> | To grant derogation for animal movements from an establishment in a surveillance zone to a slaughterhouse located outside the restricted zone, clinical examination and sample collection for laboratory investigation should be performed as described in the Section 4.1.1.1. |
| <p>14th scenario 4.1.2.4 From an establishment in a surveillance zone to pastures situated within the surveillance zone</p> | No sampling procedures are defined for PPR for this scenario | <p>Animals in a surveillance zone, for which a specific derogation has been granted to be moved to pastures, should be subjected to clinical surveillance, including laboratory examinations.</p> <p>Sampling procedures for laboratory examination should ensure that the animals do not pose a risk of transmission with a confidence level of 95%, as described in Section 4.1.1.1.</p> | |
| <p>15th scenario 4.1.2.5 From an establishment in a surveillance zone to an establishment belonging to the same supply chain, located in or outside the surveillance zone</p> | No sampling procedures are defined for PPR for this scenario | <p>Animals in a surveillance zone, for which a specific derogation has been granted to be moved to an establishment in or outside the surveillance zone, should be subjected and found negative to clinical examination, at least a sample with 95% confidence, including laboratory examinations.</p> <p>Sampling procedures should be implemented as described in Section 4.1.2.1.</p> <p>In case of clinical suspicion, the procedures for the laboratory confirmation as in Section 4.1.1.1 should be followed, and movement prohibited until confirmation of being negative.</p> | |

| Sampling procedure | Laboratory guidelines based on Council Directive 2003/85/EC if not stated otherwise | Conclusions | Recommendations |
|--|---|--|-----------------|
| <p>16th scenario For day-old-chicks from a non-affected establishment located in the surveillance zone, to an establishment located in the same Member State where they were hatched</p> | <p>Not applicable. Poultry is not a listed species for PPR</p> | | |
| <p>17th scenario For ready-to-lay poultry located in the surveillance zone to establishments located in the same MS</p> | <p>Not applicable. Poultry is not a listed species for PPR</p> | | |
| <p>18th scenario 4.1.2.6 From an establishment located in the restricted zone to move within the restricted zone when restriction measures are maintained beyond the period set out in Annex XI of the Delegated Regulation</p> | <p>No sampling procedures are defined for PPR for this scenario.</p> | <p>Animals in the restricted zone, for which a specific derogation has been granted for movement within the restricted zone, should be subjected to clinical examination; if they are not immediately slaughtered, they should also be sampled for laboratory examinations. Sampling procedures for laboratory examination should ensure that the animals do not pose a risk of transmission with a confidence level of 95%.</p> | |
| ToR 1: For repopulation purposes | | | |
| <p>19th scenario 4.1.3.1 For the animals that are kept for the repopulation</p> | <p>No sampling procedures are defined for PPR for this scenario.</p> | <p>Animals intended for repopulation should be subjected to clinical examinations, if not all at least a sample ensuring 95% confidence. For animals that are introduced from disease-free areas outside the restricted zone, sampling can be omitted because they have not been exposed to virus before entry</p> | |

| Sampling procedure | Laboratory guidelines based on Council Directive 2003/85/EC if not stated otherwise | Conclusions | Recommendations |
|---|---|--|-----------------|
| prior to their introduction | | and, consequently, can only produce a negative test result. If animals are sourced from restricted areas, all the animals in the establishment of origin should be sampled. Sampling procedures for laboratory examination should ensure that the animals do not pose a risk of transmission at a confidence level of 95%. | |
| 20th scenario 4.1.3.2 In the event of unusual mortalities or clinical signs being notified during the repopulation. | No sampling procedures are defined for PPR for this scenario. | In the case of unusual mortalities or clinical signs compatible with PPR notified during the repopulation, the establishment is considered suspected, the repopulation should be stopped and the procedures for the laboratory confirmation as described in the Section 4.1.1.1 should be followed. | |
| 21st scenario 4.1.3.3 For animals that have been repopulated | No sampling procedures are defined for PPR for this scenario. | The animals that have been used for the repopulation should be submitted to thorough clinical and, if showing signs, laboratory examination in order to rule out the presence of the disease. Animals must be subjected to clinical inspection at least every three days for the first 14 days following the introduction, and weekly from 15 to at least 21 days (monitoring period) after re-introduction. The last day of the monitoring period following the latest day of animals' introduction, all the animals (or at least a sample ensuring 95% confidence) should be subjected to thorough clinical examination as described in Section 4.1.1.1 and should be sampled for laboratory examination in accordance to the procedures there. In case of clinical suspicion, then the procedures for the laboratory confirmation that are described in the Section 4.1.1.1 should be followed. | |

ToR 2

| Description | Conclusions | Recommendations |
|---|--|-----------------|
| 4.2 Assessment of the length of the monitoring period of PPR | The length of the monitoring period of 21 days as defined in the Delegated Regulation is considered effective for all scenarios mentioned in ToR 2, except for the first affected establishments detected in an area, where a monitoring period of 33 days is recommended. | |

| ToR 3 | | |
|--|---|------------------------|
| Description | Conclusions | Recommendations |
| Section 4.3.1: Assessment of the minimum radius | The estimated value of probability of transmission beyond the protection zone of 3 km radius (as indicated in the Delegated Regulation) is 9.6% (95% CI: 3.1–25.8%) and 2.3% (95% CI: 1–5.5%) for 10 km radius (surveillance zone), which may be considered sufficient to contain the disease spread. The 95% probability of containing transmission would correspond to 5.3 km (95% CI: 1.8–10.6 km). If the aim is to reduce the probability of transmission beyond the surveillance zone of 10 km to 1%, the radius should be increased to 19 km (95% CI: 9.8–26.8). This, nonetheless, would on average increase the number of farms in the surveillance zone (affected by movement restrictions) fourfold. | |
| Section 4.3.2: Assessment of the minimum period for the restriction measures | The minimum period of 21 days indicated in the Delegated Regulation for the restriction measures in the protection zone is considered effective to detect infected establishments and to prevent the movement of infected animals from the protection zone. The minimum period of 30 days indicated in the Delegated Regulation for the restriction measures in the surveillance zone should be extended up to 33 days, so to detect infected establishments and to prevent the movement of infected animals from the surveillance zone. | |

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Abbreviations

| | |
|---------|---|
| AGID | agar gel diffusion |
| AHS | African horse sickness |
| ASF | African swine fever |
| bELISA | blocking ELISA |
| C-ELISA | competitive ELISA |
| CSF | classical swine fever |
| CBPP | contagious bovine pleuropneumonia |
| CCPP | contagious caprine pleuropneumonia |
| CF | complement fixation |
| DIVA | Differentiating Infected from Vaccinated Animals |
| Dpi | days post inoculation |
| d.p.in | days after disease introduction |
| ELISA | enzyme-linked immunosorbent assay |
| ELS | extensive literature search |
| FMD | foot and mouth disease |
| FMDV | foot and mouth disease virus |
| GF-TADS | Global Framework for the progressive control of Transboundary Animal Diseases |
| H-ELISA | haemagglutinin ELISA |
| HPAI | highly pathogenic avian influenza |

| | |
|-------------|--|
| indirect Ab | ELISA indirect antibody ELISA |
| LFD | lateral flow device |
| LSD | lumpy skin disease virus |
| NCD | Newcastle disease virus |
| OIE | World Organization for Animal Health |
| PCR | polymerase chain reaction |
| PPR | peste des petits ruminants |
| PPRV | PPR virus |
| PZ | protection zone |
| RP | rinderpest virus |
| RT-LAMP | reverse transcription-loop mediated isothermal amplification technique |
| RT-PCR | reverse transcription polymerase chain reaction |
| RVFV | Rift Valley fever virus |
| SN | serum neutralisation |
| SGP | sheep and goat pox |
| SPGP | sheep pox and goat pox |
| SZ | surveillance zone |
| ToR | Terms of Reference |
| VNT | virus neutralisation test |

Annex A – Definitions in EU legislation

| Terms | Definitions |
|-------------------------------|---|
| Clinical examination | The clinical examination comprises: (i) an initial general evaluation of the animal health status of the establishment which comprises all the animals of listed species kept in the establishment; and (ii) an individual examination of the animals included in the sample referred to in point (a). The sampling of animals for clinical examination is carried out in accordance with point A.1 of Annex I for terrestrial animals (Delegated Regulation article 3) |
| Confined establishment | Means any permanent, geographically limited establishment, created on a voluntary basis and approved for the purpose of movements, where the animals are: (a) kept or bred for the purposes of exhibitions, education, the conservation of species or research; (b) confined and separated from the surrounding environment; and (c) subject to animal health surveillance and biosecurity measures; (AHL: Regulation 2016/429 article 4(48)) |
| Epidemiological unit | Means a group of animals with the same likelihood of exposure to a disease agent; (AHL: Regulation 2016/429 article 4(39)) |
| Establishment | Means any premises, structure, or, in the case of open-air farming, any environment or place, where animals or germinal products are kept, on a temporary or permanent basis, except for: (a) households where pet animals are kept; (b) veterinary practices or clinics; (AHL: Regulation 2016/429 article 4(27)) |
| Health status | Means the disease status as regards the listed diseases relevant for a particular listed species with respect to: (a) an animal; (b) animals within: (i) an epidemiological unit; (ii) an establishment; (iii) a zone; (iv) a compartment; (v) a Member State; (vi) a third country or territory; (AHL: Regulation 2016/429 article 4(34)) |
| Infected zone | Means a zone in which restrictions on the movements of kept and wild animals or products and other disease control and biosecurity measures may be applied with the view to preventing the spread of a category A disease in the event of official confirmation of the disease in wild animals. (Delegated Regulation article 2(15)) |
| Kept animals | Means animals which are kept by humans, including, in the case of aquatic animals, aquaculture animals; (AHL: Regulation 2016/429 article 4(5)) |
| Outbreak | Means the officially confirmed occurrence of a listed disease or an emerging disease in one or more animals in an establishment or other place where animals are kept or located; (AHL: Regulation 2016/429 article 4 (40)) |
| Protection zone | Means a zone around and including the location of an outbreak, where disease control measures are applied in order to prevent the spread of the disease from that zone; (AHL: Regulation 2016/429 article 4(42)) |
| Listed diseases | Means diseases listed in accordance with Article 5(1); (AHL: Regulation 2016/429 article 4 (18)) List of the diseases (AHL: Regulation 2016/429, Annex II) |
| Listed species | Means an animal species or group of animal species listed in accordance with Article 8 (2), or, in the case of emerging diseases, an animal species or group of animal species which meets the criteria for listed species laid down in Article 8(2); (AHL: Regulation 2016/429 article 4(20)) List of species and groups of species (Commission Implemented Regulation 2018/1882) |
| Monitoring periods | It is appropriate to follow a single approach for the measures to apply in the event of a category A disease. However, the epidemiology of diseases should be taken into account to establish the appropriate moment for the competent authority to apply control measures and to carry out investigations if there is suspicion or confirmation of those diseases. Therefore 'monitoring periods' should be provided, as reference time frames for each category A disease affecting terrestrial animals based on incubation periods and other relevant elements that may affect the spread of the disease. (Delegated Regulation whereas 10). |
| Restricted zone | Means a zone in which restrictions on the movements of certain animals or products and other disease control measures are applied, with a view to preventing the spread of a particular disease into areas where no restrictions are applied; a restricted zone may, when relevant, include protection and surveillance zones; (AHL: Regulation 2016/429 article 4(41)) |
| Surveillance zone | Means a zone which is established around the protection zone, and where disease control measures are applied in order to prevent the spread of the disease from the protection zone; (AHL: Regulation 2016/429 article 4(43)) |

| Terms | Definitions |
|---------------------|---|
| Wild animals | Means animals which are not kept animals; (AHL: Regulation 2016/429 article 4(8)) |
| Zone | Means: (a) for terrestrial animals, an area of a Member State, third country or territory with a precise geographical delimitation, containing an animal subpopulation with a distinct health status with respect to a specific disease or specific diseases subject to appropriate surveillance, disease control and biosecurity measures; (AHL: Regulation 2016/429 article 4 (35)) |

Annex B – Scenarios of ToR 1

| ToRs | Legislation | Scenario | Description of the Scenario | Elements of the Scenario |
|--|---|--------------|--|--|
| In the event of suspicion or confirmation | | | | |
| ToR 1.1 ToR 1.2 | 6(2) of the 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 (ToR 1.1) and laboratory examination (ToR 1.2), 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)). | <ul style="list-style-type: none"> • 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 |
| ToR 1.2 | Art. 12(3), Art. 7 (4) (Preventive killing) of the Delegated Regulation, and Art. 57 Reg.2016/429 | 2nd scenario | To assess the effectiveness of disease-specific sampling procedures, based on laboratory examination (ToR 1.2), 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. | <ul style="list-style-type: none"> • affected establishment officially confirmed • kept animals of listed species found dead or before/when they are killed • competent authority collects samples for laboratory examination for the purposes of: <ul style="list-style-type: none"> a) supporting the epidemiological enquiry: <ul style="list-style-type: none"> – 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 |
| ToR 1.1 ToR 1.2 | Article 13(3)c of the Delegated Regulation | 3rd scenario | To assess the effectiveness of disease-specific sampling procedures based on clinical (ToR 1.1) and laboratory (ToR 1.2) 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 | <ul style="list-style-type: none"> • affected establishment officially confirmed • kept animals of listed species of specific categories • animal categories based on article 13(2): <ul style="list-style-type: none"> 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 |

| ToRs | Legislation | Scenario | Description of the Scenario | Elements of the Scenario |
|--------------------|---|--------------|--|--|
| | | | ensuring that they do not pose a risk for the transmission of the disease. | <ul style="list-style-type: none"> the competent authority may grant specific derogation from killing all the animals of listed species belonging to any of the above categories in an affected establishment, provided that specific conditions are fulfilled the animals should be subjected to clinical surveillance, including laboratory examinations sampling procedures should ensure that the animals do not pose a risk of transmission of the category A disease if left alive |
| ToR 1.1 ToR 1.2 | Article 14(1) of the Delegated Regulation Art. 57 Reg. 2016/429 | 4th scenario | To assess the effectiveness of disease-specific sampling procedures based on clinical (ToR 1.1) and laboratory (ToR 1.2) examinations of the animals of non-listed species kept in an affected establishment, in their ability to ensure the detection of the virus if the virus is present in these species. | <ul style="list-style-type: none"> kept animals of non-listed species of epidemiological relevance for the control of the disease animals of non-listed species are those animals that are not listed in Commission Implementing Regulation (EU) 2018/1882 for each of the category A diseases animal species acting purely as mechanical carriers of the virus will not be covered The competent authority is not obliged to carry out the sampling of non-listed species, but they may establish it in addition to other measures sampling procedures to ensure detection of the virus in these species |
| ToR 1.1 ToR 1.2 | Article 14(1) of the Delegated Regulation Art. 57 Reg. 2016/429 | 5th scenario | To assess the effectiveness of disease-specific sampling procedures based on clinical (ToR 1.1) and laboratory (ToR 1.2) examinations of the wild animals of listed species within the affected establishment and in its surroundings. The purpose of the sampling procedures is to ensure the detection of the virus, if the virus is present in these wild species | <ul style="list-style-type: none"> affected establishment officially confirmed wild animals of listed species within the establishment and in the surroundings of the establishment the competent authority may establish these sampling procedures in addition to other measures sampling procedures in wild animals of listed species to ensure the detection of the virus, if the virus is present in these wild species |
| ToR 1.1 ToR 1.2 | Article 26(2) of the Delegated Regulation | 6th scenario | To assess the effectiveness of disease-specific sampling procedures based on clinical (ToR 1.1) and laboratory (ToR 1.2) examinations of the animals of listed species in establishments located in the protection zone. The purpose of the sampling procedures is to ensure the | <ul style="list-style-type: none"> protection zone with radius up to 3 km non-affected establishments with kept animals of listed species all the non-affected establishments within the protection zone official veterinarians must visit at least once all the establishments among others, they must perform a clinical examination of kept animals of listed species and if necessary, collection of samples for laboratory examination |

| ToRs | Legislation | Scenario | Description of the Scenario | Elements of the Scenario |
|--|--|--------------|--|---|
| | | | detection of the virus, if the virus is present in these animals. | <ul style="list-style-type: none"> sampling procedures to confirm or rule out the presence of a category A disease |
| ToR 1.3 | Article 26(5) of the Delegated Regulation point A.3 of Annex I | 7th scenario | To assess the effectiveness of disease-specific sampling procedures, based on clinical (ToR 1.1) and laboratory (ToR 1.2) examinations of the animals of listed species, for the sampling of establishments located in a protection zone when the radius is larger than 3 km. The purpose of the sampling procedure is to ensure disease detection of the virus if the virus is present in establishments within the protection zone | <ul style="list-style-type: none"> protection zone with radius larger than 3 km non-affected establishments of kept animals of listed species sample of the non-affected establishments in the protection zone in a protection zone with a radius equal to 3 km, official veterinarians must carry inspections in all establishments within the 3 km In case of a radius larger than 3 km, official veterinarians may not visit all establishments, but a sample of those. EFSA is requested to assess how many of these establishments should be inspected, in order to ensure the detection of the virus, if the virus is present in animals in these establishments among others perform clinical examination of kept animals of listed species and if necessary, collection of samples for laboratory examination sampling procedure to ensure the detection of the disease if the disease is present in any of these establishments |
| ToR 1.3 | Article 41 of the Delegated Regulation | 8th scenario | To assess the effectiveness of disease-specific sampling procedures, based on clinical (ToR 1.1) and laboratory (ToR 1.2) examinations of the animals of listed species, for the sampling of the establishments located within the surveillance zone. The purpose of the sampling procedure is to ensure disease detection if the virus is present in establishments within the surveillance zone | <ul style="list-style-type: none"> surveillance zone establishments of kept animals of listed species sample of the establishments in the surveillance zone official veterinarians carry out visits to a sample of the establishments among others perform clinical examination of kept animals of listed species and if necessary, collection of samples for laboratory examination sampling procedure to ensure the detection of the disease if the disease is present in any of the establishments |
| Derogations to allow animal movements | | | | |
| ToR 1.4 | Article 28(5) of the Delegated Regulation Article 29 of the Delegated Regulation | 9th scenario | To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations of the animals of an establishment in a protection zone, in order to grant a derogation from prohibitions in the movement of animals, and allow for the | <ul style="list-style-type: none"> protection zone kept animals of listed species grant derogation for movement from a non-affected establishment in the protection zone to be moved to a slaughterhouse located within the protection zone or in the surveillance zone or outside the restricted zone |

| ToRs | Legislation | Scenario | Description of the Scenario | Elements of the Scenario |
|---------|---|---------------|---|--|
| | | | animals to be moved to a slaughterhouse located within the protection zone or in the surveillance zone or outside the restricted zone (Art. 29) | <ul style="list-style-type: none"> clinical examinations and laboratory examination of animals kept in the establishment, including those animals to be moved |
| ToR 1.4 | Article 28(5) and Article 30(1) of the Delegated Regulation | 10th scenario | To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations, to grant a derogation from prohibitions in the movement of day-old-chicks located in the protection zone and hatched from eggs originating in the restricted zone or outside the restricted zone. The sampling procedures should ensure that the movement of these day-old-chicks to an establishment located in the same Member State but if possible, outside the restricted zone | <ul style="list-style-type: none"> protection zone grant derogation for movement from a non-affected establishment in the protection zone day-old-chicks from non-affected establishment located in the protection zone, hatched from eggs originating in or outside the restricted zone to be moved to an establishment located in the same Member State but if possible, outside the restricted zone clinical examinations and laboratory examination of animals kept in the establishment, including those animals to be moved |
| ToR 1.4 | Article 28(5) and Article 30(2) of the Delegated Regulation | 11th scenario | To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations, to grant a derogation from prohibitions in the movement of ready-to-lay poultry located in the protection zone to establishments located in the same MS and if possible within the restricted zone. | <ul style="list-style-type: none"> protection zone ready-to-lay poultry grant derogation for movement from a non-affected establishment in the protection zone to be moved to an establishment located in the same Member State and if possible, within the restricted zone clinical examinations and laboratory examination of animals kept in the establishment, including those animals to be moved |
| ToR 1.4 | Article 28(5) and Article 37 of the Delegated Regulation | 12th scenario | To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations of the animals of an establishment in a protection zone, in order to grant derogation from prohibitions in the movement of these animals to a plant approved for processing or disposal of animal by-products in which the kept animals are immediately killed (Art. 37) | <ul style="list-style-type: none"> protection zone kept animals of listed species grant derogation for movement from a non-affected establishment in the protection zone to be moved to a plant approved for processing or disposal of animal by-products in which the kept animals are immediately killed clinical examinations and laboratory examinations of animals kept in the establishment, including those animals to be moved |
| ToR 1.4 | | 13th scenario | To assess the effectiveness of disease-specific sampling procedures based on | <ul style="list-style-type: none"> surveillance zone kept animals of listed species |

| ToRs | Legislation | Scenario | Description of the Scenario | Elements of the Scenario |
|---------|---|---------------|--|--|
| | Article 43(5) and Article 44 of the Delegated Regulation | | clinical and/or laboratory examinations of the animals of listed species in order to grant derogation from prohibitions and allow for these animals to be moved: a) from an establishment in a surveillance zone to a slaughterhouse located within or outside the restricted zone, b) from an establishment outside the surveillance zone to a slaughterhouse situated in the surveillance zone | <ul style="list-style-type: none"> grant derogation for movement from an establishment in the surveillance zone to be moved to a slaughterhouse within the restricted zone or outside the restricted zone grant derogation for movement from an establishment outside the surveillance zone to a slaughterhouse situated in the surveillance zone clinical examinations and laboratory examination of animals kept in the establishment, including those animals to be moved |
| ToR 1.4 | Article 43(5) and Article 45(1) of the Delegated Regulation | 14th scenario | To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations of kept ungulates of listed species in order to grant a derogation and allow for the animals to be moved from an establishment in the surveillance zone to pastures situated within the surveillance zone | <ul style="list-style-type: none"> surveillance zone kept ungulates of listed species grant derogation for movement from an establishment in the surveillance zone to be moved to pastures situated within the surveillance zone clinical examinations and laboratory examination of animals kept in the establishment, including those animals to be moved |
| ToR 1.4 | Article 43(5) and Article 45(2) of the Delegated Regulation | 15th scenario | To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations of kept ungulates of listed species in order to grant derogation and allow to be moved from an establishment in the surveillance zone to an establishment belonging to the same supply chain, located in or outside the surveillance zone, in order to complete the production cycle before slaughter | <ul style="list-style-type: none"> surveillance zone kept animals of listed species grant derogation for movement from the surveillance zone to be moved to an establishment belonging to the same supply chain, located in or outside the surveillance zone, to complete the production cycle before slaughter clinical examinations and laboratory examination of animals kept in the establishment, including those animals to be moved |
| ToR 1.4 | Article 43(5) and Article 46(1) of the Delegated Regulation | 16th scenario | To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations to grant derogation of movements of day-old-chicks hatched from establishment located in the surveillance zone, from eggs originating within the surveillance zone and eggs originating outside the restricted zone, to an establishment located in the same Member State where they were hatched | <ul style="list-style-type: none"> surveillance zone kept birds of listed species grant derogation for movement of day-old-chicks hatched from establishment located in the surveillance zone, from eggs originating from establishment within the surveillance zone or eggs originating from outside the restricted zone to be moved to an establishment located in the same Member State clinical examinations and laboratory examination of animals kept in the establishment, including those animals to be moved |

| ToRs | Legislation | Scenario | Description of the Scenario | Elements of the Scenario |
|---------------------|---|---------------|---|--|
| ToR 1.4 | Article 43(5) and Article 46(2) of the Delegated Regulation | 17th scenario | To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations, to grant a derogation from prohibitions in the movement of ready-to-lay poultry located in the surveillance zone to establishments located in the same MS. | <ul style="list-style-type: none"> surveillance zone ready-to-lay poultry to be moved to an establishment located in the same Member State clinical examinations and laboratory examination of animals kept in the establishment, including those animals to be moved |
| ToR 1.4 | Article 56(1)c of the Delegated Regulation | 18th scenario | To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations of the animals of an establishment located in the restricted zone of an outbreak in order to allow their move within the restricted zone, when restriction measures are maintained beyond the period set out in Annex XI | <ul style="list-style-type: none"> restricted zone when restriction measures are maintained beyond the period set out in Annex XI kept animals of listed species grant derogation for movement from an establishment within the restricted zone clinical examinations and laboratory examination of animals kept in the establishment, including those animals to be moved |
| Repopulation | | | | |
| ToR 1.5 | Article 59(2),(3) of the Delegated Regulation | 19th scenario | To assess the effectiveness of disease-specific sampling procedures based on laboratory examinations of the animals that are kept for the repopulation prior to their introduction to rule out the presence of the disease. | <ul style="list-style-type: none"> repopulation of a previous affected establishment kept animals of listed species Animals intended to repopulation shall be sampled prior to their introduction into the establishment of destination samples shall be collected from a representative number of animals to be introduced of each consignment from each establishment or from a representative number of animals of each consignment (if animals are all to be introduced at different times or from different establishments of origin) laboratory examinations sampling procedures to rule out the presence of the disease |
| ToR 1.5 | Article 59(9) of the Delegated Regulation | 20th scenario | To assess the effectiveness of disease-specific sampling procedures based on laboratory examinations of the animals that have been repopulated, in the event of unusual mortalities or clinical signs being notified during the repopulation; to rule out the presence of the disease. | <ul style="list-style-type: none"> repopulated establishment unusual mortalities or clinical signs during the repopulation the official veterinarians shall without delay collect samples for laboratory examination sampling procedures to rule out the presence of the disease |
| ToR 1.5 | Article 59(5) of the Delegated Regulation | 21st scenario | To assess the effectiveness of disease-specific sampling procedures based on | <ul style="list-style-type: none"> repopulated establishment kept animals of listed species |

| ToRs | Legislation | Scenario | Description of the Scenario | Elements of the Scenario |
|------|-------------|----------|---|--|
| | | | laboratory examinations of the animals that have been repopulated, on the last day of the monitoring period calculated forward from the date on which the animals were placed in the repopulated establishment. In case the repopulation takes place in several days, the monitoring period will be calculated forward from the last day in which the last animal is introduced in the establishment. | <ul style="list-style-type: none">• Animals that have been used for repopulation• Laboratory examinations• Sampling procedures to rule out the presence of the disease |

Annex C – Sampling procedures for PPR

Sampling scenarios for PPR – Based on **Council Directive 92/119/EEC** if not stated otherwise

| Scenario | Description of the Scenario | Clinical guidelines | Laboratory guidelines |
|----------|---|---|--|
| 1st | To assess the effectiveness of disease-specific sampling procedures of animals of listed species in a suspected establishment, based on clinical examination (ToR 1.1) and laboratory examination (ToR 1.2), 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)). | <p>Article 4:</p> <p>1) <u>When animals on a holding are suspected of being infected or contaminated with PPR,</u> Member States shall ensure that the official veterinarian immediately activates official investigation arrangements to confirm or rule out the presence of the disease in question</p> <p>2) As soon as the suspected presence of the disease is notified, the competent authority shall have the holding placed under official surveillance and shall in particular require that:</p> <p>a) a <u>census</u> be made of all categories of animals of susceptible species and that, in respect of each of these categories, <u>the number of animals already dead, infected or liable to be infected or contaminated</u> be recorded; the census must be kept up to date to take account of animals born or dying during the period of suspicion; the information in the census must be kept up to date and produced on request and may be checked at each visit;</p> <p>b) all animals of susceptible species on the holding be kept in their living quarters or confined in some other place where they can be isolated taking into account the possible role of vectors, where appropriate;</p> <p>c) no animals of susceptible species enter or leave the holding;</p> <p>d) all movement:</p> <ul style="list-style-type: none"> – of persons, animals of other species not susceptible to the disease and vehicles to or from the holding, – of meat or animal carcasses, or of animal feed, equipment, waste, droppings, litter, manure, or anything liable to transmit the disease in question | <p>Article 4:</p> <p>1. When animals on a holding are suspected of being infected or contaminated with PPR, Member States shall ensure that the official veterinarian immediately activates official investigation arrangements to confirm or rule out the presence of the disease in question and, <u>in particular, must take or have taken the samples necessary for laboratory examination.</u> To that end the animals in question may be transported to the laboratories under the supervision of the competent authority, which shall take appropriate steps to prevent the disease from spreading.</p> <p><i>EURL-PPR Sampling instructions in case of PPR suspicion (CIRAD, 2017):</i></p> <p><u>Samples to be collected and tests to be conducted in case of a suspicion, according to the animal's status:</u></p> <ul style="list-style-type: none"> – Alive with symptoms: Priority samples: Nasal/Ocular swabs; Optional samples: Whole Blood for buffy coat □ Detect virus with qPCR – Dead: Priority samples: Nasal/Ocular swabs, lymph node, lung; Optional samples: Whole Blood for buffy coat □ Detect virus with qPCR – Alive without symptoms: serum □ Detect antibodies with c-ELISA <p><i>OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, heading 'B. Diagnostic techniques' (OIE, 2019b):</i></p> <p>A tentative diagnosis can be made based on clinical signs, but is considered provisional until <u>laboratory confirmation</u> is made for differential diagnosis with other diseases with similar signs.</p> <p><u>Samples to be taken for the diagnosis of PPR:</u></p> <ul style="list-style-type: none"> – Live animals: In live animals, swabs are made of the conjunctival discharges or from the nasal, buccal or rectal mucosae. During the very early stage of the disease, whole blood is also collected in anticoagulant for virus isolation, PCR and haematology (either ethylene diamine tetra-acetic acid or heparin can be used as anticoagulant, though the former is preferred for samples that will be tested using PCR). Samples for virus isolation must be kept chilled in transit to the laboratory. |

| Scenario | Description of the Scenario | Clinical guidelines | Laboratory guidelines |
|----------|-----------------------------|---|--|
| | | <p>e) be subject to authorization by the competent authority, which shall lay down the conditions for preventing any risk of the disease spreading; appropriate means of disinfection be installed at the entrances and exits of buildings or places housing animals of susceptible species and of the holding itself.</p> <p>OIE Terrestrial Code (OIE, 2019a):</p> <p>In the case of peracute cases the presenting sign may be sudden death. In the case of sub-acute (mild) cases, clinical signs are displayed irregularly and are difficult to detect. <u>All significant epidemiological events consistent with PPR, such as pneumo-enteritis syndrome, should be reported and investigated immediately.</u> Where suspicion cannot be resolved by epidemiological and clinical investigation, samples should be taken and submitted to a laboratory.</p> <p>Epidemiology and Control of Peste des Petits Ruminants (ECo-PPR): Field research manual (ILRI, 2020):</p> <p><u>In case of a suspicion of PPR, an outbreak investigation is conducted.</u> The outbreak investigation includes an interview with the livestock keepers to gather epidemiological information about the disease problem, followed by a <u>general examination of the flock and clinical examination of sick animals.</u></p> <p>Australian Veterinary Emergency Plan (AUSVETPLAN): Response Strategy (Animal Health Australia, 2020):</p> <p><u>In suspected premises: daily physical surveillance of sheep and goats will be required for a period of 15 days, then weekly inspections for a further 2 weeks.</u></p> | <p>– At necropsy: samples from two to three animals should be collected aseptically from lymph nodes, especially the mesenteric and bronchial nodes, lungs, spleen and intestinal mucosae, Real-time RT-PCR assay is the method of choice for laboratories that have the necessary equipment.</p> <p>It is good practice to collect blood for serological diagnosis at all stages, but particularly later in the outbreak.</p> <p>FAO Field Manual (FAO, 1999):</p> <p><u>Always sample several animals in an outbreak.</u> The samples required are tears, gum debris. For post-mortem: mediastinal and mesenteric lymph nodes, portions of spleen and lungs. Two sets of each tissue are required. Unclothed blood for virus isolation should be collected in bottles containing anticoagulants. Clotted blood or serum for antibody detection.</p> <p>Epidemiology and Control of Peste des Petits Ruminants (ECo-PPR): Field research manual (ILRI, 2020):</p> <p>In case of a suspicion of PPR, an outbreak investigation is conducted. If the disease problem is judged to fit the case definition for PPR-like disease then samples are collected from 1 to 5 animals for PPRV rapid diagnostic test and for submission to the laboratory for PCR and sequencing. The best animals to test are those that have been sick for 1–3 days with a raised temperature ($\geq 40.0^{\circ}\text{C}$) and early signs of PPR disease; ocular and/or nasal discharge, with or without mouth lesions, coughing, sneezing and diarrhoea. If there are any recently dead sheep or goats (within 24 h) then a post mortem examination can also be carried out and tissue samples collected for laboratory submission.</p> <p>If you get a positive animal, then collect a full set of samples from the positive animal and from 2 to 3 other animals with early PPR clinical signs for laboratory testing (eye and nose swabs, and a plain blood sample for serum). If all the rapid diagnostic tests are negative, but the clinical signs and epidemiological information are strongly suspicious of PPR disease, then collect samples from six animals with early clinical signs for laboratory analysis.</p> |

| Scenario | Description of the Scenario | Clinical guidelines | Laboratory guidelines |
|----------|-----------------------------|---------------------|---|
| | | | <p data-bbox="1279 245 2040 300">Australian Veterinary Emergency Plan (AUSVETPLAN): Response Strategy (Animal Health Australia, 2020):</p> <p data-bbox="1279 316 2040 400">Laboratory confirmation of PPR in Australia would be based on real-time reverse transcriptase PCR with sequencing, and virus isolation in selected cases.</p> <p data-bbox="1279 432 2040 517">Emergency animal diseases: A field guide for Australian veterinarians; Chapter 3.17. Peste des petits ruminants (Breed et al., 2019):</p> <p data-bbox="1279 549 2040 665">Collect <u>samples from clinically affected animals, ideally during the pyrexia stage, before the onset of diarrhoea.</u> Alternatively, collect samples from animals that have <u>recently died, or immediately after euthanised</u> for post-mortem.</p> <p data-bbox="1279 665 2040 692"><u>Samples to collect for diagnostic testing are:</u></p> <ul data-bbox="1279 692 2040 1075" style="list-style-type: none"> • serum, from at least 10 animals (if possible) towards the end of the acute phase or from recovered animals. • EDTA blood, from live, clinically affected animals (7–10 mL/animal) during the acute phase (preferably from pyrexia animals). • fresh tissue, including lymph node (especially the mesenteric and bronchial nodes), lungs, spleen, tonsils, tongue, affected areas of the alimentary tract (2 g of each tissue). • fixed tissue, comprising a full range of tissues including lungs, intestine, spleen, mesenteric lymph nodes, liver and kidneys (in 10% neutral-buffered formalin) • swabs, of conjunctival discharge as well as nasal, buccal and rectal mucosa. Collect from live, clinically affected animals (early during the acute phase) and preferably from pyrexia animals. <p data-bbox="1279 1107 2040 1192">The Foreign Animal Disease Preparedness and Response Plan (FAD PReP)—Disease Response Strategy (USDA-APHIS, 2013):</p> <p data-bbox="1279 1224 2040 1367">When PPR is suspected, laboratory diagnostic testing will be performed at the National Veterinary Services Laboratories, Foreign Animal Disease Diagnostic Laboratory (NVSL FADDL) at Plum Island, NY. Confirmatory tests include histopathology, polymerase chain reaction (PCR), virus isolation (VI), and virus neutralization (VN).</p> |

| Scenario | Description of the Scenario | Clinical guidelines | Laboratory guidelines |
|----------|--|--|---|
| 2nd | <p>To assess the effectiveness of disease-specific sampling procedures, based on laboratory examination (ToR 1.2), 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.</p> | <p>NA</p> <p>Note: Australian Veterinary Emergency Plan (AUSVETPLAN): Response Strategy (Animal Health Australia, 2020):</p> <p>In infected premises: daily physical surveillance of sheep and goats will be required for a period of 15 days, then weekly inspections for a further 2 weeks.</p> | <p>No specific guidelines described in legislation</p> <p>Article 8:</p> <p>1) The epizootiological enquiry shall deal with:</p> <p>a) the length of time during which the disease may have existed on the holding before being notified or suspected;</p> <p>b) the possible origin of the disease on the holding and the identification of other holdings on which there are animals of susceptible species which may have become infected or contaminated;</p> <p>c) the movement of persons, animals, carcasses, vehicles, equipment or any other substances likely to have carried the agent of the disease to or from the holdings in question;</p> <p>2) A crisis unit shall be established in order to provide full coordination of all measures necessary to ensure eradication of the disease as quickly as possible and for the purpose of carrying out the epizootiological enquiry.</p> |
| 3rd | <p>To assess the effectiveness of disease-specific sampling procedures based on clinical (ToR 1.1) and laboratory (ToR 1.2) 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.</p> | <p>NA</p> <p>Article 5:</p> <p>1) Once it has been officially confirmed that PPR is present on a holding, Member States shall ensure that, in addition to the measures laid down in Article 4 (2), the competent authority requires application of the following measures:</p> <p>a) <u>all animals of susceptible species on the holding shall be killed on the spot, without delay.</u> The animals which have died or been killed shall either be burnt or buried on the spot, if possible, or destroyed in a carcase disposal plant. These operations shall be carried out in such a way as to minimize the risk of disseminating the agent of the disease.</p> | <p>NA</p> |

| Scenario | Description of the Scenario | Clinical guidelines | Laboratory guidelines |
|----------|---|--|--|
| 4th | To assess the effectiveness of disease-specific sampling procedures, based on clinical (ToR 1.1) and laboratory (ToR 1.2) examinations of the animals of non-listed species kept in an affected establishment, in their ability to ensure the detection of the virus if the virus is present in these species. | No specific guidelines described in legislation | No specific guidelines described in legislation <i>Australian Veterinary Emergency Plan (AUSVETPLAN): Response Strategy (Animal Health Australia, 2020):</i> Tracing and surveillance will be used to determine the distribution of the disease and the disease-free areas. <u>Ruminants (especially cattle) not for slaughter will be identified for possible later serological testing.</u> Note: Subclinical infection, with subsequent antibody production, has been reported in <u>cattle</u> by natural and experimental infection, but cattle do not transmit PPR virus. <u>Pigs</u> can be subclinically infected with PPR but they do not transmit the virus. They are not considered to be important in the epidemiology of PPR (Nawathe DR and Taylor WP (1979). Experimental infection of domestic pigs with the virus of peste des petits ruminants. Tropical Animal Health and Production 11:120–122.). |
| 5th | To assess the effectiveness of disease-specific sampling procedures, based on clinical (ToR 1.1) and laboratory (ToR 1.2) examinations of the wild animals of listed species within the affected establishment and in its surroundings. The purpose of the sampling procedures is to ensure the detection of the virus, if the virus is present in these wild species. | No specific guidelines described in legislation <i>Australian Veterinary Emergency Plan (AUSVETPLAN): Response Strategy (Animal Health Australia, 2020):</i> Tracing and surveillance will be used to determine the distribution of the disease and the disease-free areas. <u>Feral goats and camels will need to be surveyed if they are present in the vicinity of the IP(s) and may have had contact with domestic sheep and goats.</u> It is unlikely that wild deer will become infected or play any part in the spread of PPR. However, as PPR has occurred in deer overseas, <u>some clinical or serological surveillance of any deer in the area may need to be undertaken. If signs are found, wild deer in the immediate area will be controlled.</u> Note: Red deer, <i>Cervus elaphus</i> , have been infected in a natural outbreak. White-tailed deer, <i>Odocoileus virginianus</i> , are susceptible to experimental infection and may develop lesions | No specific guidelines described in legislation <i>Note: Eradication of Peste des Petits Ruminants virus and the wildlife-livestock interface (Fine et al., 2020)</i> Diagnostic tools for PPRV detection, primarily developed for livestock species, have not been standardized and adequately validated for wildlife. Clear guidelines and standards for application and interpretation of PPR diagnostic tests in wildlife species need to be established. There is a need to improve wildlife health surveillance systems and systematically conduct thorough wildlife disease outbreak investigations, in particular at the wildlife-livestock interface. |

| Scenario | Description of the Scenario | Clinical guidelines | Laboratory guidelines |
|----------|--|---|---|
| | | <p>similar to those seen in sheep and goats. Some deer may become subclinically infected with virus and show no visible signs (Hamby FM and Dardiri AH (1976). Response of white-tailed deer to infection with peste des petits ruminants virus. J Wildlife Diseases 12:516–522.).</p> <p>Note: The Foreign Animal Disease Preparedness and Response Plan (FAD PReP)—Disease Response Strategy (USDA-APHIS, 2013):</p> <p>Wild animals may become exposed or contribute to the transmission of the disease to domestic animals either as biological or mechanical vectors. Wildlife management and vector control involves identifying susceptible wild-life species, determining how many species may be infected, and preventing the spread by implementing control measures. In the event of a PPR outbreak in domestic sheep and/or goats, APHIS VS will work in close collaboration and coordination with other agencies, entities, and units that have primary jurisdiction over wildlife.</p> | |
| 6th | <p>To assess the effectiveness of disease-specific sampling procedures based on clinical (ToR 1.1) and laboratory (ToR 1.2) examinations of the animals of listed species in establishments located in the protection zone. The purpose of the sampling procedures is to ensure the detection of the virus, if the virus is present in these animals.</p> | <p>Article 11:</p> <p>1) Member States shall ensure that the following measures are applied <u>in the protection zone</u>:</p> <p>a) <u>all holdings</u> within the zone having animals of susceptible species shall be identified;</p> <p>b) there shall be <u>periodic visits to holdings having animals of susceptible species, a clinical examination of those animals</u>; a record of visits and findings must be kept, with the <u>frequency of visits being proportional to the seriousness of the epizootic on those holdings at greatest risk</u></p> | <p>No specific guidelines described in legislation</p> <p>Article 11:</p> <p>1) Member States shall ensure that the following measures are applied <u>in the protection zone</u>:</p> <p>a) <u>all holdings</u> within the zone having animals of susceptible species shall be identified;</p> <p>b) there shall be periodic visits to holdings having animals of susceptible species, a clinical examination of those animals including, if necessary, the <u>collection of samples for laboratory examination</u>; a record of visits and findings must be kept, with the frequency of visits being proportional to the seriousness of the epizootic on those holdings at greatest risk.</p> |

| Scenario | Description of the Scenario | Clinical guidelines | Laboratory guidelines |
|----------|---|---|--|
| 7th | <p>To assess the effectiveness of disease-specific sampling procedures, based on clinical (ToR 1.1) and laboratory (ToR 1.2) examinations of the animals of listed species, for the sampling of establishments located in a protection zone when the radius is larger than 3 km. The purpose of the sampling procedure is to ensure disease detection of the virus if the virus is present in establishments within the protection zone.</p> | <p>Article 10:</p> <p>1) Once the diagnosis of one of the diseases in question has been officially confirmed, Member States shall ensure that the competent authority establishes around the infected holding a <u>protection zone with a minimum radius of three kilometres</u>, itself contained in a surveillance zone with a minimum radius of 10 kilometres. The establishment of the zones must take account of geographical, administrative, ecological and epizootiological factors relating to the disease in question, and of monitoring facilities.</p> <p>→ <u>See 6th scenario</u></p> | <p>→ <u>See 6th scenario</u></p> |
| 8th | <p>To assess the effectiveness of disease-specific sampling procedures, based on clinical (ToR 1.1) and laboratory (ToR 1.2) examinations of the animals of listed species, for the sampling of the establishments located within the surveillance zone. The purpose of the sampling procedure is to ensure disease detection if the virus is present in establishments within the surveillance zone.</p> | <p>No specific guidelines described in legislation</p> <p>Article 12:</p> <p>1) Member States shall ensure that the following measures are applied <u>in the surveillance zone</u>:</p> <p>a) all holdings having <u>animals of susceptible species</u> shall be identified;</p> <p>b) the movement of animals of susceptible species on public roads shall be prohibited except for the purpose of leading them to pasture or animal buildings; the competent authority may, however, grant a derogation from that prohibition for the transit of animals by road or rail without unloading or stopping;</p> <p>c) the transport of animals of susceptible species within the surveillance zone shall be subject to authorization by the competent authority;</p> <p>d) animals of susceptible species must remain inside the surveillance zone for a maximum incubation period after the most recent recorded case of disease.</p> | <p>No specific guidelines described in legislation</p> |

| Scenario | Description of the Scenario | Clinical guidelines | Laboratory guidelines |
|--|---|---|---|
| Derogations to allow animal movements | | | |
| 9th | To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations of the animals of an establishment in a protection zone, in order to grant a derogation from prohibitions in the movement of animals, and allow for the animals to be moved to a slaughterhouse located within the protection zone or in the surveillance zone or outside the restricted zone (Art. 29). | <p>Article 11:</p> <p>1. Member States shall ensure that the following measures are applied in the protection zone:</p> <p>d) <u>animals of susceptible species must remain on the holding on which they are being kept, except to be transported under official supervision directly to a slaughterhouse located in that zone for emergency slaughter or, if that zone has no slaughterhouse under veterinary supervision, to a slaughterhouse in the surveillance zone designated by the competent authority. Such transport may be authorized by the competent authority only after the official veterinarian has carried out an examination of all the animals of susceptible species on the holding and confirmed that none of the animals is suspected of being infected.</u> The competent authority responsible for the slaughterhouse shall be informed of the intention to send animals to it.</p> | No specific guidelines described in legislation |
| 10th | To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations, to grant a derogation from prohibitions in the movement of day-old-chicks located in the protection zone and hatched from eggs originating in the restricted zone or outside the restricted zone. The sampling procedures should ensure that the movement of these day-old-chicks to an establishment located in the same Member | NA | NA |

| Scenario | Description of the Scenario | Clinical guidelines | Laboratory guidelines |
|----------|--|---|---|
| | State but if possible, outside the restricted zone. | | |
| 11th | To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations, to grant a derogation from prohibitions in the movement of ready-to-lay poultry located in the protection zone, to establishments located in the same Member State and if possible within the restricted zone. | NA | NA |
| 12th | To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations of the animals of an establishment in a protection zone, in order to grant derogation from prohibitions in the movement of these animals to a plant approved for processing or disposal of animal by-products in which the kept animals are immediately killed (Art. 37). | No specific guidelines described in legislation | No specific guidelines described in legislation |
| 13th | To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations of the animals of listed species in order to grant derogation from prohibitions and allow for these animals to be moved: | <p>Article 12:</p> <p>1) Member States shall ensure that the following measures are applied in the surveillance zone: (d) animals of susceptible species must remain inside the surveillance zone for a maximum incubation period after the most recent recorded case of disease. Thereafter, animals may be removed from that zone to be transported under</p> | No specific guidelines described in legislation |

| Scenario | Description of the Scenario | Clinical guidelines | Laboratory guidelines |
|----------|---|--|-----------------------|
| | <p>a) from an establishment in a surveillance zone to a slaughterhouse located within or outside the restricted zone,</p> <p>b) from an establishment outside the surveillance zone to a slaughterhouse situated in the surveillance zone.</p> | <p>official supervision <u>directly to a slaughterhouse</u> designated by the competent authority for emergency slaughter. Such transport may be authorized by the competent authority <u>only after the official veterinarian has carried out an examination of all the animals of the susceptible species on the holding and confirmed that none of the animals is suspected of being infected.</u> The competent authority responsible for the slaughterhouse shall be informed of the intention to send animals to it.</p> | |
| 14th | <p>To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations of kept ungulates of listed species in order to grant a derogation and allow for the animals to be moved from an establishment in the surveillance zone to pastures situated within the surveillance zone.</p> | <p>NA</p> <p>Article 12:</p> <p>1. Member States shall ensure that the following measures are applied in the surveillance zone:</p> <p>b) <u>the movement of animals of susceptible species on public roads shall be prohibited except for the purpose of leading them to pasture or animal buildings.</u></p> | NA |
| 15th | <p>To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations of kept ungulates of listed species in order to grant derogation and allow for them to be moved from an establishment in the surveillance zone to an establishment belonging to the same supply chain, located in or outside the surveillance zone, in order to</p> | <p>NA</p> <p>Article 12:</p> <p>1) Member States shall ensure that the following measures are applied in the surveillance zone:</p> <p>b) <u>the movement of animals of susceptible species on public roads shall be prohibited except for the purpose of leading them to pasture or animal buildings.</u></p> | NA |

| Scenario | Description of the Scenario | Clinical guidelines | Laboratory guidelines |
|-------------|--|---|---|
| | complete the production cycle before slaughter. | | |
| 16th | To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations to grant derogation of movements of day-old-chicks hatched from establishment located in the surveillance zone, from eggs originating within the surveillance zone and eggs originating outside the restricted zone, to an establishment located in the same Member State where they were hatched. | NA | NA |
| 17th | To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations, to grant a derogation from prohibitions in the movement of ready-to-lay poultry located in the surveillance zone to establishments located in the same Member State. | NA | NA |
| 18th | To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations of the animals of an establishment located in the restricted zone of an outbreak in order to allow their move within the | <p>Article 13:</p> <p>Where the prohibitions provided for in Articles <u>11 (1) (d)</u> and <u>12 (1) (d)</u> are maintained beyond 30 days because of the occurrence of further cases of the disease and as a result problems arise in keeping the animals, the competent authority may, following an application by the owner explaining the rounds for such application, by the</p> | No specific guidelines described in legislation |

| Scenario | Description of the Scenario | Clinical guidelines | Laboratory guidelines |
|---------------------|---|--|---|
| | restricted zone, when restriction measures are maintained beyond the period set out in Annex XI. | owner explaining the grounds for such applications authorize the removal of the animals from a holding within the protection zone or the surveillance zone, provided that: a) the official veterinarian has verified the facts; b) <u>an inspection of all animals on the holding has been carried out;</u> c) <u>the animals to be transported have undergone a clinical examination, with negative result;</u> d) each animal has been marked by ear marking or has been identified by any other approved method; e) the holding of destination is located either in the protection zone or within the surveillance zone. | |
| Repopulation | | | |
| 19th | To assess the effectiveness of disease-specific sampling procedures based on laboratory examinations of the animals that are kept for the repopulation prior to their introduction to rule out the presence of the disease. | NA | No specific guidelines described in legislation |
| 20th | To assess the effectiveness of disease-specific sampling procedures based on laboratory examinations of the animals that have been repopulated, in the event of unusual mortalities or clinical signs being notified during the repopulation; to rule out the presence of the disease. | NA | No specific guidelines described in legislation |
| 21st | To assess the effectiveness of disease-specific sampling procedures based on laboratory examinations of | NA | No specific guidelines described in legislation |

| Scenario | Description of the Scenario | Clinical guidelines | Laboratory guidelines |
|----------|---|---------------------|-----------------------|
| | the animals that have been repopulated, on the last day of the monitoring period calculated forward from the date on which the animals were placed in the repopulated establishment. In case the repopulation takes place in several days, the monitoring period will be calculated forward from the last day in which the last animal is introduced in the establishment. | | |

Annex D – Scenarios of ToR 2, effectiveness of the length of the monitoring periods

| ToRs | Legislation | Scenario | Description of the Scenario | Elements of the Scenarios |
|-------|---|--------------|--|---|
| ToR 2 | <p>Article 8 of the Delegated Regulation</p> <p>Article 57 of 2016/429 Regulation</p> <p>Annex II of the Delegated Regulation</p> | 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. | <ul style="list-style-type: none"> • 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 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 enquiry is: <ol style="list-style-type: none"> 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 | <p>Article 17(2) and Article 57 of 2016/429 Regulation</p> <p>Annex II of the Delegated Regulation</p> | 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. | <ul style="list-style-type: none"> • 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 enquiry is the same as above. |
| ToR 2 | Article 13(b) of the Delegated Regulation | 3rd scenario | To assess the effectiveness of the length of the Monitoring Period, as the time period | <ul style="list-style-type: none"> • event of confirmation of a category A disease |

| ToRs | Legislation | Scenario | Description of the Scenario | Elements of the Scenarios |
|-------|--|--------------|---|--|
| | Annex II of the Delegated Regulation | | calculated backwards from the date of confirmation of a category A disease in an establishment with kept animals of listed species, during which the epidemiological units in which the disease has not been confirmed were kept completely separated and handled by different personnel, in order to provide derogations from killing. | <ul style="list-style-type: none"> in an affected establishment with kept animals of listed species non-affected epidemiological units kept separated to provide derogation from killing for animals in non-affected separated epidemiological units to exclude any possible contact between the affected establishment and the separated epidemiological units as per the epidemiological enquiry time period calculated backwards from the date of the confirmation time period before the confirmation, during which the pathogenic agent may have been introduced in the separated non-affected epidemiological units of the affected establishment. |
| ToR 2 | Article 27(3)c of the Delegated Regulation Annex II of the Delegated Regulation | 4th 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 the latest outbreak of a category A disease in the protection zone. Products or other materials likely to spread the disease, must had been obtained or produced, before this time period in order to be exempted from prohibitions of movements. | <ul style="list-style-type: none"> protection zone non-affected establishments Products or other materials likely to spread the disease, obtained or produced, before the start of the monitoring period of the affected establishment that originated the protection zone time period calculated backwards from the date of suspicion of the latest outbreak in the protection zone time period before the notification of the suspicion, during which the products and materials produced in the non-affected establishments of a protection zone may have been contaminated by the pathogenic agent of the disease. |
| ToR 2 | Article 32(c) of the Delegated Regulation Article 48(c) of the Delegated Regulation Annex II of the Delegated Regulation | 5th scenario | To assess the effectiveness of the length of the Monitoring Period, as the time period calculated forwards from the date of semen collection from animals of listed species kept in approved germinal product establishments in the protection or in the surveillance zone, to prove that the donor animal has tested favourable on a sample taken not earlier than 7 days after the monitoring period. | <ul style="list-style-type: none"> protection or surveillance zone non-affected approved germinal establishments semen from kept animals (donor) of listed species semen collected after the estimated date of the earliest infection of the earliest affected establishment that originated the protection zone/surveillance zone (if belonging to more than one protection or surveillance zones) to take samples from the donor for laboratory analysis at least 7 days after the end of the monitoring period |

| ToRs | Legislation | Scenario | Description of the Scenario | Elements of the Scenarios |
|-------|--|--------------|--|---|
| | | | | <ul style="list-style-type: none"> to authorise movements of semen from approved germinal product establishments located in the protection or surveillance zones in case of favourable laboratory results time period calculated forwards from the date of semen collection time period after the semen collection, during which the animal donor if infected could be detected by the relevant diagnostic test. |
| ToR 2 | Article 57(1)b of the Delegated Regulation Annex II of the Delegated Regulation | 6th scenario | To assess the effectiveness of the length of the Monitoring Period, as the appropriate time period calculated forwards from the date after the final cleaning and disinfection and when relevant control of insects and rodents was carried out in an affected establishment, after which the repopulation of the establishment may be allowed by the competent authority. | <ul style="list-style-type: none"> repopulation of a previous affected establishment kept animals of listed species to allow the repopulation of an affected establishment time period calculated forwards from the date of the final cleaning and disinfection of the establishment time period to ensure that the repopulation exercise is not put at risk due to the disease being unknowingly present in an establishment in the surrounding area. |
| ToR 2 | Article 59(4)b of the Delegated Regulation Annex II of the Delegated Regulation | 7th scenario | To assess the effectiveness of the length of the Monitoring Period, as the appropriate time period calculated forwards the date when the first animal was introduced, during which all the animals of listed species intended for repopulation should be introduced. | <ul style="list-style-type: none"> repopulation of a previous affected establishment kept animals of listed species to be repopulated the animals may not be introduced at the same time time period calculated forwards from the date when the first animal was introduced time period during which animals intended for repopulation, should be introduced and the process of repopulation be completed. |

Annex E – Minimum radius and minimum period of duration of protection and surveillance zones Minimum radius and minimum period of duration of protection and surveillance zones

| Category A diseases | Minimum radius of Protection zone Annex V | Minimum radius of Surveillance zone Annex V | Minimum period of duration of measures in the protection zone (Article 39(1)) Annex X | Additional period of duration of surveillance measures in the protection zone (Article 39(3)) Annex X | Minimum period of duration of measures in the surveillance zone (as referred to in Articles 55 and 56 of this Regulation) Annex XI |
|--|---|---|---|---|--|
| Foot and mouth disease (FMD) | 3 km | 10 km | 15 days | 15 days | 30 days |
| Infection with rinderpest virus (RP) | 3 km | 10 km | 21 days | 9 days | 30 days |
| Infection with Rift Valley fever virus (RVFV) | 20 km | 50 km | 30 days | 15 days | 45 days |
| Infection with lumpy skin disease virus (LSD) | 20 km | 50 km | 28 days | 17 days | 45 days |
| Infection with <i>Mycoplasma mycoides</i> subsp. <i>mycoides</i> SC (Contagious bovine pleuropneumonia) (CBPP) | Establishment | 3 km | 45 days | Not applicable | 45 days |
| Sheep pox and goat pox (SPGP) | 3 km | 10 km | 21 days | 9 days | 30 days |
| Infection with peste des petits ruminant virus (PPR) | 3 km | 10 km | 21 days | 9 days | 30 days |
| Contagious caprine pleuropneumonia (CCPP) | Establishment | 3 km | 45 days | Not applicable | 45 days |
| African horse sickness (AHS) | 100 km | 150 km | 12 months | Not applicable | 12 months |
| Infection with <i>Burkholderia mallei</i> (Glanders) | Establishment | Establishment | 6 months | Not applicable | Not applicable |
| Classical swine fever (CSF) | 3 km | 10 km | 15 days | 15 days | 30 days |
| African swine fever (ASF) | 3 km | 10 km | 15 days | 15 days | 30 days |
| Highly pathogenic avian influenza (HPAI) | 3 km | 10 km | 21 day | 9 days | 30 days |
| Infection with Newcastle disease virus (NCD) | 3 km | 10 km | 21 days | 9 days | 30 days |

Annex F – Uncertainty

| Source or location of the uncertainty | # | Nature or cause of uncertainty as described by the experts | Impact of the uncertainty on the assessment |
|---------------------------------------|---|--|--|
| ToR 1 | 1 | Parameters governing transmission dynamics and mortality rates in the model used for answering scenarios under ToR 1 are based on a limited number of studies (several on experimental challenges). There is a great variability of morbidity and mortality rates due to different hosts (animal breeds, husbandry conditions,) and virus factors (mainly virulence). This affects the precision of any estimation. | The effectiveness of the sampling strategies could be over or underestimated |
| | 2 | Disease transmission is assumed to follow the same dynamics in sheep and goat flocks although evidences suggest a higher virulence/pathogenicity of PPRV in goat flocks. | The effectiveness of the sampling strategies could be over or underestimated |
| | 3 | Diagnostic tests are assumed to have 100% Sensitivity and Specificity. Although this is a reasonable assumption given the evidence retrieved there may be instances in which test performance may not be perfect (particularly with regards to serological tests). | The effectiveness of the sampling strategies could be overestimated |
| ToR 2 | 4 | Very few references available to estimate the time from infection to suspicion, and no data obtained from EU | The effectiveness of the proposed strategy could be over or underestimated |
| | 5 | In order to use references providing periods between first suspicion and report of suspicion, the incubation period was assumed to be 7 days (between 3 and 10). | The effectiveness of the proposed strategy could be over or underestimated |
| | 6 | References used to estimate the time between infection and seroconversion are based on experimental inoculation of PPRV (instead of natural infection), what may not mimic the situation in naturally infected animals (particularly with lower infectious doses) | The effectiveness of the proposed strategy could be over or underestimated |
| ToR 3 | 7 | No transmission kernels are available for PPR. Transmission kernels for sheep and goat pox were used as a proxy. Although the causative agents of both viruses share certain features they also have different characteristics that may impact transmission and thus kernel estimates may not be directly applicable for modelling risk of PPRV transmission. | The effectiveness of the proposed zone size could be underestimated |
| | 8 | SGP kernels were fitted only on data from a single region in Greece and thus may not be representative of transmission in different epidemiological situation | The effectiveness of the proposed zone size could be over or underestimated |
| | 8 | | |

Annex G – Literature search for seroconversion period of PPR

Methodology

For the assessment of scenario 5 of the 2nd ToR, the methodology described in Section 2.3 of the Technical Report published by EFSA (<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2020.EN-1988>) and in scientific opinion for PPR was followed.

Framework of methodology

Framework to meet the objectives is depicted in Table 1.

Framework of methodology.

| | |
|------------------|---|
| Years | From 2000 onwards Comments/Explanation: This will depend on the availability of the bibliographic databases |
| Language | Only studies written in English will be reviewed Comments/Explanation: |
| Publication type | Only primary research studies will be reviewed Comments/Explanation: <ul style="list-style-type: none"> • Reviews (i.e. secondary research studies) will not be included in the review, but they reference lists will be screened as sources of studies • Book chapters, theses and unpublished data will not be included • Letters and editorials will be excluded as normally these do not include any primary research studies • Patents will be excluded • No geographical limits |
| Population | <i>Ovis ssp.</i> , <i>Capra ssp.</i> , Camelidae, Cervidae Comments/Explanation: |
| Intervention | Serological diagnostic tests for PPR Comments/Explanation: |
| Target | PPR virus (family Paramyxoviridae, genus <i>Morbillivirus</i>) will be the targeted pathogens Comments/Explanation: |

Information sources

Search strategies included the use of electronic search engines for bibliographic databases. Two databases were searched:

- PubMed, and
- Mendeley

Due to the specificity of the objective and time constrains only clinical trials and randomised controlled trials were included. Moreover, recent Oie diagnostic manual and relevant previous EFSA scientific opinions were also included. Book chapters, theses and informally reported or unpublished data were not collated.

Search strategy

The following search strategy was followed:

- Population: goat* or sheep or ovi* or capr* or "small ruminants" or cattle or camel* or Cervidae
- Serological Tests: "diagnostic test" or serolog* or antibod* or "immune diffusion" or *ELISA
- Target: "Peste des petits ruminants" or PPRV or Paramyxoviridae or Morbillivirus or "small ruminant pest" or "pest of small ruminants" or pest*

A scoping search identified:

- 834 papers in PubMed, and
- 1.562 papers in Mendeley

A database of the electronic search results was created with Mendeley software. Duplicate citations were deleted automatically or manually when appropriated (n = 350).

Study selection

Study selection was based on the following predefined inclusion criteria (questions):

| | | | |
|---|-----|---------|----|
| 1) Is the paper in English? | Yes | Unclear | No |
| 2) Is the paper an original clinical trial or a randomized controlled trial for the targeted listed species? | Yes | Unclear | No |
| 3) Is the paper describing a serological diagnostic test for PPR? | Yes | Unclear | No |
| 4) Is the paper describing the earliest day of seroconversion and the latest day of antibodies detection after infection | Yes | Unclear | No |

Final decision: Include Review Exclude

All papers with a 'no' or 'unclear' for any question were excluded based on title/abstract.

All papers with a 'yes' for each question were reviewed based on title/abstract.

Screening of titles and abstracts after the application of the above inclusion criteria was conducted for 172 papers.

Annex H – Method for kernel estimation

This appendix presents full details of the modelling approach used to estimate kernels for the spread of sheep and goat pox between farms.

Epidemiological data

The location and time of destruction for reported outbreaks of sheep and goat pox from the epidemic in the Evros region of Greece between 2013 and 2015 were extracted from ADNS. Because times of infection are not observed, farms were assumed to become infected (and infectious) 30 days prior to destruction (the sensitivity of the estimates to this assumption was assessed; see Table H.1).

Modelling approach

The spread of sheep and goat pox was modelled at the farm level. Transmission between farms was modelled using a kernel-based approach. In this case, the force of infection, $\lambda_i(t)$, for farm i on day t is given by,

$$\lambda_i(t) = h_B + h_K N_i \sum_{j \neq i} K(d_{ij}) N_j I_j(t),$$

where h_B is the background transmission rate (e.g. due to introductions of SPGP from outside Greece, unobserved infected farms or unexpectedly long distance animal movements), h_K is the kernel transmission rate (i.e. due to known infected farms), N_i is the number of small ruminants (sheep and goats) on farm i , $K(d_{ij})$ is the transmission kernel (see below), d_{ij} is the great circle distance between farms i and j , and $I_j(t)$ is a variable indicating whether farm j is infectious (1) or not (0) on day t .

Four functional forms were considered for the kernel (Table H.1), which differ in their shape and the rate at which they decay to zero. In each kernel the parameter d_0 is the distance scaling and in the alternative fat-tailed kernel α controls how rapidly the kernel decays with distance.

Parameter estimation

Parameters in the model were estimated using maximum likelihood methods. Because locations are available only for affected farms, we used a conditional likelihood for the data (Szmaragd et al., 2009). In this case, the likelihood is given by,

$$L = \prod_i \frac{\exp\left(-\sum_{t=t_0}^{t_{inf}-1} \lambda_i(t)\right) \times (1 - \exp(\lambda_i(t_{inf})))}{\sum_{\tau=t_0}^{t_{end}} \exp\left(-\sum_{t=t_0}^{\tau-1} \lambda_i(t)\right) \times (1 - \exp(\lambda_i(\tau)))},$$

where $\lambda_i(t)$ is the force of infection defined above t_{inf} is the time at which the farm became infected, t_0 is the time at the start of the epidemic and t_{end} is the time at the end of the epidemic.

Selection of the best-fit kernel was based on the Akaike information criterion,

$$AIC = -2 \times \log L_{max} + 2k,$$

where L_{max} is the maximum likelihood and k is the number of parameters in the model. The model with the smallest AIC is preferred. Confidence intervals for the kernel parameters (d_0 and α) were computed using the profile likelihood.

The sensitivity of the best-fit kernel and the kernel estimates to assumptions about the duration of a within-farm outbreak was assessed by fitting each of the four kernels assuming four outbreak durations (15, 30, 60 or 90 days). For each assumed outbreak duration, the best-fitting kernel was the alternative fat-tailed, followed by the fat-tailed, exponential and Gaussian (Table H.1). In addition, the kernel estimates did not differ greatly in each case (Table H.1). Finally, the lowest AICs were obtained when the assumed outbreak duration was 30 days. Kernel estimates from this analysis (i.e. 30 days) were used to assess the minimum size of the protection and surveillance zones.

Table H.1: Transmission kernels for sheep and goat pox and the impact of assumed outbreak duration on kernel selection and estimates

| Kernel | Function | Outbreak duration | | | |
|------------------------|---|---|---|---|---|
| | | 15 days | 30 days | 60 days | 90 days |
| Fat-tailed | $k(d) = \left(1 + \left(\frac{d}{d_0}\right)^2\right)^{-1}$ | AIC = 2,591 $d_0 = 2.47$ | AIC = 2,568 $d_0 = 2.28$ | AIC = 2,585 $d_0 = 2.14$ | AIC = 2,641 $d_0 = 1.90$ |
| Gaussian | $k(d) = \exp\left(-\left(\frac{d}{d_0}\right)^2\right)$ | AIC = 2,604 $d_0 = 11.54$ | AIC = 2,584 $d_0 = 10.04$ | AIC = 2,603 $d_0 = 9.56$ | AIC = 2,660 $d_0 = 9.97$ |
| Exponential | $k(d) = \exp\left(-\frac{d}{d_0}\right)$ | AIC = 2,595 $d_0 = 6.39$ | AIC = 2,577 $d_0 = 5.67$ | AIC = 2,597 $d_0 = 5.45$ | AIC = 2,653 $d_0 = 7.60$ |
| Alternative fat-tailed | $k(d) = \left(1 + \frac{d}{d_0}\right)^{-\alpha}$ | AIC = 2,576 $d_0 = 0.14$ $\alpha = 1.07$ | AIC = 2,561 $d_0 = 0.61$ $\alpha = 1.32$ | AIC = 2,578 $d_0 = 0.69$ $\alpha = 1.35$ | AIC = 2,635 $d_0 = 0.70$ $\alpha = 1.37$ |

Annex I – Performance of diagnostic test for PPR

The summary results from the literature review performed by DACRHA on performance of diagnostic test for PPR are presented in Table I.1.

Table I.1: Average sensitivity and specificity of diagnostic test for PPR from literature review

| Diagnostic test | No. papers | Average of sensitivity | Min of sensitivity | Max of sensitivity | Average of specificity | Min of specificity | Max of specificity |
|---|------------|------------------------|--------------------|--------------------|------------------------|--------------------|--------------------|
| ELISA, Blocking ELISA (B-ELISA) | | | | | | | |
| Goat (<i>Capra aegagrus hircus</i>) | 1 | 90,4 | 90,4 | 90,4 | 98,9 | 98,9 | 98,9 |
| ELISA, Competitive ELISA (C-ELISA) | | | | | | | |
| CATTLE - Cattle (<i>Bos taurus</i>) | 2 | 93,4 | 93,4 | 93,4 | 98,5 | 98,5 | 98,5 |
| Goat (<i>Capra aegagrus hircus</i>) | 14 | 93,47 | 68,65 | 100 | 98,06 | 93,53 | 100 |
| Sheep (<i>Ovis aries</i>) | 6 | 96,7 | 93,4 | 100 | 99,25 | 98,5 | 100 |
| Enzyme linked immunosorbent assay (ELISA) | | | | | | | |
| Goat (<i>Capra aegagrus hircus</i>) | 16 | 91,2 | 78 | 100 | 100 | 100 | 100 |
| Sheep (<i>Ovis aries</i>) | 4 | 85 | 85 | 85 | 83 | 83 | 83 |
| Indirect ELISA (I-ELISA) | | | | | | | |
| Goat (<i>Capra aegagrus hircus</i>) | 6 | 86,62 | 79,16 | 100 | 95,77 | 83,76 | 100 |
| Sheep (<i>Ovis aries</i>) | 1 | 93,75 | 93,75 | 93,75 | 100,83 | 100,83 | 100,83 |
| Lateral Flow Test | | | | | | | |
| Goat (<i>Capra aegagrus hircus</i>) | 4 | 76,5 | 75 | 78 | 100 | 100 | 100 |
| Sheep (<i>Ovis aries</i>) | 7 | 97,67 | 97,67 | 97,67 | 99,47 | 99,47 | 99,47 |
| loop-mediated isothermal amplification (LAMP) | | | | | | | |
| Goat (<i>Capra aegagrus hircus</i>) | 23 | 100 | 100 | 100 | 100 | 100 | 100 |
| Real time Loop-mediated isothermal amplification (RT-LAMP) | | | | | | | |
| Goat (<i>Capra aegagrus hircus</i>) | 2 | 100 | 100 | 100 | 88,2 | 88,2 | 88,2 |
| Sheep (<i>Ovis aries</i>) | 2 | 100 | 100 | 100 | 100 | 100 | 100 |
| Real-time PCR (qualitative or quantitative) | | | | | | | |
| Goat (<i>Capra aegagrus hircus</i>) | 23 | 100 | 100 | 100 | 100 | 100 | 100 |
| Sheep (<i>Ovis aries</i>) | 16 | 100 | 100 | 100 | 100 | 100 | 100 |
| Reverse-transcription PCR (RT-PCR) | | | | | | | |
| Goat (<i>Capra aegagrus hircus</i>) | 66 | 100 | 100 | 100 | 100 | 100 | 100 |
| Sheep (<i>Ovis aries</i>) | 34 | 100 | 100 | 100 | 100 | 100 | 100 |
| Sandwich ELISA | | | | | | | |
| Goat (<i>Capra aegagrus hircus</i>) | 1 | 88,9 | 88,9 | 88,9 | 92,8 | 92,8 | 92,8 |

| Diagnostic test | No. papers | Average of sensitivity | Min of sensitivity | Max of sensitivity | Average of specificity | Min of specificity | Max of specificity |
|--|------------|------------------------|--------------------|--------------------|------------------------|--------------------|--------------------|
| Sheep (<i>Ovis aries</i>) | 1 | 100 | 100 | 100 | 100 | 100 | 100 |
| Virus neutralisation test (VNT) | | | | | | | |
| CATTLE - Cattle (<i>Bos taurus</i>) | 2 | 100 | 100 | 100 | 100 | 100 | 100 |
| Goat (<i>Capra aegagrus hircus</i>) | 6 | 100 | 100 | 100 | 100 | 100 | 100 |
| Sheep (<i>Ovis aries</i>) | 2 | 100 | 100 | 100 | 100 | 100 | 100 |

Annex J – Protocol of literature review for length of monitoring period

Rationale

The EFSA has been requested to provide scientific opinions to support the European Commission (EC) in the production of amending and implementing acts related to Regulation 2016/429 (the 'Animal Health Law' (AHL)) which lays down rules for the prevention and control of transmissible animal diseases. One of these scientific opinions will consist in assessing the effectiveness of several control measures for Category A (listed) diseases such as the length of the monitoring periods set out in Annex II of the Delegated Regulation (Mandate ToRs 2) and the duration of the control measures in restricted zones set out in Annex X-XI for each category A disease of terrestrial animals (ToR 3b).

As part of this, EFSA has asked P95 (within FWC OC/EFSA/ALPHA/2020/02 LOT 2) to carry out an extensive literature review (ELR) on the epidemiological parameter 'time for an outbreak to be reported' for the following diseases: PPR, classical swine fever (CSF), Newcastle Disease (ND), sheep pox and goat pox (SPGP), Rift Valley Fever (RVF), Glanders, contagious caprine pleuropneumoniae (CCPP), contagious bovine pleuropneumoniae (CBPP) and Rinderpest.

The current protocol describes the methodology that will be used by P95 to conduct the ELR.

Review question

The specific objective of this review will be to answer the epidemiological question of: 'what is the average, shortest and longest period of time (measured as the number of days from the earliest point of infection with the agent, to the time of reporting of a suspicion by the competent authority after the clinical investigation by an official veterinarian) for an outbreak of each of the 9 diseases of concern to be reported'.

Criteria for including studies

Starting with the objectives of the review stated above, the study inclusion criteria are based on the PICOS strategy:

| Population | Domestic animal species |
|--------------|--|
| Intervention | PPR, CSF, ND, SPGP, RVF, Glanders, CCPP, CBPP, Rinderpest |
| Comparison | Not applicable |
| Outcome | <ul style="list-style-type: none"> • Number of days between the earliest point of infection and the suspicion report • Number of days between the earliest point of infection and the first suspicion⁽¹⁾ • Number of days between the earliest point of infection and the confirmation report • Number of days between the first suspicion and the suspicion report • Number of days between the first suspicion and the confirmation report • Number of days between the suspicion report and the confirmation report |
| Study design | Outbreak investigation, case report, surveillance data, modelling studies |

(1): The suspicion based on the first observed clinical signs.

Exclusion criteria

- 1) The references will be excluded from the ELR if they meet one or more of following criteria:
- 2) References in another language than English, Spanish, German, Dutch, Portuguese and French.
- 3) Review papers. However, original studies included in the review papers complying with the inclusion/exclusion criteria will be included.
- 4) References published before 01/01/2000.
- 5) References pertaining exclusively to diagnostics/vaccine development, entomology, in vitro/vivo studies.
- 6) References where the earliest point of infection is determined only by subtracting a known incubation period from the date of the suspicion of the outbreak. However, after discussion with EFSA and comment from experts, outbreaks investigations that do not determine the true date of infection but report about the time between the onset of clinical signs and date of suspicion of the disease could be included.
- 7) References presenting simulation exercises. However, if none or very few articles are retrieved (less or equal to 5) in the first search, these studies may be included but their data

should be presented in a separate table in the report together with a description of the methodology.

- 8) References from outside the EU/EEA countries. However, If none or very few articles are retrieved (less or equal to 5) in the first search, the search should be extended to the rest of the world.
- 9) References related to outbreaks that took place in a slaughterhouse. Nonetheless, references referring to outbreaks that occurred elsewhere, and are detected in a slaughterhouse may be included if all other conditions for inclusion are met.

Information sources

Electronic databases

We will conduct a literature search in MEDLINE (via PubMed) and EMBASE to obtain peer-reviewed, scientific publications related to the ELR.

Reference checking and hand searching

The reference list of relevant studies retrieved from the electronic database search will be hand searched to identify additional studies.

Grey literature selection

Data in the public domain pertaining to the objective of this study, outbreak investigation reports or surveillance data will be obtained via PAFF, OIE, EFSA, FAO, EuFMD websites, Google scholar, and websites of EU veterinary reference laboratories for to the nine investigated diseases as well as websites of national veterinary/animal health institutes, reference veterinary laboratories or ministry of livestock from EU countries that previously experienced outbreaks of any of the five investigated diseases.

Search strategy

The following search strategy will be used in Pubmed:

| # | Search string | # of results |
|---|--|--------------|
| 1 | <p>((((((((((((((((((("first infection"[All Fields] OR "index case"[All Fields]) OR ("introduction"[All Fields] OR "introductions"[All Fields])) OR "source of infection"[All Fields]) OR "clinical signs"[All Fields]) OR "clinical symptoms"[All Fields]) OR "case studies"[All Fields]) OR ("suspicion"[All Fields] OR "suspicions"[All Fields])) OR (((("suspect"[All Fields] OR "suspected"[All Fields]) OR "suspecting"[All Fields]) OR "suspects"[All Fields])) OR ((((((("confirm"[All Fields] OR "confirmation"[All Fields]) OR "confirmations"[All Fields]) OR "confirmative"[All Fields]) OR "confirmed"[All Fields]) OR "confirming"[All Fields]) OR "confirms"[All Fields])) OR ((((((("confirm"[All Fields] OR "confirmation"[All Fields]) OR "confirmations"[All Fields]) OR "confirmative"[All Fields]) OR "confirmed"[All Fields]) OR "confirming"[All Fields]) OR "confirms"[All Fields])) OR (((((((("reportable"[All Fields] OR "reporting"[All Fields]) OR "reportings"[All Fields]) OR "research report"[MeSH Terms]) OR ("research"[All Fields] AND "report"[All Fields])) OR "research report"[All Fields]) OR "report"[All Fields]) OR "reported"[All Fields]) OR "reports"[All Fields]) OR (((((((("reportable"[All Fields] OR "reporting"[All Fields]) OR "reportings"[All Fields]) OR "research report"[MeSH Terms]) OR ("research"[All Fields] AND "report"[All Fields])) OR "research report"[All Fields]) OR "report"[All Fields]) OR "reported"[All Fields]) OR "reports"[All Fields])) OR (((((((("reportable"[All Fields] OR "reporting"[All Fields]) OR "reportings"[All Fields]) OR "research report"[MeSH Terms]) OR ("research"[All Fields] AND "report"[All Fields])) OR "research report"[All Fields]) OR "report"[All Fields]) OR "reported"[All Fields]) OR "reports"[All Fields])) OR ((("notification"[All Fields] OR "notifications"[All Fields])) OR (((("notifiable"[All Fields] OR "notified"[All Fields]) OR "notifier"[All Fields]) OR "notifiers"[All Fields]) OR "notifies"[All Fields]) OR "notify"[All Fields]) OR "notifying"[All Fields])) OR (((("declaration"[All Fields] OR "declarations"[All Fields]) OR "declare"[All Fields]) OR "declared"[All Fields]) OR "declares"[All Fields]) OR "declaring"[All Fields])) OR (((((((("declaration"[All Fields] OR "declaration s"[All Fields]) OR "declarations"[All Fields]) OR "declare"[All Fields]) OR "declared"[All Fields]) OR "declares"[All Fields]) OR "declaring"[All Fields])) OR (((((((("detect"[All Fields] OR "detectabilities"[All Fields]) OR "detectability"[All Fields]) OR "detectable"[All Fields]) OR "detectables"[All Fields]) OR</p> | 11,433,545 |

| # | Search string | # of results |
|----|--|-------------------|
| | "detectably"[All Fields] OR "detected"[All Fields] OR "detectible"[All Fields] OR "detecting"[All Fields] OR "detection"[All Fields] OR "detections"[All Fields] OR "detects"[All Fields] OR (((("trace"[All Fields] OR "traced"[All Fields] OR "traces"[All Fields] OR "tracing"[All Fields] OR "tracings"[All Fields])) OR (((((((("investigated"[All Fields] OR "investigates"[All Fields] OR "investigating"[All Fields] OR "investigation"[All Fields] OR "investigations"[All Fields] OR "investigative"[All Fields] OR "investigator s"[All Fields] OR "research personnel"[MeSH Terms] OR ("research"[All Fields] AND "personnel"[All Fields])) OR "research personnel"[All Fields] OR "investigator"[All Fields] OR "investigators"[All Fields])))) | |
| 2 | #1 AND "time"[MeSH Terms] OR "time"[All Fields] OR "delay"[All Fields] OR "delayed"[All Fields] OR "delaying"[All Fields] OR "delays"[All Fields] OR "length"[All Fields] OR "lengths"[All Fields] OR "period"[All Fields] OR "periodic"[All Fields] OR "periodical"[All Fields] OR "periodically"[All Fields] OR "periodicals"[All Fields] OR "periodicity"[MeSH Terms] OR "periodicity"[All Fields] OR "periodicities"[All Fields] OR "periods"[All Fields] OR "duration"[All Fields] OR "durations"[All Fields] OR "days"[All Fields] OR "date"[All Fields] OR "timelier"[All Fields] OR "timeliness"[All Fields] OR "timelier"[All Fields] OR "timeliness"[All Fields] OR "timely"[All Fields] OR "timing"[All Fields] OR "timings"[All Fields] | 3,497,425 |
| 3a | #2 AND ("peste des petits ruminants") Filters: from 2000 to 2021 | <u>168</u> |
| 3b | #2 AND ("classical swine fever") Filters: from 2000 to 2021 | <u>530</u> |
| 3c | #2 AND ("newcastle disease") Filters: from 2000 to 2021 | <u>821</u> |
| 3d | #2 AND ("sheep pox and goat pox") Filters: from 2000 to 2021 | <u>31</u> |
| 3e | #2 AND ("rift valley fever") Filters: from 2000 to 2021 | <u>360</u> |
| 3f | #2 AND ("glanders") Filters: from 2000 to 2021 | <u>57</u> |
| 3g | #2 AND ("contagious caprine pleuropneumonia") Filters: from 2000 to 2021 | <u>18</u> |
| 3h | #2 AND ("contagious bovine pleuropneumonia") Filters: from 2000 to 2021 | <u>47</u> |
| 3i | #2 AND ("rinderpest") Filters: from 2000 to 2021 | <u>66</u> |

Review methods

Selection of the studies

The list of studies identified from the different databases will be appended into a single file using Endnote and de-duplicated. The resulting list will be exported to Rayyan⁵ to proceed with the title, abstract and key words screening and study selection.

To decrease the risk of selection bias, two P95 reviewers will independently review the list of references obtained by screening key words in title/abstract to identify studies that fulfil the above-

⁵ <https://rayyan.qcri.org>

mentioned selection criteria. Discrepancies will be discussed, and if not resolved, a third reviewer will take the final decision.

All identified reviews and studies conducted outside EU/EEA will be classified in specific folders for subsequent use.

Data extraction

In the second phase, full papers will be assessed for eligibility by a single reviewer. Data from the eligible full-text papers identified will be extracted by two reviewers using a standardised extraction form in MS Excel (see Annex) to ensure that all relevant data are collected systematically. In addition, the section of the pdf manuscript from where data will be collected will be noted and/or highlighted.

The complete selection process will be documented in an Endnote file, containing folders that reflect the selection criteria.

Analysis and reporting

During the selection process, the results of the literature search will be imported into Endnote where a clear track of the selection process will be maintained, and the flow of publications will be noted. Based on these numbers, a flowchart of the studies selected in accordance with the PRISMA guidelines will be prepared for use in the subsequent reports.

If needed, extracted dates of interest will be combined together in order to calculate the periods of interest. Extracted data on age of the lesions can also be used to estimate the earliest point of infection. All these calculations will be described in an assigned column of the extraction form:

ID

Reference

Source

Author

Disease

Objective

Country

Region

Year

Species

Farm type

Level

Sample size

Parameter_type

Parameter_unit

Parameter_value

Comment

Calculation_description

Calculation_output

Using the data collected, a qualitative data synthesis of results will be performed for each specific disease and parameter in terms of average, shortest and longest period of time. The different findings will be synthesised using tables providing sufficient details on the methodology used in the references.

Annex K – Estimated prediction intervals for the time to determined PPR prevalence levels and for prevalence at given times post introduction

Table K.1: Median (M), lower (L) and upper (U) 95% prediction intervals for the time (days post introduction) to five sheep or goats with clinical signs of PPR

| Scenario | | Herd size | | | | | | | | | | | |
|----------------|-------------------|-----------|----|----|-----|----|----|-----|----|----|-------|----|----|
| | | 50 | | | 100 | | | 500 | | | 1,000 | | |
| | | M | L | U | M | L | U | M | L | U | M | L | U |
| Low mortality | Low transmission | 27 | 16 | 44 | 24 | 13 | 44 | 26 | 16 | 40 | 25 | 16 | 49 |
| | High transmission | 20 | 13 | 32 | 20 | 13 | 30 | 19 | 13 | 27 | 19 | 12 | 32 |
| High mortality | Low transmission | 18 | 12 | 42 | 19 | 11 | 39 | 18 | 10 | 32 | 18 | 10 | 36 |
| | High transmission | 14 | 8 | 26 | 14 | 9 | 29 | 14 | 9 | 21 | 13 | 8 | 28 |

Table K.2: Median (M), lower (L) and upper (U) 95% prediction intervals for the time (days post introduction) to five sheep or goats dying of PPR

| Scenario | | Herd size | | | | | | | | | | | |
|----------------|-------------------|-----------|----|----|-----|----|----|-----|----|----|-------|----|----|
| | | 50 | | | 100 | | | 500 | | | 1,000 | | |
| | | M | L | U | M | L | U | M | L | U | M | L | U |
| Low mortality | Low transmission | 48 | 30 | 68 | 44 | 31 | 58 | 41 | 29 | 54 | 40 | 27 | 57 |
| | High transmission | 38 | 25 | 53 | 33 | 24 | 46 | 30 | 23 | 39 | 31 | 22 | 46 |
| High mortality | Low transmission | 25 | 18 | 48 | 27 | 16 | 38 | 26 | 16 | 40 | 25 | 17 | 38 |
| | High transmission | 21 | 15 | 30 | 22 | 16 | 32 | 21 | 14 | 26 | 20 | 14 | 33 |

Table K.3: Median (M), lower (L) and upper (U) 95% prediction intervals for the time (days post introduction) to 5% infection prevalence of peste des petits ruminants virus in sheep and goats

| Scenario | | Herd size | | | | | | | | | | | |
|----------------|-------------------|-----------|---|----|-----|----|----|-----|----|----|-------|----|----|
| | | 50 | | | 100 | | | 500 | | | 1,000 | | |
| | | M | L | U | M | L | U | M | L | U | M | L | U |
| Low mortality | Low transmission | 12 | 6 | 33 | 18 | 10 | 32 | 32 | 23 | 47 | 37 | 27 | 59 |
| | High transmission | 10 | 5 | 19 | 14 | 8 | 24 | 23 | 17 | 32 | 27 | 20 | 42 |
| High mortality | Low transmission | 10 | 6 | 30 | 17 | 9 | 34 | 29 | 21 | 44 | 33 | 24 | 52 |
| | High transmission | 8 | 4 | 21 | 12 | 8 | 27 | 21 | 16 | 29 | 24 | 19 | 39 |

Table K.4: Median (M), lower (L) and upper (U) 95% prediction intervals for the time (days post introduction) to 10% infection prevalence of peste des petits ruminants virus in sheep and goats

| Scenario | | Herd size | | | | | | | | | | | |
|----------------|-------------------|-----------|----|----|-----|----|----|-----|----|----|-------|----|----|
| | | 50 | | | 100 | | | 500 | | | 1,000 | | |
| | | M | L | U | M | L | U | M | L | U | M | L | U |
| Low mortality | Low transmission | 19 | 11 | 36 | 24 | 15 | 41 | 39 | 29 | 53 | 43 | 34 | 65 |
| | High transmission | 14 | 9 | 24 | 19 | 12 | 28 | 27 | 21 | 36 | 32 | 25 | 46 |
| High mortality | Low transmission | 15 | 10 | 34 | 22 | 15 | 43 | 34 | 26 | 50 | 39 | 29 | 57 |
| | High transmission | 12 | 8 | 22 | 16 | 11 | 33 | 24 | 20 | 34 | 28 | 22 | 43 |

Table K.5: Median (M), lower (L) and upper (U) 95% prediction intervals for the time (days post introduction) to 5% seroprevalence of peste des petits ruminants virus in sheep and goats

| Scenario | | Herd size | | | | | | | | | | | |
|----------------|-------------------|-----------|---|----|-----|----|----|-----|----|----|-------|----|----|
| | | 50 | | | 100 | | | 500 | | | 1,000 | | |
| | | M | L | U | M | L | U | M | L | U | M | L | U |
| Low mortality | Low transmission | 12 | 6 | 25 | 18 | 10 | 31 | 31 | 23 | 47 | 36 | 27 | 58 |
| | High transmission | 10 | 5 | 19 | 14 | 8 | 25 | 23 | 17 | 32 | 27 | 21 | 42 |
| High mortality | Low transmission | 10 | 6 | 25 | 18 | 11 | 30 | 29 | 21 | 43 | 33 | 24 | 52 |
| | High transmission | 8 | 4 | 20 | 13 | 9 | 27 | 21 | 16 | 29 | 24 | 19 | 39 |

Table K.6: Median (M), lower (L) and upper (U) 95% prediction intervals for the time (days post introduction) to 10% seroprevalence of peste des petits ruminants virus in sheep and goats

| Scenario | | Herd size | | | | | | | | | | | |
|----------------|-------------------|-----------|----|----|-----|----|----|-----|----|----|-------|----|----|
| | | 50 | | | 100 | | | 500 | | | 1,000 | | |
| | | M | L | U | M | L | U | M | L | U | M | L | U |
| Low mortality | Low transmission | 19 | 12 | 34 | 23 | 15 | 39 | 38 | 29 | 53 | 43 | 33 | 64 |
| | High transmission | 14 | 9 | 24 | 18 | 13 | 27 | 28 | 21 | 35 | 31 | 25 | 46 |
| High mortality | Low transmission | 16 | 11 | 32 | 22 | 15 | 41 | 34 | 26 | 49 | 39 | 29 | 57 |
| | High transmission | 12 | 8 | 22 | 16 | 12 | 33 | 24 | 20 | 34 | 28 | 22 | 43 |

Table K.7: Median (M), lower (L) and upper (U) 95% prediction intervals for the infection prevalence (%) of peste des petits ruminants virus in sheep and goats at 7 days post introduction

| Scenario | | Herd size | | | | | | | | | | | |
|----------------|-------------------|------------|-----|----|------------|-----|-----|------------|-----|-----|------------|-----|-----|
| | | 50 | | | 100 | | | 500 | | | 1,000 | | |
| | | M | L | U | M | L | U | M | L | U | M | L | U |
| Low mortality | Low transmission | 2.0 | 2.0 | 6 | 1.0 | 0.0 | 4.0 | 0.2 | 0.0 | 0.6 | 0.1 | 0.0 | 0.4 |
| | High transmission | 4.0 | 2.0 | 10 | 2.0 | 1.0 | 5.0 | 0.4 | 0.0 | 1.0 | 0.2 | 0.0 | 0.5 |
| High mortality | Low transmission | 2.0 | 0.0 | 8 | 1.0 | 0.0 | 4.0 | 0.2 | 0.0 | 0.8 | 0.1 | 0.0 | 0.4 |
| | High transmission | 4.0 | 0.0 | 10 | 2.0 | 0.0 | 5.0 | 0.4 | 0.0 | 1.0 | 0.2 | 0.0 | 0.5 |

Table K.8: Median (M), lower (L) and upper (U) 95% prediction intervals for the infection prevalence (%) of peste des petits ruminants virus in sheep and goats at 14 days post introduction

| Scenario | | Herd size | | | | | | | | | | | |
|----------------|-------------------|-----------|-----|------|-----|-----|------|-----|-----|-----|-------|-----|-----|
| | | 50 | | | 100 | | | 500 | | | 1,000 | | |
| | | M | L | U | M | L | U | M | L | U | M | L | U |
| Low mortality | Low transmission | 6.0 | 0.0 | 20.0 | 3.0 | 0.0 | 9.1 | 0.6 | 0.0 | 1.6 | 0.3 | 0.0 | 1.0 |
| | High transmission | 10.2 | 2.0 | 26.5 | 6.0 | 1.0 | 13.4 | 1.1 | 0.0 | 3.4 | 0.6 | 0.0 | 1.7 |
| High mortality | Low transmission | 8.2 | 0.0 | 20.8 | 4.0 | 0.0 | 9.3 | 0.7 | 0.0 | 2.0 | 0.3 | 0.0 | 1.4 |
| | High transmission | 14.6 | 0.0 | 40.4 | 6.2 | 0.0 | 18.6 | 1.4 | 0.0 | 3.4 | 0.9 | 0.0 | 2.4 |

Table K.9: Median (M), lower (L) and upper (U) 95% prediction intervals for the infection prevalence (%) of peste des petits ruminants virus in sheep and goats at 21 days post introduction

| Scenario | | Herd size | | | | | | | | | | | |
|----------------|-------------------|-------------|-----|------|-------------|-----|------|------------|-----|------|------------|-----|-----|
| | | 50 | | | 100 | | | 500 | | | 1,000 | | |
| | | M | L | U | M | L | U | M | L | U | M | L | U |
| Low mortality | Low transmission | 13.3 | 0.0 | 37 | 7 | 0.0 | 21.2 | 1.2 | 0.0 | 3.6 | 0.8 | 0.0 | 2.6 |
| | High transmission | 30.6 | 0.0 | 63.3 | 16 | 2.0 | 41.2 | 3.6 | 0.0 | 10.0 | 1.9 | 0.0 | 5.6 |
| High mortality | Low transmission | 15.1 | 0.0 | 50 | 8.2 | 0.0 | 24.5 | 1.6 | 0.0 | 5.8 | 0.9 | 0.0 | 3.2 |
| | High transmission | 38.1 | 0.0 | 79.5 | 22.7 | 0.0 | 53.9 | 5.3 | 0.0 | 12.7 | 3.1 | 0.0 | 8.8 |

Table K.10: Median (M), lower (L) and upper (U) 95% prediction intervals for the infection prevalence (%) of peste des petits ruminants virus in sheep and goats at 28 days post introduction

| Scenario | | Herd size | | | | | | | | | | | |
|----------------|-------------------|-----------|-----|------|------|-----|------|------|-----|------|-------|-----|------|
| | | 50 | | | 100 | | | 500 | | | 1,000 | | |
| | | M | L | U | M | L | U | M | L | U | M | L | U |
| Low mortality | Low transmission | 24.7 | 0.0 | 59.6 | 14.0 | 0.0 | 41.7 | 3.0 | 0.0 | 9.1 | 1.6 | 0.0 | 5.6 |
| | High transmission | 56.7 | 0.0 | 84.8 | 42.3 | 9.2 | 73.2 | 10.8 | 0.0 | 27.4 | 6.2 | 0.0 | 17.0 |
| High mortality | Low transmission | 28.9 | 0.0 | 66.7 | 18.1 | 0.0 | 46.5 | 4.0 | 0.0 | 13.8 | 2.3 | 0.0 | 8.8 |
| | High transmission | 70.5 | 0.0 | 90.9 | 55.1 | 0.0 | 83.8 | 18.3 | 0.0 | 41.2 | 11.5 | 0.0 | 29.8 |

Table K.11: Median (M), lower (L) and upper (U) 95% prediction intervals for the seroprevalence (%) of peste des petits ruminants virus in sheep and goats at 7 days post introduction

| Scenario | | Herd size | | | | | | | | | | | |
|----------------|-------------------|-----------|-----|-----|-----|-----|-----|-----|-----|-----|-------|-----|-----|
| | | 50 | | | 100 | | | 500 | | | 1,000 | | |
| | | M | L | U | M | L | U | M | L | U | M | L | U |
| Low mortality | Low transmission | 1.9 | 1.9 | 5.8 | 1.0 | 0.0 | 3.9 | 0.2 | 0.0 | 0.6 | 0.1 | 0.0 | 0.4 |
| | High transmission | 3.9 | 1.9 | 9.7 | 1.9 | 1.0 | 4.8 | 0.4 | 0.0 | 1.0 | 0.2 | 0.0 | 0.5 |
| High mortality | Low transmission | 2.0 | 0.0 | 7.8 | 1.0 | 0.0 | 3.9 | 0.2 | 0.0 | 0.8 | 0.1 | 0.0 | 0.4 |
| | High transmission | 3.9 | 0.0 | 9.7 | 1.9 | 0.0 | 4.8 | 0.4 | 0.0 | 1.0 | 0.2 | 0.0 | 0.5 |

Table K.12: Median (M), lower (L) and upper (U) 95% prediction intervals for the seroprevalence (%) of peste des petits ruminants virus in sheep and goats at 14 days post introduction

| Scenario | | Herd size | | | | | | | | | | | |
|----------------|-------------------|-----------|-----|------|-----|-----|------|-----|-----|-----|-------|-----|-----|
| | | 50 | | | 100 | | | 500 | | | 1,000 | | |
| | | M | L | U | M | L | U | M | L | U | M | L | U |
| Low mortality | Low transmission | 5.9 | 1.9 | 19.4 | 2.9 | 0.0 | 8.8 | 0.6 | 0.0 | 1.6 | 0.3 | 0.0 | 1.0 |
| | High transmission | 9.9 | 1.9 | 25.7 | 5.8 | 1.0 | 13.0 | 1.2 | 0.0 | 3.3 | 0.6 | 0.0 | 1.7 |
| High mortality | Low transmission | 7.9 | 0.0 | 20.2 | 3.9 | 0.0 | 9.0 | 0.8 | 0.0 | 2.1 | 0.3 | 0.0 | 1.4 |
| | High transmission | 14.1 | 0.0 | 39.2 | 6.4 | 0.0 | 18.0 | 1.4 | 0.0 | 3.4 | 0.8 | 0.0 | 2.3 |

Table K.13: Median (M), lower (L) and upper (U) 95% prediction intervals for the seroprevalence (%) of peste des petits ruminants virus in sheep and goats at 21 days post introduction

| Scenario | | Herd size | | | | | | | | | | | |
|----------------|-------------------|-----------|-----|------|------|-----|------|-----|-----|------|-------|-----|-----|
| | | 50 | | | 100 | | | 500 | | | 1,000 | | |
| | | M | L | U | M | L | U | M | L | U | M | L | U |
| Low mortality | Low transmission | 13.6 | 2.0 | 36.4 | 7.8 | 0.0 | 21 | 1.4 | 0.0 | 3.5 | 0.8 | 0.0 | 2.5 |
| | High transmission | 31.7 | 0.0 | 64 | 16.5 | 1.9 | 40.3 | 3.8 | 0.0 | 10.1 | 1.9 | 0.0 | 5.5 |
| High mortality | Low transmission | 14.8 | 0.0 | 52.7 | 8.8 | 0.0 | 25.9 | 1.6 | 0.0 | 5.9 | 0.9 | 0.0 | 3.2 |
| | High transmission | 37.9 | 0 | 79.4 | 22.9 | 0 | 54.9 | 5.2 | 0.0 | 12.5 | 3.1 | 0 | 8.9 |

Table K.14: Median (M), lower (L) and upper (U) 95% prediction intervals for the seroprevalence (%) of peste des petits ruminants virus in sheep and goats at 28 days post introduction

| Scenario | | Herd size | | | | | | | | | | | |
|----------------|-------------------|-----------|-----|------|------|-----|------|------|-----|------|-------|-----|------|
| | | 50 | | | 100 | | | 500 | | | 1,000 | | |
| | | M | L | U | M | L | U | M | L | U | M | L | U |
| Low mortality | Low transmission | 28.3 | 2.0 | 65.5 | 15.7 | 0.0 | 43.5 | 3.3 | 0.0 | 9.8 | 1.7 | 0.0 | 5.8 |
| | High transmission | 63.6 | 0.0 | 91.4 | 43.1 | 9.9 | 77.6 | 10.9 | 0.0 | 28.0 | 6.3 | 0.0 | 16.9 |
| High mortality | Low transmission | 30.1 | 0.0 | 73 | 19.4 | 0.0 | 47.4 | 4.1 | 0.0 | 13.7 | 2.4 | 0.0 | 9.0 |
| | High transmission | 72.8 | 0.0 | 97.3 | 56.6 | 0.0 | 91.8 | 18.2 | 0.0 | 41.0 | 11.5 | 0.0 | 29.6 |