

ADOPTED: 15 December 2021

doi: 10.2903/j.efsa.2022.7071

## Assessment of the control measures of category A diseases of the Animal Health Law: Infection with rinderpest virus (Rinderpest)

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### Abstract

EFSA received a mandate from the European Commission to assess the effectiveness of 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 are assessed, with this opinion covering the assessment of control measures for rinderpest (RP), the only animal disease to have been globally eradicated. In this opinion, the AHAW Panel reviewed the effectiveness of: (i) clinical and laboratory sampling procedures, (ii) monitoring period and (iii) the minimum radius of the protection and surveillance zone, 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. The transmission kernels used for the assessment of the minimum radius of the protection and surveillance zones are shown. Several scenarios for which control measures had to be assessed were agreed prior to the assessment. Considering that RP has been eradicated globally, a re-emergence that is not stopped in its early phases could have a devastating impact on animal health and the economy. The panel concludes that no suitable strategies are available to entirely mitigate the risk associated with granting derogations from killing of animals in an affected establishment or for animal movements. Therefore, the panel recommends to not grant any derogations. The monitoring period of 21 days was assessed as effective, except for the hypothetical first re-emergence of RP, when lack of awareness and diagnostic capability may extend the time to detection. It was concluded that the protection and the surveillance zones would contain 90% and > 99%, respectively, of the infections from an affected establishment. Enlarging the protection zone to 4 km would contain the disease spread with 95% probability.

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**Keywords:** disease control measures, rinderpest, RP, sampling procedures, monitoring period, protection zone, surveillance zone

**Requestor:** European Commission

**Question number:** EFSA-Q-2020-00805

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**Declarations of interest:** The declarations of interest of all scientific experts active in EFSA's work are available at <https://ess.efsa.europa.eu/doi/doiweb/doisearch>.

**Acknowledgments:** The Panel wishes to thank the following for the support provided to this scientific output: staff members Verena Oswaldi, Inmaculada Aznar Asensio.

**Suggested citation:** EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare), Nielsen SS, Alvarez J, Bicout DJ, Calistri P, Canali E, Drewe JA, Garin-Bastuji B, Gonzales Rojas JL, Gortázar C, Herskin M, Michel V, Miranda Chueca MÁ, Padalino B, Pasquali P, Spoolder H, Ståhl K, Velarde A, Viltrop A, Winckler C, De Clercq K, Gubbins S, Libeau G, Gervelmeyer A and Roberts HC, 2022. Scientific Opinion on the assessment of the control measures of category A diseases of the Animal Health Law: Infection with rinderpest virus (Rinderpest). EFSA Journal 2022;20(1):7071, 79 pp. <https://doi.org/10.2903/j.efsa.2022.7071>

**ISSN:** 1831-4732

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The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.



## Summary

This opinion is part of a series of opinions, in which the three first Terms of Reference (ToRs) 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 of this mandate request an assessment of the effectiveness of:

- the clinical and laboratory investigation 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 restricted 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 and duration of the restricted zones, in their capacity for mitigating disease spread (ToR 3).

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 rinderpest (RP) for each scenario of ToR 1 have been assessed. For assessing the effectiveness of detecting RP in a herd, a model to study the within herd transmission of RP was designed. This allowed the calculation of infection and seroprevalence at different points in time from RP introduction in a herd, to calculate the sample size needed for early detection of suspected animals in an infected herd. With a suspicion of RP in an establishment, the purpose of the clinical examination based on detection of clinical signs related to RP, is to identify potentially infected animals in order to inform the sampling strategy. The confirmation of a clinical suspicion is based on laboratory testing, mainly by confirming presence of the virus nucleic acids by reverse transcription polymerase chain reaction (RT-PCR) or of antibodies by virus neutralisation test (VNT).

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 susceptible animals with RP virus (RPV) and the time of reporting of a suspicion by the competent authority. Based on the assessment, the minimum period of 21 days for the restriction measures being in place in the protection zone defined in the Delegated Regulation is considered effective for all scenarios mentioned in ToR 2, except for the hypothetical first re-emergence of RP, when lack of awareness and diagnostic capability may extend the time to detection. For this case, the length of the monitoring period should be based on a risk assessment of the competent authorities and may be modified as a result. The minimum period of 30 days indicated in the Delegated Regulation for the restriction measures in the surveillance zone is considered effective to detect infected establishments and to prevent the spread via 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), a transmission kernel from the published literature for lineage-1 RPV was used. The estimated probability of transmission from an infected establishment beyond a protection zone of 3 km if transmission occurred is 9.9%, and probability of transmission beyond a surveillance zone of 10 km is 0.1%. Therefore, the radius of the protection zone of 3 km is considered to be sufficient to contain the disease spread with 90% probability. If the aim is to contain the disease spread with 95% probability, the radius of the protection zone should be increased to 4 km. For the surveillance zone, the expected effectiveness to contain the disease spread within 10 km corresponds to > 99% probability.

Considering that RP has been eradicated globally, a re-emergence that is not stopped in its early phases could have a devastating impact on animal health and the economy. The panel concludes that no suitable strategies are available to entirely mitigate the risk associated with granting derogations from killing of animals in an affected establishment or for animal movements. Therefore, the panel recommends to not grant any derogations.

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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 the Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed 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 peste des petits ruminants virus (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 investigations 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 investigations 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 investigations 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 per 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 opinion is one of these 14 opinions and covers ToRs 1, 2 and 3 for rinderpest (RP).
- 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 Regulation (EC) 2020/687 (hereinafter referred to as Delegated Regulation), for which the effectiveness of the sampling procedures will be assessed (Annex B). 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 requestor 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. If the length of the monitoring period estimated by EFSA is longer than the existing monitoring periods, 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 possible 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 radius 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 larger the closer the establishment is to an affected establishment. The validity of this statement will not be assessed in this opinion; nonetheless, the limitations that this assumption may have in the control of certain diseases will, where relevant, be discussed.
- f) The following scenarios of the ToR 1 of Annex B are not relevant for RP, and therefore not included in the assessment of the current Opinion:
  - i) scenario 6 because the minimum radius of the protection zone for RP is 3 km,
  - ii) scenarios 10, 11, 16 and 17 because they are referring to poultry.
- g) The duration of the monitoring period for RP as described in Annex II of the Delegated Regulation is 21 days.
- h) The minimum length of the radius of the protection zone (PZ) and surveillance zone (SZ) for RP 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 RP as described in Annexes X and XI of the Delegated Regulation are 21 and 30 days, respectively.

## 2. Epidemiology and geographical distribution of rinderpest

### 2.1. Epidemiology

#### Aetiology

Rinderpest, also known as cattle plague, was officially declared as eradicated worldwide in 2011, with no field outbreaks reported since 2001. It was a highly contagious viral disease affecting many



species of domestic and wild Artiodactyls (cloven-hooved ungulates), but mostly domestic cattle and buffalo. The causative agent is the rinderpest virus (RPV), an RNA virus, of the family *Paramyxoviridae*, genus *Morbillivirus*, which also includes peste des petits ruminants, canine distemper and measles viruses. Three genetically distinct wild lineages were originally described, each with a distinct geographical distribution, representing only one serotype (Lefèvre, 2010; CFSPH, 2016; OIE, 2018, 2020). Recent whole genome analysis has reduced the number of wild-type lineages to only two (King et al., 2020).

## Epidemiology

Although declared eradicated worldwide in 2011, RP remains a notifiable disease to the OIE since live RPV strains remain under sequestration in specialised, secure research and approved vaccine manufacturing laboratories, and an accidental escape or deliberate release of the virus could trigger a re-emergence of the disease (Fournié et al., 2014; OIE, 2018, 2020).

RPV infected mostly domestic cattle (*Bos taurus* and *Bos indicus*), water buffalo (*Bubalus bubalis*) and yaks (*Bos grunniens*). Sheep and goats were infected, but typically exhibited a mild form of the disease. Camelids were rarely infected. Pigs are susceptible, especially Asian breeds. Some wild species are highly (African buffalo [*Syncerus caffer*], giraffes [*Giraffa camelopardalis*], warthogs [*Phacochoerus* spp.], elands [*Taurotragus* spp.], kudu [*Tragelaphus* spp.]) to moderately susceptible (wildebeest [*Connochaetes* spp.], gazelles [*Gazella* spp.]). Dogs can seroconvert (Lefèvre, 2010; CFSPH, 2016; OIE, 2020).

RPV was mainly transmitted by direct or close indirect contact between animals. Airborne transmission, only over short distances, and transmission through fomites were of limited importance since the virus does not persist more than 2–3 days in the environment. The virus was found 1–2 days before the onset of fever not only in ocular and nasal discharges, and later on in saliva, urine, faeces, semen, vaginal discharges and milk, but also in the exhaled air of infected animals. Recovered animals would not remain carriers. Pigs could be infected by contaminated meat which can harbour viral particles during a longer period if it has been chilled or frozen (Lefèvre, 2010; CFSPH, 2016; OIE, 2020).

The disease was known in Europe at least since the Middle Ages. While RP was successfully eradicated from Europe with control measures adopted in the 18th and 19th century, comprising slaughter of infected and exposed animals, disposal of carcasses (deep burying or burning), decontamination of infected premises, quarantine measures and movement restrictions, the disease was still widely present in Asia and the Middle East. The great RP pandemic started in Eritrea in early 1887 through imports of infected zebu, and then spread across Africa during the 19th century (Rweymamu et al., 2006). North and South America were never contaminated apart from limited outbreaks in Brazil (1921). The last RP outbreaks were reported in 2001 in Kenya (Lefèvre, 2010; CFSPH, 2016; OIE, 2020).

The disease was eradicated following yearly mass vaccination campaigns of cattle and domestic buffalos older than 1 year with a live attenuated vaccine, combined with extensive surveillance. Young animals were protected by maternal antibodies until 6–11 months. Vaccination is now prohibited. Outbreaks were also controlled with focal/ring vaccination where needed (CFSPH, 2016; OIE, 2020).

## Clinical signs and diagnosis

The severity of the disease depends on the RPV strain, host species, breed, health status, immune and vaccination status. Virulent strains in naive European cattle breeds have led to 90–100% morbidity and mortality. In endemic areas, during the last stage of eradication, the average mortality rate in affected herds was 30% (Lefèvre, 2010; CFSPH, 2016). The last, less virulent strains isolated from cattle in East Africa belonging to lineage 2 caused less deaths, but these strains caused severe disease with high morbidity and mortality in susceptible wildlife (kudu) (Roeder et al., 2006).

The incubation period would typically be 4–7 days (range 3–15 days, with a maximum length established for zoosanitary measures by OIE of 21 days). In the acute classical form, the prodromal phase (2–5 days) was characterised by high fever (41–42°C), depression, anorexia, decreased rumination, constipation, decreased milk yield, congestion of mucous membranes, dry muzzle and serous ocular and nasal discharges. It was followed by the erosive phase characterised by pinhead-sized white necrotic lesions on the mucosa of the mouth: gums, lips, dental pad, tongue, cheeks, soft and hard palate. The lesions enlarged and became coalescent forming non-haemorrhagic erosions with grey/yellow pseudo-membranes. This was accompanied by profuse salivation and foetid purulent

discharge from the mouth. Erosions were sometimes present on other mucosa (nares, vulva, vagina, preputial sheath). One to three days after the first erosions, gastro-intestinal signs would appear with watery diarrhoea containing mucous and blood and with tenesmus leading to dehydration, hypothermia, weakness, recumbency and death 1–2 weeks after the onset the disease. Other clinical signs in this phase were muco-purulent nasal and ocular discharge, cracked muzzle, photophobia, dyspnoea, cough, abortion. In surviving animals, convalescence could take several weeks (Wohlsein and Saliki, 2006; Lefèvre, 2010; CFSPH, 2016; OIE, 2018, 2020).

In the peracute form, typically affecting new-born and young animals, or in case of infection with highly virulent RPV strain in adults, sudden death occurred within 1–2 days during the prodromic phase. A milder form of RP, caused by less virulent strains (lineage 2), was observed in endemic areas in the last years before complete eradication. Clinical signs were less pronounced, and recovery was more frequent and rapid in cattle, although the same strain provoked a severe form in wildlife (CFSPH, 2016; OIE, 2018, 2020).

In sheep, goats, pigs and camels infected with RPV, the disease was usually less pronounced (mild fever, nasal discharge, sometimes diarrhoea) or subclinical, except in Asian breeds of pig, which could exhibit acute forms and high mortality (Wohlsein and Saliki, 2006; Lefèvre, 2010; OIE, 2020).

The detection of RPV during the acute febrile phase of the disease can be made from swabs of ocular and nasal secretions or of mouth lesions or from unclotted EDTA blood samples. The best samples from dead animals are spleen and mesenteric lymph nodes. The method of choice is RT-PCR or real-time RT-PCR, which have a high degree of specificity and sensitivity for RPV (Forsyth and Barrett, 1995; Carrillo et al., 2010). RT-PCR can be carried out in any laboratory, using the specific primer set with a PPRV-positive control instead of a RPV-positive control. Virus isolation and agar gel immunodiffusion (AGID) are alternative methods; the latter being less sensitive and specific (cross-reactions with peste des petits ruminants virus) (CFSPH, 2016; OIE, 2018, 2020). The detection of antibodies for surveillance is performed by viral neutralisation test (VNT) in approved FAO and OIE high security laboratories since it involves live virus. The VNT has a sensitivity of 83.7% (Taylor and Rowe, 1984), in PPR-free countries, its specificity can be assumed to be comparable to PPR (98.1–99.2%). Competitive antibody ELISA and antigen-capture ELISA were used in the past for surveillance but are no longer available. Serological tests cannot differentiate infected from vaccinated animals (OIE, 2020).

## 2.2. Geographical distribution of rinderpest

Currently, there are six FAO-OIE designated rinderpest Holding Facilities for storing RPV containing material, excluding vaccine stocks, and four rinderpest Vaccine Holding Facilities for storing only manufactured vaccines, vaccine stocks and material solely for their production (Table 1). These facilities have been designated by FAO and OIE after careful consideration by the RP advisory committee, including a document review process and a site inspection. These facilities abide by high standards of biosecurity and are re-assessed every 3 years.

**Table 1:** Rinderpest Holding Facilities designated by FAO-OIE (status: June 2021)

<b>Rinderpest Holding Facility for storing rinderpest virus containing material, excluding vaccine stocks</b>	<b>Rinderpest Vaccine Holding Facility for storing only manufactured vaccines, vaccine stocks and material solely for their production</b>
Pan African Veterinary Vaccine Centre African Union (AU-PANVAC), Debre-Zeit, Ethiopia	Pan African Veterinary Vaccine Centre African Union (AU-PANVAC), Debre-Zeit, Ethiopia
Centre de coopération internationale en recherche agronomique pour le développement (CIRAD), Montpellier, France	Centre de coopération internationale en recherche agronomique pour le développement (CIRAD), Montpellier, France
China Institute of Veterinary Drug Control/China Veterinary Culture Collection Center (IVDC), Beijing, China	China Institute of Veterinary Drug Control/China Veterinary Culture Collection Center (IVDC), Beijing, China
High Containment Facilities of Exotic Diseases Research Station, National Institute of Animal Health, Kodaira, Tokyo, Japan	Building for Safety Evaluation Research, Production Center for Biologicals; Building for Biologics Research and Development (storage), National Institute of Animal Health, Tsukuba, Ibaraki, Japan
USDA-APHIS, Foreign Animal Disease Diagnostic Laboratory (FADDL), Plum Island, New York, United States of America	
The Pirbright Institute, United Kingdom	

### 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 RP opinion are presented below.

#### Mathematical model and transmission scenarios considered

For the purpose of TOR 1 (i.e. to assess the effectiveness of available sampling procedures) the within-herd dynamics of RPV in cattle were modelled using a stochastic SEIR epidemic model (Keeling and Rohani, 2008). The cattle 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).

The force of infection is given by,

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

where  $\beta$  is the transmission rate,  $I(t)$  is the number of infectious animals 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, 2008). The durations of the latent and infectious periods were assumed to follow gamma distributions with means  $\mu_E$  and  $\mu_I$  and shape parameters  $k_E$  and  $k_I$ , respectively (i.e. with variances  $\mu_E^2/k_E$  and  $\mu_I^2/k_I$ ). This was incorporated into the model by subdividing the latent and infectious classes into  $k_E$  and  $k_I$  stages each of mean duration  $\mu_E/k_E$  and  $\mu_I/k_I$ , 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 short time interval  $\delta t$  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  $\delta t$ ) as parameters.

The initial herd size was assumed to be 50, 100 or 200 cattle. Transmission parameters were extracted from the published literature for lineage-1 RPV (Mariner et al., 2005). Parameters were also available for lineage-2 RPV (Mariner et al., 2005). However, this lineage caused predominantly mild disease, which is unlikely to be representative of an outbreak in Europe, and so was not considered further. Case fatality for lineage-1 RPV was estimated to be 40% (Mariner et al., 2005). However,

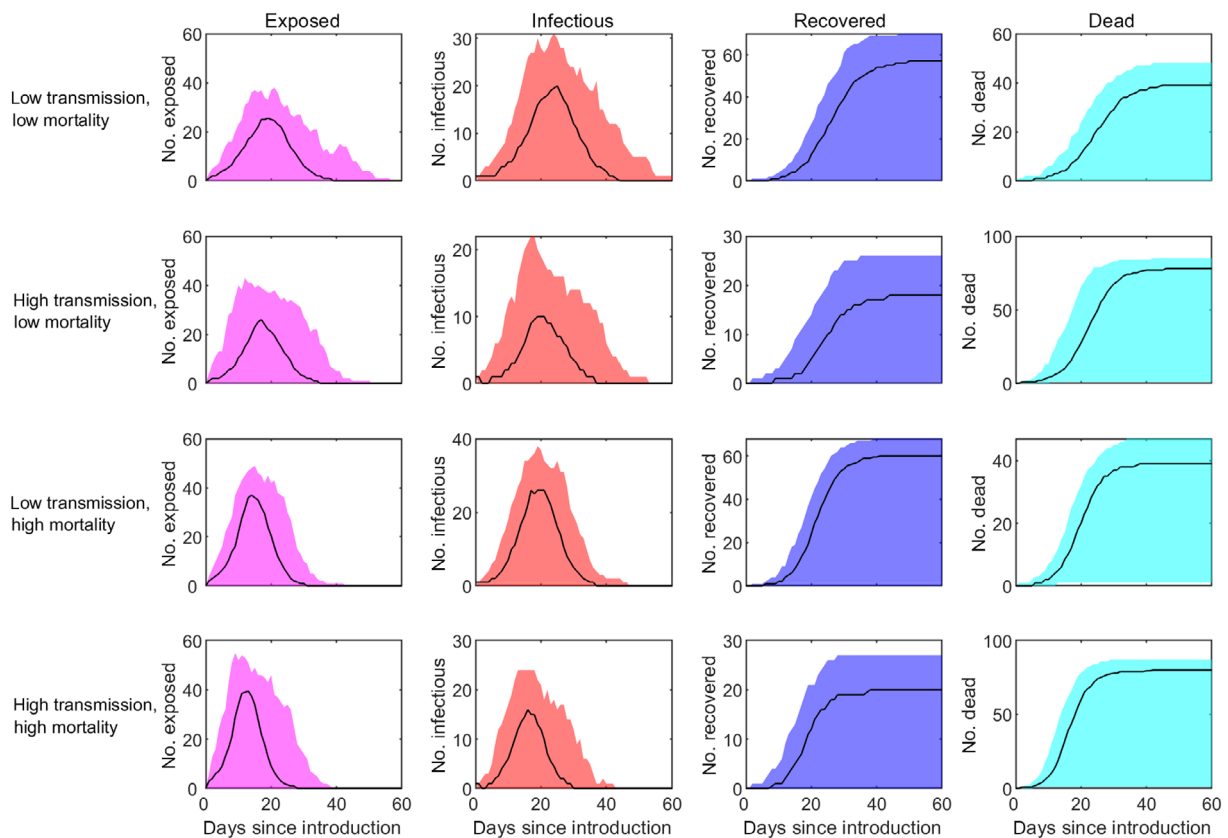
mortality in a naïve population may be much higher, so a high mortality scenario was also considered, in which case fatality was 80%. In total, four scenarios were considered, which differed in transmission rate and mortality (Table 2) (Figure 1).

**Table 2:** Parameters in the model for the transmission of rinderpest virus in cattle

Scenario	$R_0$	$\beta^{(a)}$	$\mu_E$	$k_E$	$\mu_I$	$k_I$	Case fatality (%)
Low transmission, low mortality	4.4	1.0	5.0	3	5.9	3	40
Low transmission, high mortality		2.0					80
High transmission, low mortality	7.0	1.6					40
High transmission, high mortality		3.2					80

(a): The transmission rate was calculated so that  $R_0$  is the same in the two scenarios for mortality.

### Within-herd dynamics of rinderpest



**Figure 1:** Within-herd dynamics of rinderpest virus in a herd of 100 cattle. The plots show the median (solid line) and 95% prediction interval (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 and mortality (rows; see Table 2 for details)

### Detection of rinderpest virus

#### Sampling live cattle

For the purpose of the assessment, virus-positive cattle was assumed to correspond to the infectious animals. Based on a time to seroconversion of 8–21 days (see Section 4.2.1.2), 22% of infectious cattle and all recovered cattle were assumed to be seropositive. The infection prevalence and seroprevalence are the proportions of live cattle virus-positive or seropositive, respectively, so the denominator in the calculations is the initial herd size minus the cumulative number of animals that have died of RPV.

**Table 3:** Median (M), lower (L) and upper (U) 95% prediction limits for the infection prevalence (%) of rinderpest virus in cattle at different days post introduction (dpi) to the herd

dpi	Scenario	Herd size								
		50			100			200		
		M	L	U	M	L	U	M	L	U
7	Low transmission, low mortality	2	0	12	2	0	6	1	0	3
	Low transmission, high mortality	2.1	0	14.3	1	0	6.3	0.5	0	3.2
	High transmission, low mortality	6	0	17.4	3	0	10	1.5	0	4
	High transmission, high mortality	4.3	0	20.9	2.6	0	12.6	1.5	0	5.3
14	Low transmission, low mortality	11	0	27.3	7.9	0	21.7	3.6	0	10.6
	Low transmission, high mortality	11.4	0	40	5.5	0	25.4	3.8	0	14.8
	High transmission, low mortality	21.8	0	48.8	18.2	0	32.2	10	0	25.3
	High transmission, high mortality	22.6	0	50	19.8	0	38.6	15.7	0	29.8
21	Low transmission, low mortality	22.1	0	42.1	21	0	34.4	11.7	0	27.5
	Low transmission, high mortality	20	0	43.8	17	0	37.1	14.1	0	30.4
	High transmission, low mortality	28.6	0	50	33.8	0	43.4	34.1	0	42.3
	High transmission, high mortality	19.1	0	42.1	27.9	0	44.7	30.9	0	43.3
28	Low transmission, low mortality	19.7	0	37.5	22.9	0	32.9	23.5	0	33.3
	Low transmission, high mortality	7.1	0	44.4	16.1	0	28.9	19.7	0	31.1
	High transmission, low mortality	9.5	0	38.9	13.2	0	36.5	22.3	0	42.1
	High transmission, high mortality	0	0	37.5	4.8	0	31	9.8	0	32

The prevalence values in Table 3 were used to compute the number of cattle that would need to be sampled to detect RPV with 95% confidence using RT-PCR assuming a 100% specificity and 100% sensitivity.

### 3.2. Methodology used in ToR 2

To estimate the time lag between infection and reporting of a RP suspicion (ToR 2), an 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 RP to be reported (measured as the number of days from the earliest point of infection with RP, 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 RP, and any other relevant grey literature or data were carried out. For the inclusion criteria in the ELS, the earliest point of infection had to have been 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 restricted to studies conducted in Europe or describing results obtained in Europe. If none or very few articles were retrieved (less or equal to 5) in the first search, the search was extended to the rest of the world. An ELS protocol similar to that shown in Annex 5 of the Methodology report (EFSA, 2020) was followed.

### 3.3. Methodology used in ToR 3

#### 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. Briefly, studies investigating the transmission of RPV between establishments using transmission kernels were identified in the published literature. The functional form, parameter estimates and the 95% confidence or credible intervals for the parameters (when provided) of the best fitting kernels were extracted from each study. For each kernel, the probability of transmission beyond given distances (if transmission were to occur from an infected establishment) was computed using the estimates and the lower and upper

95% confidence limits for the parameters. 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, along with its lower and upper 95% confidence limits. More details are provided in the Technical report (EFSA, 2020).

### 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 followed to deal with uncertainty is provided in a Methodology report published by EFSA (2020). A summary of the overall uncertainty assessment is given in Section 4.4, and a detailed description of the nature or cause of the uncertainty related to the different ToRs and its impact on the assessment is provided in Annex F.

## 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 rinderpest

##### 4.1.1.1. In the event of a suspicion of RP 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 investigation (ToR 1.2), in their ability to detect RPV 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 (EU) 2020/687
- Commission Implementing 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 RP in an establishment with kept animals of the listed species;
- 2) The listed species for RP as provided in Commission Implementing Regulation 2018/1882 are those belonging to the Artiodactyla;
- 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 sampling procedures for clinical or laboratory investigation in the event of a suspicion of RP are provided in EU legislation.

The FAO Manual of the diagnosis of RP<sup>1</sup> and the OIE Technical Disease Cards on RP<sup>2</sup> provide detailed descriptions of procedures to follow.

<sup>1</sup> <http://www.fao.org/3/W0049E/W0049E00.htm#Contents>

<sup>2</sup> <https://www.oie.int/app/uploads/2021/03/rinderpest.pdf>

## Assessment

In the event of a suspicion of RP in an establishment, the purpose of the clinical examination<sup>3</sup> (including both the initial visual inspection of the herd and the individual examination of the animals) aiming at detecting clinical signs such as fever, mucosal erosions in the mouth, profuse salivation and ocular discharge, watery diarrhoea, is to identify potentially infected animals to inform the sampling strategy.

The confirmation of clinical suspicion is based on laboratory tests, mainly by confirming presence of the virus nucleic acids (RT-PCR, real-time RT-PCR) or antibodies (VNT). RT-PCR can be carried out in any laboratory, using the specific primer set with a PPRV-positive control instead of a RPV-positive control, while VNT can only be carried out in OIE reference laboratories for RP.

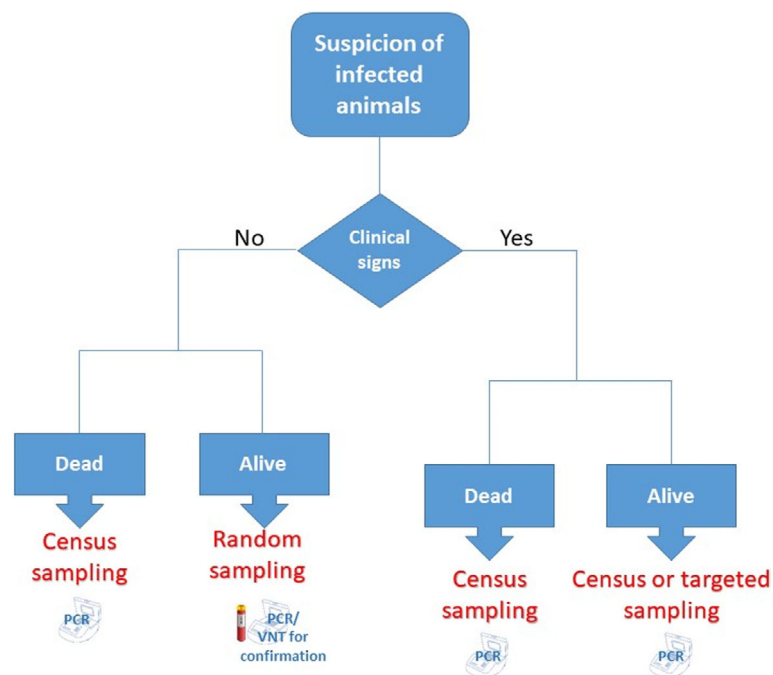
The collection of samples for RT-PCR testing can be performed either on dead or alive animals. In the latter, samples should be collected in the acute phase of the disease, when clinical signs are apparent, to maximise the probability of detecting the viral genome. The recommended samples from live animals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

In dead (including euthanised) animals, the best samples for RT-PCR examination are the spleen and mesenteric lymph nodes. Considering the rapid inactivation of the virus after death of the animal, samples should preferably be collected from sick live animals or from freshly slaughtered animals or overnight deaths (Anderson et al., 2006). All samples must be refrigerated and quickly dispatched to the laboratory, within 24 h (FAO, 1996).

Detection of antibodies for RP confirmation can complement the RT-PCR testing, taking into account that antibodies are detectable only from 8 to 14 days after the infection (OIE, 2020).

## Development of new procedures

In Figure 2, a schematic decision tree showing the diagnostic procedure for RP confirmation is reported.



**Figure 2:** Decision tree of the diagnostic procedure for RP confirmation

<sup>3</sup> The definition of the term 'clinical examination' is provided in 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.

**Table 4:** Sample sizes for random sampling to detect RPV infection with 95% confidence based on different values of infection prevalence (median values from Table 3) at 7, 14, 21 and 28 days after RPV introduction (dpi) into the herd for testing by PCR (Se and Sp: 100%) for different herd sizes in four scenarios for transmission and mortality

dpi	Scenario	Herd size		
		50	100	200
7	Low transmission, low mortality	48	76	155
	Low transmission, high mortality	47	89	190
	High transmission, low mortality	31	63	126
	High transmission, high mortality	38	69	122
14	Low transmission, low mortality	22	29	68
	Low transmission, high mortality	20	37	62
	High transmission, low mortality	12	14	27
	High transmission, high mortality	13	16	18
21	Low transmission, low mortality	14	11	23
	Low transmission, high mortality	18	14	17
	High transmission, low mortality	10	7	8
	High transmission, high mortality	14	13	9
28	Low transmission, low mortality	17	9	11
	Low transmission, high mortality	18	14	12
	High transmission, low mortality	25	18	12
	High transmission, high mortality	13	27	24

**Table 5:** Sample sizes for random sampling to detect RP at least one seropositive animal with 95% confidence based on different values of apparent seroprevalence (median values based on simulated outbreaks) at 14, 21 and 28 days after RPV introduction (dpi) into the herd when testing by VNT (Se: 83.7%, Sp: 98.6%) for different herd sizes in four scenarios for transmission and mortality

dpi	Scenario	Herd size		
		50	100	200
14	Low transmission, low mortality	26	35	77
	Low transmission, high mortality	29	43	81
	High transmission, low mortality	15	24	46
	High transmission, high mortality	18	29	36
21	Low transmission, low mortality	12	11	28
	Low transmission, high mortality	13	17	25
	High transmission, low mortality	6	6	11
	High transmission, high mortality	6	8	8
28	Low transmission, low mortality	7	4	8
	Low transmission, high mortality	5	6	7
	High transmission, low mortality	4	3	4
	High transmission, high mortality <sup>(a)</sup>	3	4	3

(a): In the high transmission/high mortality scenario, the outbreak is over at this stage.

For sampling purposes, when clinical signs are present, even generic signs such as fever, lethargy, loss of 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 RP are expected to be viraemic. Post-mortem examination should be carried out on euthanised or recently dead susceptible animals for the collection of organs and tissues on which virological tests will be performed.



Ideally, all euthanised and sick animals should be sampled, to maximise the probability of detecting the virus or its genome. However, when large numbers of animals show clinical signs, those showing fever and other signs typical of the acute phase of the disease are preferred. Cachectic or pre-agonic animals, in the final stages of the disease, are not the best option for RPV detection.

If clinical signs are not evident in the herd (e.g. suspicion because of contact, import, etc.), the sampling of randomly selected asymptomatic animals can be performed.

Given the variability of RP spread and mortality, the sample size needed (based on random sampling) is based on the median values of infection prevalence and serological prevalence predicted in four scenarios as presented in Section 3.1, combining low and high transmission ( $R_0 = 4.4$  and 7, respectively) and low and high case fatality (40% and 80%) (Table 2), at different points in time after introduction of the virus into the herd and for different herd sizes, i.e. 50, 100 and 200 animals, respectively (Tables 4 and 5). The mortality is considered to occur continuously during the whole outbreak period, not only at the end of infectious period.

It must be considered that, according to the model simulation as displayed in Table 3, in a period between 14 and 28 days after disease introduction (dpi), depending on the herd size, at least five animals are expected to be PCR positive and, for the purpose of this assessment, assumed to be clinically affected. Given this, considering the high sensitivity of RT-PCR (100%, see Section 2.1 and Annex C: Existing sampling procedures for rinderpest), the probability of not detecting the infection after testing five affected animals is negligible.

If clinical signs are absent (in case of suspicion because of contact, import, etc.), then serological testing using VNT should also be performed (sensitivity of VNT is 83.7% (Taylor and Rowe, 1984)), 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 the sample size needed to reveal positive animals did not consider the 7 dpi (Table 5), since at that point in time detectable levels of antibodies cannot yet be found in infected animals. In PPR-free countries, the specificity of the RP-VNT can be assumed to be comparable to PPR (98.1–99.2%). The reference laboratories will test the samples by VNT in parallel for RP and PPR.

#### 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 RP

The purpose of this section is to assess the effectiveness of disease-specific sampling procedures, based on laboratory investigation (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 (EU) 2020/687
- 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

No sampling procedures for the purposes of the epidemiological enquiry in an establishment affected and officially confirmed with RP are provided in EU legislation.

### Assessment

#### Length of infection

For RP, 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 vary greatly. In addition, it is not possible to estimate the time of infection using laboratory results. Antibodies are detectable from 8 to 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 > 8 days prior to detection of antibodies, but no other inference 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 transient antibody classes.

#### Origin of infection

Genomic information of RPV stored at Holding Facilities is being collected into a sequence database that could be useful for tracing the origin of a possible outbreak of RP, which previous studies based on a short sequence of the nucleocapsid (N) gene could not do. Full genome sequence carried out recently shows only two lineages and a clear differentiation between isolates from countries in Asia, the Middle East and those from countries in Africa (King et al., 2020). A single RPV serotype has been described (Section 2.1). Today, the majority of RPV isolates are held in high security laboratories of designated FAO-OIE rinderpest Virus/Vaccine Holding Facilities. A RP re-emergence would be assumed to be linked to places/facilities that hold RPV stocks.

#### 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 an RP 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) of the Delegated Regulation (EU) 2020/687

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; and
  - 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

No sampling procedures for granting a derogation from killing of animals in an affected establishment are provided in EU legislation.

### Assessment

All animals in the affected establishment for which a specific derogation from killing has been requested should be subjected to clinical and laboratory investigation. These animals should be tested for virus identification, antigen and antibody detection at regular intervals during the monitoring period. To prevent transmission during sampling, biosecurity procedures must be strictly observed to ensure that the animals do not pose a risk of transmission if left alive. Animals of the holding that are negative for RP antibodies and virus do not pose a risk of transmission of RP.

### Development of new procedures

A 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 animals intended for derogation from killing should be individually examined and those displaying clinical signs should be sampled for virological testing (see Section 4.1.1.1 for details).

Sampling all the animals for laboratory investigation for derogation (both for virus detection and antibodies), as soon as the derogation from killing is requested and irrespective of the presence of clinical signs, will identify infected animals without clinical signs, estimate the prevalence of RP in the establishment and evaluate the risk. Sampling for laboratory investigation 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 investigations in order to detect or rule out the presence of RPV should follow the procedures described in Section 4.1.1.1.

However, the panel concludes that no suitable strategies are available to entirely mitigate the risk associated with granting derogations from killing of animals in an affected establishment. Considering that RP has been eradicated globally, and that a re-emergence that is not stopped in its early phases could have a devastating impact on animal health and the economy, the panel recommends to not grant any derogations.

#### 4.1.1.4. For the animals of non-listed species kept in an RP 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 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 (EU) 2020/687
- 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

No sampling procedures are defined for animals of non-listed species kept in an RP-affected establishment are defined in EU legislation.

### Assessment

The listed species for RP according to Commission Implementing Regulation (EU) 2018/18823 are Artiodactyla. Species other than Artiodactyla are not involved in the RP epidemiology and therefore no testing is required.

#### 4.1.1.5. For wild animals of the listed species within a rinderpest 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 (EU) 2020/687
- 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 a rinderpest affected establishment (officially confirmed);
- 2) It refers to 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 rinderpest; the wild animals of listed species animals are those of *wild Artiodactylae species, e.g. wild Bovidae, Cervidae, Suidae species*;
- 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 animals.

## Summary of sampling procedures

No sampling procedures for wild animals of the listed species within the RP affected establishment and its surroundings are defined in EU legislation.

### Assessment

In the scenario where wild cloven-hoofed ruminants such as wild cervids (e.g. roe deer, red deer, fallow deer), wild bovids (e.g. mouflon, chamois, ibex, etc.) or wild suids are kept or are living in the area surrounding the affected establishment, they 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 from wild species.

### 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 RT-PCR and VNT. Unexpected mortality events in susceptible wildlife should be investigated.

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

#### 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 (EU) 2020/687

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 RP.

#### Summary of sampling procedures

No sampling procedures for animals of listed species in the non-affected establishments located in a RP-protection zone are defined in EU legislation.

#### Assessment

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

Active surveillance via 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 RP strain with no or very mild clinical signs.

On the other hand, if the classical form of RP has been identified in a limited area, preventive culling of susceptible species could be considered with view to enabling stamping out of the re-emerged RP.

#### 4.1.1.7. 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 (EU) 2020/687

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

No sampling procedures for animals of listed species in the non-affected establishments located in a RP-surveillance zone are defined in EU legislation.

### Assessment

It is extremely unlikely (subjective probability range 1–5%) that establishments in this zone that are not epidemiologically linked to an outbreak will become infected with RPV without having additional outbreaks in the protection zone.

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

### Development of new procedures

Any establishment where generic signs of disease such as mortality, fever, lethargy, lost appetite, nasal/oral discharge, diarrhoea and even changes in the individual animal behaviour 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.

#### 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

The purpose of this section is to assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory investigations 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.

- **9th scenario of sampling procedures**
- ToR 1.4 in accordance with Article 28(5) of the Delegated Regulation (EU) 2020/687
- 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.

## Summary of sampling procedures

No sampling procedures to grant derogations for animal movements from non-affected establishments located in the RP-protection zone to slaughterhouses located within the RP-protection zone or in the RP-surveillance zone or outside the restricted zone are defined in EU legislation.

### Assessment

Clinical examination of listed species is not sensitive enough to confirm RP when outside the diagnostic window. There is a risk of undiagnosed infected animals spreading the disease during movement. Sending the animals to slaughter undoubtedly reduces this risk of spread from the zone in general as the number of susceptible animals is reduced. 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 restricted zones. The risk of spreading the disease from undiagnosed animals increases from (a) to (c).

## Development of new procedures

Clinical examinations must be carried out on all animals in each subunit of the establishment from which the kept listed species are to be moved, following the procedures described in Section 4.1.1.

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

If individual clinical examination of all the animals is not feasible, the number of animals indicated by the sample size calculations with at least 95% confidence, as described in Section 4.1.1.1, should be examined.

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

However, the panel concludes that no suitable strategies are available to entirely mitigate the risk associated with granting derogations for animal movements. Considering that RP has been eradicated globally, and that a re-emergence that is not stopped in its early phases could have a devastating impact on animal health and the economy, the panel recommends to not grant any derogations.

### 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 investigations 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 (EU) 2020/687

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 sampling procedures to grant derogations for animal movements from non-affected establishments located in the RP-protection zone to a plant approved for processing or disposal of animal by-products in which the animals are immediately killed are defined in EU legislation.

## Assessment

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

## Development of new procedures

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

However, the panel concludes that no suitable strategies are available to entirely mitigate the risk associated with granting derogations for animal movements. Considering that RP has been eradicated globally, and that a re-emergence that is not stopped in its early phases could have a devastating impact on animal health and the economy, the panel recommends to not grant any derogations.

#### 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 investigations 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 (EU) 2020/687

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 to grant derogations for animal movements from an establishment in a RP-surveillance zone to a slaughterhouse located within or outside the restricted zone and from an establishment outside the RP-surveillance zone to a slaughterhouse situated in the RP-surveillance zone are defined in EU legislation.

#### Assessment

This scenario is very similar to the scenario of Section [4.1.2.1](#); 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 should be performed as described in 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 investigations, if, based on the national risk assessment, there are no other reasons to recommend it (e.g. an epidemiological link with an affected establishment or area). A clinical examination as described above would be sufficient.

However, the panel concludes that no suitable strategies are available to entirely mitigate the risk associated with granting derogations for animal movements. Considering that RP has been eradicated globally, and that a re-emergence that is not stopped in its early phases could have a devastating impact on animal health and the economy, the panel recommends to not grant any derogations.

#### 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 investigations 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](#).



- **14th scenario of sampling procedures**
- ToR 1.4 in accordance with article 43(5) and article 45(1) of the Delegated Regulation (EU) 2020/687

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.

### Summary of sampling procedures

No sampling procedures to grant derogations for animal movements from an establishment in a RP-surveillance zone to pastures situated within the surveillance zone are defined in the EU legislation.

### Assessment

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

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

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

### Development of new procedures

The same procedures outlined in Section 4.1.1.1 should be applied before the animals are moved to pasture. Contact to other animals on pasture has to be avoided. Animals should be tested again on completion of the monitoring period.

However, the panel concludes that no suitable strategies are available to entirely mitigate the risk associated with granting derogations for animal movements. Considering that RP has been eradicated globally, and that a re-emergence that is not stopped in its early phases could have a devastating impact on animal health and the economy, the panel recommends to not grant any derogations.

#### 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 investigations 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 (EU) 2020/687

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 sampling procedures to grant derogations for animal movements from an establishment in a RP-surveillance zone to an establishment belonging to the same supply chain, located in or outside the RP-surveillance zone are defined in the EU legislation.

## Assessment

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

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

Moving animals from a non-affected establishment found negative at the clinical examination and negative to virus and antibodies in laboratory investigation, according to procedures described in Section 4.1.1.1, minimises the risk of RPV 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 Section 4.1.1.1. Visual inspection of the herd would be helpful to identify animals with signs compatible with RP.

In an establishment with a large number of animals, the individual clinical examination of all 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 Section 4.1.1.1.

Where clinical signs compatible to RP are identified, the establishment is considered suspected and the procedures for the laboratory confirmation as described in 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 investigation, following the procedures described in Section 4.1.1.1, in order to exclude infected subclinical animals with a confidence level of 95%.

However, the panel concludes that no suitable strategies are available to entirely mitigate the risk associated with granting derogations for animal movements. Considering that RP has been eradicated globally, and that a re-emergence that is not stopped in its early phases could have a devastating impact on animal health and the economy, the panel recommends to not grant any derogations.

### 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 investigations 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 (EU) 2020/687

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 sampling procedures to grant derogations for animal movements 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 are defined in the EU legislation.

## Assessment

Animals in the restricted zone, for which a specific derogation has been requested 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 investigations.

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

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

## Development of new procedures

Sampling procedures should be implemented as described in Sections 4.1.1.1, 4.1.2.3, 4.1.2.4 and 4.1.2.5.

However, the panel concludes that no suitable strategies are available to entirely mitigate the risk associated with granting derogations for animal movements. Considering that RP has been eradicated globally, and that a re-emergence that is not stopped in its early phases could have a devastating impact on animal health and the economy, the panel recommends to not grant any derogations.

### 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 investigations 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 (EU) 2020/687

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

No sampling procedures for repopulation purposes for the animals that are kept for the repopulation prior to their introduction are provided in EU legislation.

## 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 RPV 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 negative according to laboratory investigations described in Section 4.1.1.1 pose a very low risk of transmission of RPV.

## Development of new procedures

If animals are sourced from restricted zones, all the animals in the establishment of origin should be clinically examined and sampled as well. Sampling procedures for laboratory investigation should

ensure, with a confidence level of 95%, that the animals do not pose a risk of transmission. Laboratory investigations should be in accordance with the procedures described in Section 4.1.1.1.

In an establishment with a large number of animals, the individual clinical examination of all 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 Section 4.1.1.1.

In the event that clinical signs compatible with RPV infection are identified, the establishment is considered suspected and the procedures for the laboratory confirmation as described in Section 4.1.1.1 should be followed. The animals intended for the repopulation, even if clinically healthy, should not be dispatched.

Where the animals originate from establishments located in free areas, there is no need for laboratory investigation unless there are other reasons based on the authorities' risk assessment to recommend it (e.g. an epidemiological link with an affected establishment or area). Clinical examination would be sufficient.

#### **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 investigations 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 (EU) 2020/687

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**

No sampling procedures for repopulation purposes for the event of unusual mortalities or clinical signs being notified during the repopulation are provided in EU legislation.

#### **Assessment**

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

#### **Development of new procedures**

If animals with clinical signs compatible with RP as they have been described in Section 4.1.1.1 are notified during the repopulation process, the establishment is considered suspected. Repopulation should be stopped and the procedures for laboratory confirmation as described in 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 Section 4.1.1.1 should be followed there 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 investigations 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 (EU) 2020/687

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

No sampling procedures for repopulation purposes for animals that have been repopulated are provided in EU legislation.

### Assessment

During the repopulation of an establishment previously affected by RP, 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 clinical signs, laboratory investigation 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 repopulation. On 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 investigation in accordance with the procedures described there.

In an establishment with a large number of animals, the individual clinical examination of all animals may not be feasible; in this case a minimum sample of animals (including all animals that have been 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 Section 4.1.1.1.

If clinical signs are identified, then the procedures for the laboratory confirmation that are described in 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).

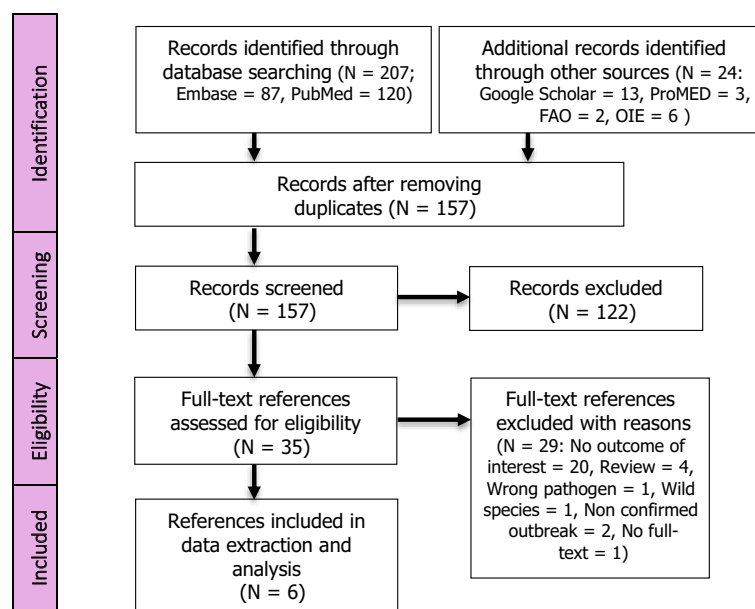
The table in Annex D in this opinion describes the seven scenarios for which an assessment of the length of the monitoring period for RP had been requested.

To answer all scenarios except no. 5, an ELS on the average, shortest and longest period of time between the earliest point of infection of an animal with RPV and the time of reporting of a suspicion by the competent authority was carried out. The time period between the reporting of a suspicion and the notification of the disease was also assessed. To answer scenario no. 5, a literature search was conducted on the seroconversion period in cattle, sheep and goats, pigs and other susceptible species, as well as the earliest time of antibody detection in blood. The results are presented below.

## 4.2.1. Results

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

An ELS was carried out for outbreak data from the EU/EEA. As no references were available for this area, the search was extended to data from the rest of the world, to simulation data and to references published before the year 2000. A total of 157 unique references were identified. Among these, six were selected to be included in the qualitative review. The full selection process is displayed in Figure 3.



**Figure 3:** PRISMA diagram, ELS on RP Monitoring period

Five out of six of the selected references reported dates instead of periods, therefore, the dates were used to calculate the different periods of interest.

Table 6 provides an overview of the data that were extracted for the main outcome of interest, i.e. the period between the earliest point of infection and the suspicion report, for which 3 references were retrieved.

**Table 6:** Summary of the rinderpest extraction for the period between earliest point of infection and suspicion report: Outbreak data

Reference	Country	Year	Species/Type	Period (days)
OIE (1996a)	Turkey	1996	<i>B. taurus</i> /fattening	4 <sup>(a)</sup>
OIE (1996b)	Kenya	1996	<i>B. taurus</i> /pastoral	16 <sup>(a)</sup>
OIE (1998)	Russia	1998	<i>B. taurus</i> /NA	13 <sup>(a)</sup>

(a): Primary outbreak; No indication on the method of estimation of the date of first infection.

As described in Table 6, the shortest period between the earliest point of infection and the suspicion report was 4 days. This was found in the context of a primary outbreak that occurred in 1996 in a small fattening cattle farm in the South-Eastern part of Turkey where animals were illegally introduced (OIE, 1996a).

The longest period found in the literature, 16 days, was retrieved in the context of an outbreak, which took place in 1996 in Kenya, in a pastoral farming area where there is cross-border (Somalia) transhumance. The outbreak is described as endemic RP of low virulence (OIE, 1996b).

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

- 1) Average period = 11 days (median = 13 days)
- 2) Shortest period = 4 days
- 3) Longest period = 16 days

#### 4.2.1.2. Seroconversion in animals

Results regarding the range of days for seroconversion and the latest detected day of antibody presence in listed species of RPV after experimental infection with the RPV are presented in Table 7.

The onset of seroconversion depends on the animal species and the virulence of the strain. Antibodies are detectable in serum of the infected animals at 8–14 days post infection (Obi et al., 1999; OIE, 2020). However, animals infected with strains of mild virulence may take 6–10 days or longer (up to 17 days) to develop neutralising antibodies (Obi et al., 1999; Carrillo et al., 2010). Moreover, the lymphotropic nature of RPV leads to immunosuppression (OIE, 2020). Therefore, a negative serological result, particularly in atypical forms of the disease or in cases with clinical signs that are compatible with RPV, has to be carefully validated, since it may not necessarily imply absence of infection (Taylor, 1986; OIE, 2018).

##### **Cattle**

In most studies with experimental infection of cattle, the detection of RPV specific antibodies was performed using the VNT; animals were usually challenged subcutaneously (SC). Most of the strains used in challenge studies were highly virulent and caused severe disease with severe clinical signs (Kabete O and Saudi 1/81 strains) (Languet et al., 1985; Giavedoni et al., 1991; Romero et al., 1993, 1994; Yamanouchi et al., 1993). Therefore, challenged cattle died or were euthanised, usually within the first week post infection, prior to antibody production, thus limiting the amount of scientific information extracted from such studies (Lund et al., 2000; Ohishi et al., 2000; Walsh et al., 2000; Anderson et al., 2001; Kamata et al., 2001; Ngichabe et al., 2002; Verardi et al., 2002). For animals that managed to survive the severe clinical signs or for those that were not euthanised, the range of seroconversion was 10–21 days post infection (dpi) (Bassiri et al., 1993; Ohishi et al., 1999); the latest day of antibody detection was 28 dpi, which was the end of the study (Ngichabe et al., 1997). The literature search regarding the presence of antibodies for long time periods after challenge has not yielded any result. In another study, cattle in contact with goats that had been inoculated with the caprinised strain of RPV, which at one time was used in Africa as a vaccine strain, seroconverted between 11 and 14 dpi (Guillemin et al., 1988).

##### **Sheep and goats**

The experimental challenge of goats with the caprinised strain of RPV led to seroconversion after 10 dpi; the last day of antibody detection was 38 dpi. In the same study, sheep that were in contact with the inoculated goats did not seroconvert (Guillemin et al., 1988).

##### **Pigs**

In pigs, the range of days for seroconversion was 7–20 dpi (Heuschele and Barber, 1963; Belsham et al., 1989). Unfortunately, in these studies the latest day of antibody detection was not specified.

##### **Other listed species**

The literature search for RPV in other Artiodactyla species (American antelope, antelope, buffalo, camel, deer, giraffe, etc.) has not yielded any result for seroconversion. Only one study reporting an RPV challenge to white-tailed American deer was found, yet the buck died at 5 dpi and no serological tests were performed (Hamdy and Dardiri, 1976).

**Table 7:** Range of days for seroconversion and latest detected day of antibody presence in Cattle and Swine after experimental inoculation with rinderpest Virus

Animals in the study	Laboratory method	Infection	Range of days for seroconversion (dpi <sup>(a)</sup> )		Latest day of antibodies detection/end of experiment	Total number of references	Reference ID
			Earliest day of seroconversion	Latest day of seroconversion			
Cattle	VNT	SC	10 dpi (Bassiri et al., 1993)	21 dpi (Ohishi et al., 1999)	28 dpi (Ngichabe et al., 1997)	3	Bassiri et al. (1993), Ngichabe et al. (1997) and Ohishi et al. (1999)
	VNT	In-contact with inoculated goats <sup>(a)</sup>	11 dpi	14 dpi	NS	1	(Guillemin et al., 1988)
Goats <sup>(a)</sup>	VNT	SC	10 dpi	10 dpi	38 dpi	1	Guillemin et al. (1988)
Sheep	VNT	In-contact with inoculated goats <sup>(a)</sup>	No seroconversion			1	Guillemin et al. (1988)
Pigs	VNT	SC	7 (Belsham et al., 1989)	20 dpi (Heuschele and Barber, 1963)	NS	2	Heuschele and Barber, (1963) and Belsham et al. (1989)

VNT: Virus neutralisation test; SC: subcutaneously; NS: not specified.

(a): The caprinised strain of RPV was used for challenge.

#### 4.2.2. Assessment

Considering the results presented above, an assessment of the effectiveness of the current monitoring period for RP, depending on the purpose of that period in the different scenarios shown in Annex D, was carried out. For RP, 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 (EU) 2020/687
- 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 RP outbreak.

- 3rd scenario of monitoring period
- ToR 2 in accordance with article 13(b) and Annex II of the Delegated Regulation (EU) 2020/687
- 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 RP 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.

- 2nd scenario of monitoring period
- ToR 2 in accordance with article 17(2) and Annex II of the Delegated Regulation (EU) 2020/687
- 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 RP outbreak.

For the first three scenarios, the main purpose of the use of the monitoring period is to be able to carry a full epidemiological investigation (i.e. in scenarios no. 1 and no. 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 back 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 no. 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 when the disease could have been present, unknowingly, in an establishment, equates then to the time period between the entry of RPV into the establishment, and the reporting of the suspicion. Once the suspicion has been officially reported, control measures are implemented, and further spread is in this way prevented.

Based on the ELS carried out and presented above we conclude that the current monitoring period for RP (21 days) is long enough to capture the period between the earliest point of infection and the suspicion report.

It should be noted however, that the ELS results cannot be directly transferred to the current context, neither in the EU nor elsewhere in the world, in the case of a first outbreak (i.e. re-emergence of RP). Twenty years have passed since the last outbreak of RP occurred in the world, and the disease has been declared eradicated more than 10 years ago. The level of awareness must be assumed to be low, and this may delay a suspicion based on clinical signs. Moreover, RP diagnostics is not part of the differential diagnosis panels used in most countries, which further may delay the confirmation of a first case. With this in mind, 21 days might not be long enough to cover the period between the earliest point of infection and the suspicion report for a first outbreak that occurs. For such situations, the length of the monitoring period should be modified based on a risk assessment of the competent authorities.

#### Scenario 4

- 4th scenario of monitoring period
- ToR 2 in accordance with article 27(3 and Annex II of the Delegated Regulation (EU) 2020/687
- 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 RP 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 no. 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 suspect establishment 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 a high awareness is expected, the length of the monitoring period 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 (EU) 2020/687
- 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 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.

RPV can be found in semen of infected animals, which can be the source of infection and further spread of the disease. In the scenario, where semen might have been collected from a donor with an inapparent infection, a serological test would indicate if the donor has ever been exposed to RPV, and therefore, if the semen has been contaminated.

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

Based on the results presented in Section 4.2.1 in relation to the seroconversion, the latest date of seroconversion was identified 21 dpi (Ohishi et al., 1999). Consequently, sampling the animals 28 ( $21 + 7$ ) days after semen collection, as it is foreseen in the Delegated Regulation, given that the infection occurred the latest at the day of semen collection, 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 (EU) 2020/687
- 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 (EU) 2020/687
- 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 no. 6 and no. 7, the monitoring period is used in the context of repopulation. In scenario no. 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 RP 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, disinfection and disinfestation of the affected establishment.

In this regard, the number of days of the monitoring period for RP, 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 in Section 4.2.1, and taking into account that a good level of awareness is expected due to the disease having been present in the area, the existing length of the monitoring period (21 days) is considered effective, as it would allow for the identification of any potentially infected establishment in the surrounding area prior to the repopulation taking place.

In scenario no. 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 animals 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 cattle introduced into the repopulated establishment is the day when all the animals have been introduced, and considering that the average length of time to detection is 11 days, it would be likely that some clinical signs would be present in cattle if this visit is carried out 21 days after the last introduction of the cattle. In this scenario, using the average length of time to detection would be justified as a high awareness will exist during the examination of the animals at the first visit. 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 cattle 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

#### Results

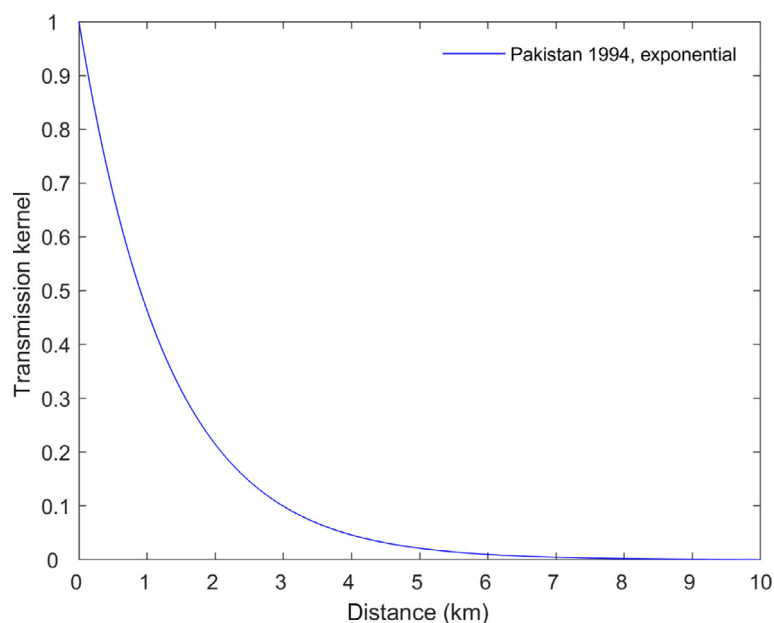
The purpose of this section is to assess the effectiveness to control the spread of RP by implementing protection and surveillance zones of a minimum radius, as set out in Annex V of the

Delegated Regulation, surrounding the establishment where the disease has been confirmed. Based on this regulation, the minimum radius of the protection and surveillance zone for RP should be of 3 and 10 km respectively (see Annex E).

To address this request, studies investigating the transmission of RPV between establishments using transmission kernels were identified in the published literature. One transmission kernel has been estimated for RPV based on data from a large outbreak in Pakistan in 1994 (Mourant et al., 2018). Specifically, an exponential kernel was estimated from outbreak data by ensuring the model simulations were consistent with the observed number of dead cattle (Table 8).

**Table 8:** Transmission kernel for rinderpest virus

Kernel	Epidemic	$d_0$ (km)
Exponential: $k(r) = \exp(-rd_0)$	Pakistan 1994	1.3



**Figure 4:** Transmission kernel for rinderpest virus

For the kernel in Table 8, the probability of transmission beyond given distances (if transmission were to occur from an infected establishment) was computed, including beyond the proposed radius for the protection and surveillance zones (3 and 10 km, respectively) (Table 9). In addition, the distances at which a threshold probability of transmission beyond that distance is reached were also calculated (Table 10).

**Table 9:** Probability (%) of transmission of rinderpest virus beyond different distances (km) from an infected establishment if transmission were to occur

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

**Table 10:** Distances (km) at which the probability of transmission of rinderpest virus beyond that distance reaches a threshold level if transmission were to occur

	Threshold probability of transmission (%)						
	0.1	0.5	1	5	10	20	50
Pakistan 1994	8.98	6.89	5.99	3.89	2.99	2.09	0.90

## Assessment

As expected, we can see from Figure 4, Tables 9 and 10 that the probability of RP transmission beyond a certain distance from an infected establishment decreases as the distance increases.

Table 9 shows that, if transmission occurs, the probability of transmission from an infected establishment beyond a protection zone of 3 km is 9.9%, and transmission beyond a surveillance zone of 10 km is 0.1%. This may be considered sufficient to contain the disease spread assuming a threshold of 90% probability. For the surveillance zone, the expected effectiveness corresponds to > 99% probability.

If the aim is to reduce the probability of transmission beyond the protection zone of 3 km to 5% (i.e. assuming a threshold probability of 95% as used in several articles of the AHL) the radius should be increased to 4 km (Table 10).

### 4.3.2. Assessment of the minimum period

The purpose of this section is to assess the effectiveness to control RP spread 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 of the Commission Delegated Regulation. The length of the minimum period of the protection zone and surveillance zone are 21 and 30 days, respectively (see Annex E). In the protection zone, all farms are visited for a clinical inspection. This aims to quickly identify infected farms where infection has started before control measures were implemented. The movement control applies for 30 days, ensuring that possibly infected kept animals from listed species/Artiodactyla in both protection and surveillance zones are not moved to uninfected farms.

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 has been used (EFSA, 2020).

Based on the results of the ELS as presented in Table 4 in Section 4.2.1, it follows that the average time between infection and notification of the suspicion is 11 days. Therefore, 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.

Consequently, the minimum period of 30 days indicated in the Delegated Regulation for the restriction measures in the surveillance zone is considered effective to detect infected establishments and to prevent the movement of infected animals from the surveillance zone.

## 4.4. 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
<b>ToR 1: In the event of suspicion or confirmation</b>			
<p><b>1st scenario</b> 4.1.1.1 In the event of a suspicion of RP in an establishment where animals of the listed species are kept</p>	<p>No specific guidelines on sampling procedures for clinical or laboratory investigation in the event of a suspicion of RP are provided in EU legislation</p>	<p>The suspicion of RP arises from the detection of RP-related clinical signs. The confirmation of a clinical suspicion is based on laboratory tests, mainly by confirming presence of the virus nucleic acids (RT-PCR, real-time RT-PCR) or of antibodies (VNT). 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. Samples from dead animals must be collected few hours after the death, as the virus is rapidly inactivated after death. In case of large numbers of animals showing clinical signs, at least five animals among those showing signs typical of the acute phase of RP should be selected for sampling. If clinical signs are not evident in the herd, sampling of randomly selected asymptomatic animals can be performed and VNT should be also performed. Detection of antibodies by VNT for RP confirmation can complement the RT-PCR testing, taking into account that antibodies are detectable only from 8 to 14 days after the infection</p>	<p>No specific recommendations</p>
<p><b>2nd scenario</b> 4.1.1.2. For the purposes of the epidemiological enquiry as referred to Article 57 of Regulation (EU)2016/429 in an RP officially confirmed establishment</p>	<p>There are no sampling procedures defined for the purposes of the epidemiological enquiry in an establishment affected and officially confirmed with RP</p>	<p>For RP, it is not possible to derive or estimate the time of exposure by the lesions, which are not disease-specific and may vary greatly. In addition, it is not possible to estimate the time of infection using laboratory results. Antibodies are detectable as of 8–14 days after infection and they probably remain for the whole productive life of the animals. Consequently, detection of antibodies suggests that infection occurred &gt; 8 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</p>	<p>No specific recommendations</p>

Sampling procedure	Laboratory guidelines based on Council Directive 2003/85/EC if not stated otherwise	Conclusions	Recommendations
<p><b>3rd scenario</b> 4.1.1.3. For granting a specific derogation from killing animals of the categories of article 13.2 of the Delegated Regulation in an RP affected establishment</p>	<p>There are no sampling procedures to grant a derogation from killing of animals in an affected establishment</p>	<p>All animals in the affected establishment for which a specific derogation from killing has been requested should be subjected to clinical and laboratory investigation. To prevent transmission during sampling, biosecurity procedures must be strictly observed to ensure that the animals do not pose a risk of transmission if left alive. Animals of the holding that are negative for RP antibodies and virus do not pose a risk of transmission of RP. A 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. However, the panel concludes that no suitable strategies are available to entirely mitigate the risk associated with granting derogations for movements of animals</p>	<p>All animals intended for derogation from killing should be individually examined and those displaying clinical signs should be sampled for virological testing. Sampling for laboratory investigation 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. Considering that RP has been eradicated globally, and that a re-emergence that is not stopped in its early phases could have a devastating impact on animal health and the economy, the panel recommends to not grant any derogations</p>
<p><b>4th scenario</b> 4.1.1.4. For the animals of non-listed species kept in an RP affected establishment</p>	<p>No sampling procedures are defined for animals of non-listed species kept in an establishment affected by RP</p>	<p>The listed species for RP according to Commission Implementing Regulation (EU) 2018/18823 are Artiodactyla. Species other than Artiodactyla are not involved in the RP epidemiology and therefore no testing is required</p>	<p>No specific recommendations</p>
<p><b>5th scenario</b> 4.1.1.5. For wild animals of the listed species within the RP affected establishment and its surroundings</p>	<p>No sampling procedures are defined for wild animals of the listed species within the RP affected establishment and its surroundings</p>	<p>In the scenario where wild cloven-hoofed ruminants such as wild cervids (e.g., roe deer, red deer, fallow deer), wild bovids (e.g. mouflon, chamois, ibex, etc.) or wild suids are kept or are living in the area surrounding the affected establishment, they may acquire the infection by direct or indirect contact with affected animals, if no or low biosecurity measures are in place to keep kept animal species separated from wild species</p>	<p>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 VNT. Unexpected mortality events in susceptible wildlife should be investigated</p>

Sampling procedure	Laboratory guidelines based on Council Directive 2003/85/EC if not stated otherwise	Conclusions	Recommendations
<p><b>6th scenario</b> 4.1.1.6. For animals of listed species in the non-affected establishments located in a protection zone</p>	<p>No sampling procedures are defined for animals of listed species in non-affected establishments located in a RP protection zone</p>	<p>All establishments located in the protection zone should be visited and the animals should be subjected to clinical examination and a laboratory investigation, to ensure the detection of the virus, if the virus were present in these animals. Active surveillance via 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 RP strain with no or very mild clinical signs</p>	<p>If the classical form of RP has been identified in a limited area, preventive culling of susceptible species could be considered with view to enabling stamping out of the re-emerged RP</p>
<p><b>7th scenario</b> 4.1.1.7 For non-affected establishments located in a protection zone with a radius larger than 3 km</p>		<p>This scenario is not applicable, since no protection zone larger than 3 km is proposed</p>	<p>No specific recommendations</p>
<p><b>8th scenario</b> 4.1.1.8. For non-affected establishments located in a surveillance zone</p>	<p>No sampling procedures are defined for animals of listed species in non-affected establishments located in a RP-surveillance zone</p>	<p>It is extremely unlikely that establishments in this zone that are not epidemiologically linked to an outbreak will become infected with RPV without having additional outbreaks in the protection zone</p>	<p>For the surveillance zone, it is recommended that the efforts will be aimed at enhancing passive surveillance by increasing awareness in all establishments, industry and public. Any establishment where generic signs of disease are reported should be visited, the animals should be clinically examined and samples should be collected (see first scenario for the procedures)</p>

**ToR 1: To grant derogations for animal movements**

<p><b>9th scenario</b> 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</p>	<p>No sampling procedures are defined for RP for this scenario</p>	<p>Clinical examinations must be carried out on all animals in each subunit of the establishment from which the kept listed species are to be moved, following the procedures described for scenario 1. If individual clinical examination of all the animals is not feasible, the number of animals indicated by the sample size calculations with at least 95% confidence, as described in the first scenario, should be examined.</p>	<p>If one or more animals exhibit clinical signs consistent with RP, the establishment is considered suspected and confirmation should follow the procedures described for scenario 1. Considering that RP has been eradicated globally, and that a</p>
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Sampling procedure	Laboratory guidelines based on Council Directive 2003/85/EC if not stated otherwise	Conclusions	Recommendations
		<p>If listed animals are moved from the protection zone to a slaughterhouse outside the restricted zones, clinical examination and sample collection for laboratory investigation should be performed as described for scenario 1.</p> <p>However, the panel concludes that no suitable strategies are available to entirely mitigate the risk associated with granting derogations for movements of animals</p>	<p>re-emergence that is not stopped in its early phases could have a devastating impact on animal health and the economy, the panel recommends to not grant any derogations</p>
<p><b>12th scenario</b> 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</p>	<p>No sampling procedures are defined for RP for this scenario</p>	<p>This scenario is very similar to the 9th scenario, therefore the assessment is the same.</p> <p>However, the panel concludes that no suitable strategies are available to entirely mitigate the risk associated with granting derogations for movements of animals</p>	<p>Considering that RP has been eradicated globally, and that a re-emergence that is not stopped in its early phases could have a devastating impact on animal health and the economy, the panel recommends to not grant any derogations</p>
<p><b>13th scenario</b> 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>	<p>No sampling procedures are defined for RP for this scenario</p>	<p>This scenario is very similar to the 9<sup>th</sup> scenario, therefore the assessment is the same.</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 investigation, if, based on the national risk assessment, there are no other reasons to recommend it (e.g. an epidemiological link with an affected establishment or area). A clinical examination as described above would be sufficient.</p> <p>However, the panel concludes that no suitable strategies are available to entirely mitigate the risk associated with granting derogations for movements of animals</p>	<p>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 should be performed as described for scenario 1.</p> <p>Considering that RP has been eradicated globally, and that a re-emergence that is not stopped in its early phases could have a devastating impact on animal health and the economy, the panel recommends to not grant any derogations</p>

Sampling procedure	Laboratory guidelines based on Council Directive 2003/85/EC if not stated otherwise	Conclusions	Recommendations
<p><b>14th scenario</b> 4.1.2.4 From an establishment in a surveillance zone to pastures situated within the surveillance zone</p>	<p>No sampling procedures are defined for RP for this scenario</p>	<p>Animals in a surveillance zone, for which a specific derogation has been requested to be moved to pastures, should be subjected to clinical examinations and laboratory analysis. Sampling procedures for laboratory analysis should ensure with a confidence level of 95%, that the animals do not pose a risk of RP transmission, as described for scenario 1. However, the panel concludes that no suitable strategies are available to entirely mitigate the risk associated with granting derogations for movements of animals</p>	<p>Considering that RP has been eradicated globally, and that a re-emergence that is not stopped in its early phases could have a devastating impact on animal health and the economy, the panel recommends to not grant any derogations</p>
<p><b>15th scenario</b> 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>	<p>No sampling procedures are defined for RP for this scenario</p>	<p>Animals in a surveillance zone, for which a specific derogation has been requested to be moved to an establishment of the same supply chain located in or outside the surveillance zone, should be subjected and found negative to clinical examination and laboratory investigation, with at least 95% confidence. Sampling procedures should be implemented as described for scenario 1. In case of clinical suspicion, the procedures for laboratory confirmation described for scenario 1 should be followed, and movement prohibited till confirmation of being negative. However, the panel concludes that no suitable strategies are available to entirely mitigate the risk associated with granting derogations for movements of animals</p>	<p>Considering that RP has been eradicated globally, and that a re-emergence that is not stopped in its early phases could have a devastating impact on animal health and the economy, the panel recommends to not grant any derogations</p>
<p><b>18th scenario</b> 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 RP for this scenario</p>	<p>Animals in the restricted zone, for which a specific derogation has been requested 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 investigations. Sampling procedures for laboratory investigation should ensure with a confidence level of 95%, that the animals do not pose a risk of RPV transmission. However, the panel concludes that no suitable strategies are available to entirely mitigate the risk associated with granting derogations for movements of animals</p>	<p>Considering that RP has been eradicated globally, and that a re-emergence that is not stopped in its early phases could have a devastating impact on animal health and the economy, the panel recommends to not grant any derogations</p>

Sampling procedure	Laboratory guidelines based on Council Directive 2003/85/EC if not stated otherwise	Conclusions	Recommendations
<b>ToR 1: For repopulation purposes</b>			
<b>19th scenario</b> 4.1.3.1 For the animals that are kept for the repopulation prior to their introduction	No sampling procedures are defined for RP for this scenario	Animals intended for repopulation should be clinically examined and sampled for laboratory analysis to ensure with 95% confidence that the animals do not pose a risk of RPV 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. If animals are sourced from restricted zones, all the animals in the establishment of origin should be clinically examined and sampled as well. Sampling procedures for laboratory investigation should ensure, with a confidence level of 95%, that the animals do not pose a risk of transmission	No specific recommendations
<b>20th scenario</b> 4.1.3.2 In the event of unusual mortalities or clinical signs being notified during the repopulation	No sampling procedures are defined for RP for this scenario	In the event of unusual mortalities or clinical signs compatible with RP, the establishment is considered suspected. Repopulation should be stopped and the procedures for laboratory confirmation as described for scenario 1 should be followed. In addition, the establishments from where the suspected animals are coming, should be considered as suspected; the procedures described for scenario 1 should be followed there as well	No specific recommendations
<b>21st scenario</b> 4.1.3.3 For animals that have been repopulated	No sampling procedures are defined for RP for this scenario	The animals that have been used for the repopulation should be submitted to thorough clinical and, if showing clinical signs, laboratory investigation 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 repopulation. On 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 for scenario 1 and should be sampled for laboratory investigation in accordance with the procedures described there If clinical signs are identified, then the procedures for laboratory confirmation that are described for scenario 1 should be followed	No specific recommendations

**ToR 2**

Description	Conclusions	Recommendations
<p>4.2 Assessment of the length of the monitoring period of RP</p>	<p>The current monitoring period for rinderpest (21 days) is long enough for all scenarios to capture the period between the earliest point of infection and the suspicion report for all outbreaks occurring after a re-emergence of RP. Regarding scenario 5, bulls should be sampled for serological testing 28 (21 + 7) days after semen collection, assuming that the infection occurred the latest at the day of semen collection</p>	<p>In the case of a first RP outbreak (i.e. re-emergence of RP) 21 days might not be long enough to cover the period between the earliest point of infection and the suspicion report. For such situations, the length of the monitoring period should be modified based on a risk assessment of the competent authorities</p>

**ToR 3**

Description	Conclusions	Recommendations
<p>4.3.1 Assessment of the minimum radius</p>	<p>The radius of the protection zone is considered to be sufficient to contain the disease spread with 90% probability.</p>	<p>If the aim is to contain the disease spread with 95% probability, the radius should be increased to 4 km. For the surveillance zone, the expected effectiveness to contain the disease spread corresponds to &gt; 99% probability.</p>
<p>4.3.2 Assessment of the minimum period</p>	<p>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 is considered effective to detect infected establishments and to prevent the movement of infected animals from the surveillance zone</p>	<p>No specific recommendations</p>

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## Abbreviations

ASF	African swine fever
AHS	African horse sickness
CSF	classical swine fever
CBPP	contagious bovine pleuropneumonia
CCPP	contagious caprine pleuropneumonia
dpi	days post inoculation
ELISA	enzyme-linked immunosorbent assay
ELS	extensive literature search
FMD	foot and mouth disease
FMDV	foot and mouth disease virus
HPAI	highly pathogenic avian influenza
LSD	lumpy skin disease virus
NCD	Newcastle disease virus
OIE	World Organization for Animal Health
PCR	polymerase chain reaction
PZ	protection zone
RP	rinderpest virus
RT-PCR	reverse transcription polymerase chain reaction
RVFV	Rift Valley fever virus
SPGP	sheep pox and goat pox
SZ	surveillance zone
ToR	Terms of Reference

## Annex A – Definitions in EU legislation

Terms	Definitions
<b>Clinical examination</b>	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)
<b>Confined establishment</b>	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))
<b>Epidemiological unit</b>	Means a group of animals with the same likelihood of exposure to a disease agent; (AHL: Regulation 2016/429 article 4(39))
<b>Establishment</b>	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))
<b>Health status</b>	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))
<b>Infected zone</b>	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))
<b>Kept animals</b>	Means animals which are kept by humans, including, in the case of aquatic animals, aquaculture animals; (AHL: Regulation 2016/429 article 4(5))
<b>Outbreak</b>	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))
<b>Protection zone</b>	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))
<b>Listed diseases</b>	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)
<b>Listed species</b>	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)



Terms	Definitions
<b>Monitoring periods</b>	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).
<b>Restricted zone</b>	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))
<b>Surveillance zone</b>	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))
<b>Wild animals</b>	Means animals which are not kept animals; (AHL: Regulation 2016/429 article 4(8))
<b>Zone</b>	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
<b>In the event of suspicion or confirmation</b>				
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 investigation (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"> <li>• event of suspicion of a category A disease</li> <li>• in an establishment</li> <li>• kept animals of listed species</li> <li>• the competent authority shall immediately conduct an investigation to confirm or rule out the presence of the suspected listed disease</li> <li>• official veterinarians perform clinical examinations and collect samples for laboratory investigations</li> </ul>
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 investigation (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"> <li>• affected establishment officially confirmed</li> <li>• kept animals of listed species found dead or before/when they are killed</li> <li>• competent authority collects samples for laboratory investigation for the purposes of:               <ul style="list-style-type: none"> <li>a) supporting the epidemiological enquiry:                   <ul style="list-style-type: none"> <li>– to identify the likely origin of the disease</li> <li>– to calculate the likely length of time that the disease is present</li> <li>– 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</li> <li>– to obtain information on the likely spread of the listed disease in the surrounding environment, including the presence and distribution of disease vectors</li> </ul> </li> <li>b) confirming/ruling out disease in the event of preventive killing</li> </ul> </li> </ul>

ToRs	Legislation	Scenario	Description of the scenario	Elements of the scenario
ToR 1.1 ToR 1.2	Article 13(3) 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 ensuring that they do not pose a risk for the transmission of the disease	<ul style="list-style-type: none"> <li>• affected establishment officially confirmed</li> <li>• kept animals of listed species of specific categories</li> <li>• animal categories based on article 13(2):               <ol style="list-style-type: none"> <li>a) animals kept in a confined establishment</li> <li>b) animals kept for scientific purposes or purposes related to conservation of protected or endangered species</li> <li>c) animals officially registered in advance as rare breeds</li> <li>d) animals with a duly justified high genetic, cultural or educational value</li> </ol> </li> <li>• 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</li> <li>• the animals should be subjected to clinical surveillance, including laboratory investigations</li> <li>• sampling procedures should ensure that the animals do not pose a risk of transmission of the category A disease if left alive</li> </ul>
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"> <li>• kept animals of non-listed species of epidemiological relevance for the control of the disease</li> <li>• 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</li> <li>• animal species acting purely as mechanical carriers of the virus will not be covered</li> <li>• 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</li> <li>• sampling procedures to ensure detection of the virus in these species</li> </ul>
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)	<ul style="list-style-type: none"> <li>• affected establishment officially confirmed</li> <li>• wild animals of listed species within the establishment and in the surroundings of the establishment</li> </ul>

ToRs	Legislation	Scenario	Description of the scenario	Elements of the scenario
			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"> <li>the competent authority may establish these sampling procedures in addition to other measures</li> <li>sampling procedures in wild animals of listed species to ensure the detection of the virus, if the virus is present in these wild species</li> </ul>
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 detection of the virus, if the virus is present in these animals	<ul style="list-style-type: none"> <li>protection zone with radius up to 3 km</li> <li>non-affected establishments with kept animals of listed species</li> <li>all the non-affected establishments within the protection zone</li> <li>official veterinarians must visit at least once all the establishments</li> <li>among others, they must perform a clinical examination of kept animals of listed species and if necessary, collection of samples for laboratory investigation</li> <li>sampling procedures to confirm or rule out the presence of a category A disease</li> </ul>
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"> <li>protection zone with radius larger than 3 km</li> <li>non-affected establishments of kept animals of listed species</li> <li>sample of the non-affected establishments in the protection zone</li> <li>in a protection zone with a radius equal to 3 km, official veterinarians must carry inspections in all establishments within the 3 km</li> <li>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</li> <li>among others perform clinical examination of kept animals of listed species and if necessary, collection of samples for laboratory investigation</li> <li>sampling procedure to ensure the detection of the disease if the disease is present in any of these establishments</li> </ul>

ToRs	Legislation	Scenario	Description of the scenario	Elements of the scenario
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"> <li>• surveillance zone</li> <li>• establishments of kept animals of listed species</li> <li>• sample of the establishments in the surveillance zone</li> <li>• official veterinarians carry out visits to a sample of the establishments</li> <li>• among others perform clinical examination of kept animals of listed species and if necessary, collection of samples for laboratory investigation</li> <li>• sampling procedure to ensure the detection of the disease if the disease is present in any of the establishments</li> </ul>
<b>Derogations to allow animal movements</b>				
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 investigations 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)	<ul style="list-style-type: none"> <li>• protection zone</li> <li>• kept animals of listed species</li> <li>• grant derogation for movement from a non-affected establishment in the protection zone</li> <li>• to be moved to a slaughterhouse located within the protection zone or in the surveillance zone or outside the restricted zone</li> <li>• clinical examinations and laboratory investigation of animals kept in the establishment, including those animals to be moved</li> </ul>
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 investigations, 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	<ul style="list-style-type: none"> <li>• protection zone</li> <li>• grant derogation for movement from a non-affected establishment in the protection zone</li> <li>• day-old-chicks from non-affected establishment located in the protection zone, hatched from eggs originating in or outside the restricted zone</li> <li>• to be moved to an establishment located in the same Member State but if possible, outside the restricted zone</li> <li>• clinical examinations and laboratory investigation of animals kept in the establishment, including those animals to be moved</li> </ul>

ToRs	Legislation	Scenario	Description of the scenario	Elements of the scenario
			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	
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 investigations, 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"> <li>• protection zone</li> <li>• ready-to-lay poultry</li> <li>• grant derogation for movement from a non-affected establishment in the protection zone</li> <li>• to be moved to an establishment located in the same Member State and if possible, within the restricted zone</li> <li>• clinical examinations and laboratory investigation of animals kept in the establishment, including those animals to be moved</li> </ul>
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 investigations 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"> <li>• protection zone</li> <li>• kept animals of listed species</li> <li>• grant derogation for movement from a non-affected establishment in the protection zone</li> <li>• to be moved to a plant approved for processing or disposal of animal by-products in which the kept animals are immediately killed</li> <li>• clinical examinations and laboratory investigations of animals kept in the establishment, including those animals to be moved</li> </ul>
ToR 1.4	Article 43(5) and Article 44 of the Delegated Regulation	13th scenario	To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory investigations 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	<ul style="list-style-type: none"> <li>• surveillance zone</li> <li>• kept animals of listed species</li> <li>• 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</li> <li>• grant derogation for movement from an establishment outside the surveillance zone to a slaughterhouse situated in the surveillance zone</li> </ul>

ToRs	Legislation	Scenario	Description of the scenario	Elements of the scenario
			within or outside the restricted zone, from an establishment outside the surveillance zone to a slaughterhouse situated in the surveillance zone	<ul style="list-style-type: none"> <li>clinical examinations and laboratory investigation of animals kept in the establishment, including those animals to be moved</li> </ul>
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 investigations 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"> <li>surveillance zone</li> <li>kept ungulates of listed species</li> <li>grant derogation for movement from an establishment in the surveillance zone</li> <li>to be moved to pastures situated within the surveillance zone</li> <li>clinical examinations and laboratory investigation of animals kept in the establishment, including those animals to be moved</li> </ul>
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 investigations 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"> <li>surveillance zone</li> <li>kept animals of listed species</li> <li>grant derogation for movement from the surveillance zone</li> <li>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</li> <li>clinical examinations and laboratory investigation of animals kept in the establishment, including those animals to be moved</li> </ul>
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 investigations 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	<ul style="list-style-type: none"> <li>surveillance zone</li> <li>kept birds of listed species</li> <li>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</li> <li>to be moved to an establishment located in the same Member State</li> </ul>

ToRs	Legislation	Scenario	Description of the scenario	Elements of the scenario
			the restricted zone, to an establishment located in the same Member State where they were hatched	<ul style="list-style-type: none"> <li>clinical examinations and laboratory investigation of animals kept in the establishment, including those animals to be moved</li> </ul>
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 investigations, 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"> <li>surveillance zone</li> <li>ready-to-lay poultry</li> <li>to be moved to an establishment located in the same Member State</li> <li>clinical examinations and laboratory investigation of animals kept in the establishment, including those animals to be moved</li> </ul>
ToR 1.4	Article 56(1 of the Delegated Regulation)	18th scenario	To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory investigations 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"> <li>restricted zone when restriction measures are maintained beyond the period set out in Annex XI</li> <li>kept animals of listed species</li> <li>grant derogation for movement from an establishment within the restricted zone</li> <li>clinical examinations and laboratory investigation of animals kept in the establishment, including those animals to be moved</li> </ul>
<b>Repopulation</b>				
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 investigations 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"> <li>repopulation of a previous affected establishment</li> <li>kept animals of listed species</li> <li>Animals intended to repopulation shall be sampled prior to their introduction into the establishment of destination</li> <li>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)</li> <li>laboratory investigations</li> </ul>



ToRs	Legislation	Scenario	Description of the scenario	Elements of the scenario
ToR 1.5	Article 59(9) of the Delegated Regulation	20th scenario	To assess the effectiveness of disease-specific sampling procedures based on laboratory investigations 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"> <li>• sampling procedures to rule out the presence of the disease</li> <li>• repopulated establishment</li> <li>• unusual mortalities or clinical signs during the repopulation</li> <li>• the official veterinarians shall without delay collect samples for laboratory investigation</li> <li>• sampling procedures to rule out the presence of the disease</li> </ul>
ToR 1.5	Article 59(5) of the Delegated Regulation	21st scenario	To assess the effectiveness of disease-specific sampling procedures based on laboratory investigations 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"> <li>• repopulated establishment</li> <li>• kept animals of listed species</li> <li>• Animals that have been used for repopulation</li> <li>• Laboratory investigations</li> <li>• Sampling procedures to rule out the presence of the disease</li> </ul>

## Annex C – Existing sampling procedures for rinderpest

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

Scenario	Description of the Scenario	Clinical guidelines	Laboratory guidelines
1st	<p><b>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 investigation (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))</b></p>	<p><b>Article 4:</b></p> <p>1. <u>When animals on a holding are suspected of being infected or contaminated with rinderpest</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 <u>holding placed under official surveillance</u> 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>OIE Terrestrial Code (OIE, 2019):</b> <b>Article 8.16.5</b> Response to recurrence of rinderpest</p> <p>1. Definition of a <b>suspected case of rinderpest</b> rinderpest should be suspected if <u>one or more animals of a susceptible species is found to be exhibiting clinical signs consistent with 'stomatitis-enteritis syndrome'</u>. Stomatitis-enteritis syndrome is defined as fever with ocular and nasal discharges in combination with:</p> <p>a) clinical signs of erosions in the oral cavity with diarrhoea, dysentery, dehydration or death; or b) necropsy findings of haemorrhages on serosal surfaces, haemorrhages and erosions on alimentary mucosal surfaces and lymphadenopathy.</p>	<p><b>Article 4:</b></p> <p>1. When animals on a holding are suspected of being infected or contaminated with rinderpest, 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 investigation</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><b>OIE Terrestrial Code (OIE, 2019):</b> <b>Article 8.16.5</b> Response to recurrence of rinderpest ...</p> <p>3. Definition of a <b>case of rinderpest</b> rinderpest should be considered as confirmed when, based on a report from an appointed OIE-FAO Reference Laboratory for rinderpest:</p> <p>a) <u>RPV has been isolated</u> from an animal or a product derived from that animal and identified; or b) <u>viral antigen or viral RNA specific to RPV has been identified</u> in samples from one or more animals; or c) <u>antibodies to RPV have been identified</u> in one or more animals with either epidemiological links to a confirmed or suspected outbreak of rinderpest or showing clinical signs consistent with recent infection with RPV.</p> <p><b>Notes:</b></p> <p><b>OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (OIE, 2018):</b> B. Diagnostic techniques</p>

Scenario	Description of the Scenario	Clinical guidelines	Laboratory guidelines
		<p>Stomatitis-enteritis syndrome could indicate a number of diseases from which rinderpest should be differentiated by appropriate laboratory investigation.</p> <p><u>The detection of RPV specific antibodies in an animal of a susceptible species with or without clinical signs is considered a suspected case of rinderpest.</u></p> <p>2. Procedures to be followed in the event of the suspicion of rinderpest</p> <p>Any direct or indirect detection of RPV in an animal or animal product shall be notified immediately. Upon detection of a suspected case, the national contingency plan should be implemented immediately. If the presence of rinderpest cannot be ruled out, samples should be collected in accordance with Chapter 3.1.19. of the Terrestrial Manual and dispatched to one of the appointed OIE-FAO Reference Laboratories for rinderpest for confirmation and, if applicable, for molecular characterisation of the virus to facilitate identification of its source. A full epidemiological investigation should be conducted simultaneously to provide supporting information and to assist in identifying the possible source and spread of the virus. . . .</p> <p><b><u>Notes:</u></b></p> <p><b><i>Response Strategy rinderpest (Animal Health Australia, 2020):</i></b></p> <p>2.5. Diagnostic criteria</p> <p>rinderpest should be suspected when acute fever with diarrhoea in cattle or buffalo is accompanied by erosions of the mouth linings and high mortality. Rapid spread from animal to animal and herd to herd can occur, with animals of all ages becoming sick and dying. Any disease outbreak with these features is highly suggestive of rinderpest.</p> <p>2.5.1 Clinical signs</p> <p>Animals</p> <p>Cattle</p>	<p><b>Table 1:</b> Test methods available for rinderpest diagnosis and their purpose:</p> <p>→purpose of "<u>confirmation of clinical cases</u>":</p> <ul style="list-style-type: none"> <li>– Confirmation of the agent: Virus isolation (recommended method), antigen detection (AGID), real-time RT-PCR (recommended method)</li> </ul> <p>→purpose of "<u>prevalence of infection and surveillance</u>":</p> <ul style="list-style-type: none"> <li>– Detection of immune response: AGID, C-ELISA, VN-Virus neutralisation (recommended method)</li> </ul> <p><b>Special Post-Eradication Note:</b></p> <p>. . . Suspect cases, that is animals with clinical signs similar to those seen in the case of infection with RPV, will still arise, and need to be tested to ensure that any future re-emergence or escape of RPV is detected in a timely manner. <u>For the initial testing of samples from suspect cases, laboratories that are not FAO-OIE-approved rinderpest Holding Facilities are recommended to use (gel-based or real-time) reverse-transcriptase polymerase chain reaction (RT-PCR) using the established primer sets.</u> The test can be run without a RPV positive control; parallel tests using (vaccine or wild type) peste des petits ruminants virus (PPRV) and published primer sets for PPRV can be used as a control for most of the stages of the assay (RNA extraction, reverse transcription and PCR reagents); alternatively the bovine actin primers can be used in parallel as an internal control reaction. For definitive diagnosis, samples should be sent to one of the FAO-OIE approved rinderpest Holding Facilities.</p> <p><u>There are no circumstances where tests for anti-RPV antibodies will be required unless there is a re-emergence or escape of the virus.</u></p> <p>1. <b>Identification of the agent:</b></p> <p>Any suspicion of rinderpest must be viewed as a potential threat to international biosecurity and must be rapidly confirmed or differentiated. RT-PCR is the most rapid and specific test. If RPV is confirmed, back-tracing measures must be immediately instigated. In addition, samples must be sent to an OIE Reference Laboratory for rinderpest for final</p>

Scenario	Description of the Scenario	Clinical guidelines	Laboratory guidelines
		<p>When the virus is introduced into a large and fully susceptible bovine population, it is probable that <u>some or all of the manifestations of classic rinderpest will be seen</u>. For example, the mortality rate, which may vary initially between 30% and 90%, may increase with repeated transmissions of the virus because of increasing virulence on passage of the virus. Under these circumstances, it is even possible that <u>peracute cases</u> will occur. However, the fever might be brief and accompanied by the transient appearance of mouth lesions, and a short and light bout of diarrhoea. <u>In such cases, it would be difficult to make a diagnosis based entirely on clinical appearance.</u></p> <p>Sheep and goats <u>Sheep and goats can be affected and develop clinical signs.</u></p> <p>...</p> <p>Pigs <u>In European pigs, usually only mild symptoms develop, with transient fever.</u> Asian pigs may develop the classical clinical symptoms seen in cattle and suffer high mortality</p> <p>7. <u>Surveillance and proof of freedom</u> A suspect premise requires daily physical surveillance of cattle for 15 days after the first appearance of clinical signs on the infected premise, followed by weekly inspections for a further 2 weeks. These premises should be included in later serosurveillance.</p> <p><b><i>Rinderpest (USAHA, 2008)</i></b></p> <p>4. HOST RANGE</p> <p>a. Domestic and wild animals Most wild and domestic cloven-footed animals can be infected by RPV. Cattle and African buffalo are highly susceptible. ... Goats and sheep are less susceptible and are either infected subclinically or exhibit milder clinical signs relative to cattle. Subclinically infected or recovered goats and sheep develop protective immunity against both RPV and PPRV. Pigs can also</p>	<p>confirmation of the diagnosis, and the virus origin should be identified by sequencing and comparison with known RPV genomic data. If possible, the virus should be isolated (Anderson et al., 1996), though this should only be attempted in an FAO-OIE approved rinderpest Holding Facility.</p> <p>1.1. Virus isolation RPV can be cultured from the leukocyte fraction of whole blood that has been collected into heparin or EDTA (ethylenediamine tetra-acetic acid) at final concentrations of 10 international units (IU)/ml and 0.5 mg/ml, respectively. Samples should be thoroughly mixed and transferred to the laboratory on ice, but never frozen. On average, the onset of viraemia slightly precedes the onset of pyrexia and may continue for 1–2 days after pyrexia begins to wane. Consequently, <u>animals showing a pyrexia are probably viraemic and therefore the best source of blood with which to attempt virus isolation.</u> However, as occasional febrile animals may no longer be viraemic, <u>samples from several febrile animals should be collected for submission.</u> Virus can also be isolated from samples of the <u>tonsil, spleen, prescapular or mesenteric lymph nodes of dead animals</u>; these samples may be frozen for transportation. Transportation must be under biosecure conditions in compliance with international transport regulations described in Chapter 1.1.2</p> <p>1.2. Antigen detection by agar gel immunodiffusion (AGID)</p> <p>... Although the test is <u>neither highly sensitive nor highly specific</u>, it is robust and adaptable to field conditions. A positive reaction from a large domestic ruminant should be treated as if it were rinderpest. From a small ruminant, a positive result should be treated as having been derived from a case of peste des petits ruminants (PPR) although further testing is recommended, given the lack of specificity in this test.</p> <p>1.3. Nucleic acid detection and characterization methods</p> <p>RT-PCR techniques based on the amplification of parts of the N or F protein genes have been developed for the specific</p>

Scenario	Description of the Scenario	Clinical guidelines	Laboratory guidelines
		<p>be naturally infected and some breeds (Swayback pigs in Thailand and the Malay Peninsula) may exhibit clinical signs and die.</p> <p>...</p> <p><b>6. CLINICAL SIGNS</b></p> <p>Depending on the strain of virus, immune status of the animal affected, and concurrent infections, <u>rinderpest can appear as a peracute, acute, or mild infection</u>. In the peracute form, usually seen in highly susceptible and young animals without colostral immunity, the only signs of illness are a fever of 104°–107°F (40°–41.7°C), congested mucous membranes, and death within 2–3 days after the onset of fever. The acute or classic form is characterized by the following sequential signs: fever of 104°–106°F (40°–41.1°C), serous to mucopurulent nasal-ocular discharges, depression, anorexia, constipation, oral erosions resulting in abundant and frothy salivation, watery and/or hemorrhagic diarrhea, dehydration, emaciation, prostration, and death 6–12 days after onset of illness. Leukopenia is a common finding.</p> <p>...</p> <p><b>9. DIAGNOSIS</b></p> <p>a. Field diagnosis</p> <p>rinderpest should be considered in <u>all ages of cattle</u> whenever there is a rapidly spreading acute febrile disease accompanied by the preceding clinical signs and lesions of rinderpest. The “all ages” stipulation is important because this will be one of the major differences between bovine virus diarrhea-mucosal disease, which predominantly affects animals between 4–24 months of age.</p> <p><b><i>Rinderpest and peste des petits ruminants (Wohlsein and Saliki, 2006):</i></b> rinderpest clinical disease (p. 69)</p> <p>...</p> <p><u>In the classic, acute form of the disease, not all clinical signs may be present in an individual animal, but among the members of an affected herd, the totality of the signs</u></p>	<p>diagnosis of RPV (Forsyth and Barrett, 1995). This technique is extremely sensitive, specific and can detect RPV in cattle as early as two days post-infection with the advantage that results are obtained in 5 h, including the RNA extraction. ...</p> <p><b><i>OIE Technical disease card: rinderpest (OIE, 2020):</i></b> Laboratory diagnosis</p> <p>...</p> <p>Identification of virus-specific antibodies</p> <p><u>The competitive enzyme-linked immunosorbent assay</u></p> <ul style="list-style-type: none"> <li>• Due to restrictions on the distribution of the RPV antigen used in this <u>ELISA, it is no longer available</u></li> </ul> <p><u>Virus neutralization</u></p> <ul style="list-style-type: none"> <li>• NB Since this test requires the manipulation of live vaccine virus, the VNT <u>can currently only be undertaken in FAO and OIE approved high security laboratories</u> with specific permission to carry out the procedure</li> <li>• <u>Antibodies are detectable in serum of infected animals at 8–14 days post infection</u></li> <li>• The presence of any detectable antibody in the lowest (usually 1:10) final serum dilution is considered to indicate previous infection with rinderpest virus</li> </ul> <p><b><i>Rinderpest (CFSPH and Iowa State University, 2016):</i></b> <u>Samples to collect</u></p> <p>Viremia can be seen a day or two before the fever begins and can continue for 1–2 days after the fever begins to wane.</p> <p><u>Samples for virus isolation and antigen or RNA detection should ideally be collected when a high fever and oral lesions are present, but before the onset of diarrhea – the period when viral titers are highest.</u> Blood (in heparin or EDTA) is the preferred sample for virus isolation in live animals. Whenever possible, <u>samples should be submitted from more than one animal</u>. Serum, swabs of lacrimal fluid, necrotic tissues from oral lesions, and aspiration biopsies of superficial lymph nodes should also be collected. At necropsy, samples should be taken from the spleen, lymph nodes (prescapular or mesenteric) and tonsil. <u>The ideal post-mortem lesions come</u></p>

Scenario	Description of the Scenario	Clinical guidelines	Laboratory guidelines
		<p>may be observed. Typical clinical signs include: a sudden onset of fever; mucopurulent oculo-nasal discharges; mucosal necrosis, erosions and ulcerations in the upper digestive and respiratory tracts; abomaso-enteritis followed by diarrhoea, dehydration and death</p>	<p>from an animal that has been euthanized during the febrile stage. A second choice would be a moribund animal that has been euthanized. Samples for RT-PCR can be taken from the lymph nodes, tonsils or blood (peripheral blood lymphocytes). The spleen is less desirable due to its high blood content. An additional set of tissue samples should be collected for histopathology and immuno-histochemistry. In addition to other tissues, it should include the base of the tongue, retropharyngeal lymph node and third eyelid. Samples for virus isolation should be kept cold on ice during transport but should not be frozen</p>
2nd	<p><b>To assess the effectiveness of disease-specific sampling procedures, based on laboratory investigation (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.</b></p>	<p>NA</p> <p><b>Notes:</b> <b><i>Response Strategy rinderpest (Animal Health Australia, 2020):</i></b> 2.5.2 <u>Pathology</u> Gross lesions Postmortem findings include a dehydrated carcass; fluid faeces, containing blood, and faecal staining of the legs; erosions of the mucosa in the mouth, pharynx and oesophagus; congestion, oedema and erosion of the abomasal mucosa; prominent necrotic Peyer's patches; and congestion and erosion of the mucosa of the large intestine, especially along the longitudinal folds, giving a 'tiger (or zebra) striping' appearance.</p> <p><b><i>Rinderpest and peste des petits ruminants (Wohlsein and Saliki, 2006):</i></b> Rinderpest pathology (p. 73) ... <u>Lesions in small domestic ruminants</u> are similar to those observed in cattle but tend to be less intense. Pulmonary involvement is more prominent. In <u>Asian pigs</u> morphological changes resemble those in cattle but there is a wide individual variation.</p>	<p><b>Article 8:</b> 1. The epizootiological enquiry shall deal with: (a) the length of time during which the disease may have existed on the holding before being notified or suspected; (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; (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; 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>

Scenario	Description of the Scenario	Clinical guidelines	Laboratory guidelines
3rd	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><b>Article 5:</b></p> <p>1. Once it has been officially confirmed that rinderpest 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) all animals of susceptible species on the holding shall be killed on the spot, without delay. The animals which have died or been killed shall either be burnt or buried on the spot, if possible, or destroyed in a carcass disposal plant</p>	No specific guidelines described in legislation
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
5th	To assess the effectiveness of disease-specific sampling procedures, based on clinical (ToR 1.1) and	<p><b>Article 6:</b></p> <p>Where animals living in the wild are infected or suspected of being infected, Member States shall ensure that appropriate action is taken.</p>	No specific guidelines described in legislation

Scenario	Description of the Scenario	Clinical guidelines	Laboratory guidelines
	<p><b>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</b></p>	<p><b>Notes:</b></p> <p><b>Rinderpest (USAHA, 2008)</b></p> <p>4. HOST RANGE</p> <p>a. Domestic and wild animals</p> <p>Most wild and domestic cloven-footed animals can be infected by RPV. Cattle and African buffalo are highly susceptible. Among wild ungulates, African buffalo, wildebeest, kudu, eland, giraffe, and warthog are highly susceptible, while Thompson's gazelle and hippopotamus are fairly susceptible. . . .</p> <p><b>Rinderpest (CFSPH and Iowa State University, 2016):</b></p> <p>Clinical signs</p> <p>. . . In susceptible wildlife, the clinical signs can include fever, nasal discharge, erosive stomatitis, gastroenteritis, and death; however, the signs can vary with the species. In buffalo, rinderpest generally resembles the disease in cattle, but lymphadenopathy, plaque-like keratinized skin lesions and keratoconjunctivitis might also be seen. Similar signs can be seen in lesser kudus, and severe keratoconjunctivitis often causes blindness, but diarrhea is uncommon in this species</p>	
6th	<p><b>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</b></p>	<p><b>Article 11:</b></p> <p>1. Member States shall ensure that the following measures are applied in the protection zone:</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 frequency of visits being proportional to the seriousness of the epizootic on those holdings at greatest risk.</p>	<p><b>Article 11:</b></p> <p>1. Member States shall ensure that the following measures are applied in the protection zone:</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 investigation</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
	<p><b>to ensure the detection of the virus, if the virus is present in these animals</b></p>	<p><b><i>OIE Terrestrial Code (OIE, 2019):</i></b>  <b>Article 8.16.5</b>            Response to recurrence of rinderpest            ...            4. Procedures to be followed after confirmation of rinderpest            ... In the event of the confirmation of rinderpest, the entire country is considered to be infected. When epidemiological investigation has indicated the extent of the infected area, <u>infected and protection zones can be defined for the purposes of disease control.</u> In the event of limited outbreaks, a single <u>containment zone</u>, which includes all cases, may be established for the purposes of minimising the impact on the country. The containment zone should be established in accordance with Chapter 4.4. and may cross international boundaries</p> <p><b><i>Response Strategy rinderpest (Animal Health Australia, 2020):</i></b>            7. <u>Surveillance and proof of freedom</u>            On other properties in the restricted area (RA), surveillance visits should be made as soon as possible after detection of the first IP in the RA, and then 1, 2, 3 and 4 weeks later. At surveillance visits, every group of cattle must be inspected, and numbers accounted for. In extensive grazing areas, where the degree of contact between groups of animals in a herd may be low, care must be taken to ensure that all groups of animals are present and healthy</p>	<p><b><i>Response Strategy rinderpest (Animal Health Australia, 2020):</i></b>            7. <u>Surveillance and proof of freedom</u>            Once the disease is confidently contained, all cattle herds within the RA should be serologically sampled to provide a 95% confidence level that the disease is not present at 10% prevalence. Small groups of animals should be kept under close examination. This should take place about 1 month after the last IP has been restocked and repeated 2 months later. Herds giving seropositive results should be further tested for evidence of infection.</p>
7th	<p><b>To assess the effectiveness of disease-specific sampling procedures, based on clinical (ToR 1.1) and laboratory (ToR 1.2)</b></p>	<p><b><i>Article 10:</i></b>            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</u> with a minimum radius of three</p>	<p>→See 6th scenario</p>

Scenario	Description of the Scenario	Clinical guidelines	Laboratory guidelines
	<p><b>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</b></p>	<p>kilometres, 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.  <u>→See 6th scenario</u></p>	
8th	<p><b>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.</b></p>	<p><b>Article 12:</b>            1. Member States shall ensure that the following measures are applied <u>in the surveillance zone</u>:            (a) all holdings having animals of susceptible species shall be identified;            (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;            (c) the transport of animals of susceptible species within the surveillance zone shall be subject to authorization by the competent authority;            (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>	No specific guidelines described in legislation
<b>Derogations to allow animal movements</b>			
9th	<p><b>To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory investigations of the</b></p>	<p><b>Article 11:</b>            1. Member States shall ensure that the following measures are applied <u>in the protection zone</u>:</p>	No specific guidelines described in legislation

Scenario	Description of the Scenario	Clinical guidelines	Laboratory guidelines
	<p><b>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).</b></p>	<p>(d) <u>animals of susceptible species</u> must remain on the holding on which they are being kept, except to be transported under official supervision directly <u>to a slaughterhouse located in that zone</u> for emergency slaughter or, if that zone has no slaughterhouse under veterinary supervision, <u>to a slaughterhouse in the surveillance zone</u> designated by the competent authority. 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 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>	
10th	<p><b>To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory investigations, 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</b></p>	NA	NA

Scenario	Description of the Scenario	Clinical guidelines	Laboratory guidelines
11th	<p>To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory investigations, 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</p>	NA	NA
12th	<p>To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory investigations 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)</p>	No specific guidelines described in legislation	No specific guidelines described in legislation

Scenario	Description of the Scenario	Clinical guidelines	Laboratory guidelines
13th	<p><b>To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory investigations 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, from an establishment outside the surveillance zone to a slaughterhouse situated in the surveillance zone</b></p>	<p><b>Article 12:</b>            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 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>	No specific guidelines described in legislation
14th	<p><b>To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory investigations 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</b></p>	<p><b>Article 12:</b>            1. Member States shall ensure that the following measures are applied in the surveillance zone:            (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>	No specific guidelines described in legislation

Scenario	Description of the Scenario	Clinical guidelines	Laboratory guidelines
15th	<p>To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory investigations 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 complete the production cycle before slaughter.</p>	<p><b>Article 12:</b>            1. Member States shall ensure that the following measures are applied in the surveillance zone:            (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>	No specific guidelines described in legislation
16th	<p>To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory investigations 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</p>	NA	NA

Scenario	Description of the Scenario	Clinical guidelines	Laboratory guidelines
	where they were hatched.		
17th	To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory investigations, 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 investigations 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.	<p><b>Article 13:</b>            Where the prohibitions provided for in Articles 11 (1) (d) and 12 (1) (d) 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 grounds for such application, by the 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:</p> <p>(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</p>	No specific guidelines described in legislation

Scenario	Description of the Scenario	Clinical guidelines	Laboratory guidelines
<b>Repopulation</b>			
19th	<p><b>To assess the effectiveness of disease-specific sampling procedures based on laboratory investigations of the animals that are kept for the repopulation prior to their introduction to rule out the presence of the disease</b></p>	NA	<p><b>Article 5:</b> The restocking of the holding shall be authorized by the competent authority, following the satisfactory inspection by the official veterinarian of the cleaning and disinfection operations carried out in accordance with Article 16.</p> <p><b>OIE Terrestrial Code (OIE, 2019):</b> <b>Article 8.16.6.</b> <u>Recovery of free status</u> Should there be a confirmed occurrence of rinderpest, as defined above, a country or zone shall be considered as RPV infected until shown to be free through targeted surveillance involving clinical, serological and virological testing procedure. The time needed to recover rinderpest free status of a country or zone, or of a containment zone if one is established, depends on the methods employed to achieve the elimination of infection. <u>One of the following waiting periods applies:</u> 1) Three months after the last case where a stamping-out policy and serological surveillance are applied in accordance with Article 8.16.8.; or 2) Three months after the slaughter of all vaccinated animals where a stamping-out policy, emergency vaccination and serological surveillance are applied in accordance with Article 8.16.8. The recovery of rinderpest free status requires an international expert mission to verify the successful application of containment and eradication measures, as well as a review of documented evidence by the OIE. The country or zone shall be considered free only after the submitted evidence has been accepted by the OIE.</p> <p><b>Response Strategy rinderpest (Animal Health Australia, 2020):</b> <u>Policy and rationale</u> As the disease has a short incubation period and does not survive long in the environment, a sentinel animal restocking</p>



Scenario	Description of the Scenario	Clinical guidelines	Laboratory guidelines
			program would be unnecessary. The farm could be safely restocked 15 days after destruction and disposal of the last clinical case
20th	<p><b>To assess the effectiveness of disease-specific sampling procedures based on laboratory investigations 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</b></p>	NA	No specific guidelines described in legislation
21st	<p><b>To assess the effectiveness of disease-specific sampling procedures based on laboratory investigations 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</b></p>	NA	<p>No specific guidelines described in legislation</p> <p><b><i>Response Strategy rinderpest (Animal Health Australia, 2020):</i></b></p> <p><b><u>7. Surveillance and proof of freedom</u></b></p> <p>Following the successful eradication of an outbreak by stamping out, Australia would be able to claim freedom from rinderpest 3 months after the last case if serological surveillance had been applied in accordance with article 8.16.8 of the World Organisation for Animal Health (OIE) Terrestrial animal health code, and if all vaccinated animals were slaughtered or destroyed. The time period is 3 months after the slaughter of all vaccinated animals where a stamping-out policy, emergency vaccination and serological surveillance are applied.</p> <p><b><u>Infected premises</u></b></p> <p>On infected premises (IPs) (and dangerous contact premises – DCPs – that have been destocked), restocking will be allowed after 15 days. On IPs where some ruminants or pigs are allowed to remain, serological evidence that no spread is occurring after the slaughter of the infected mob will be</p>

Scenario	Description of the Scenario	Clinical guidelines	Laboratory guidelines
			<p>required before restocking. Surveillance visits of all restocked premises should be made weekly for 4 weeks, then fortnightly for another month.</p> <p><u>Suspect or dangerous contact premises</u>            A suspect premise (SP) or DCP requires daily physical surveillance of cattle for 15 days after the first appearance of clinical signs on the IP, followed by weekly inspections for a further 2 weeks. These premises should be included in later serosurveillance.</p> <p><u>Restricted area</u>            On other properties in the restricted area (RA), surveillance visits should be made as soon as possible after detection of the first IP in the RA, and then 1, 2, 3 and 4 weeks later. At surveillance visits, every group of cattle must be inspected, and numbers accounted for. In extensive grazing areas, where the degree of contact between groups of animals in a herd may be low, care must be taken to ensure that all groups of animals are present and healthy. If feral animals are detected, appropriate measures must be taken to destroy them. Once the disease is confidently contained, all cattle herds within the RA should be serologically sampled to provide a 95% confidence level that the disease is not present at 10% prevalence. Small groups of animals should be kept under close examination. This should take place about 1 month after the last IP has been restocked and repeated 2 months later. Herds giving seropositive results should be further tested for evidence of infection.</p> <p><u>Control area</u>            All reports of disease in the control area (CA) will need to be investigated. Random sampling should be carried out about 1 month after the last IP has been restocked and then 2 months later</p>

## Annex D – Scenarios of ToR 2

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"> <li>• event of suspicion of a category A disease</li> <li>• in an establishment with kept animals of listed species</li> <li>• time period calculated backwards from the date of the of the notification of the suspicion</li> <li>• time period before the suspicion, during which the pathogenic agent may have been introduced in the establishment and may have spread outside the establishment</li> <li>• the aim of the epidemiological enquiry is:               <ol style="list-style-type: none"> <li>a) identify the likely origin of the listed disease in question and the means of its spread</li> <li>b) calculate the likely length of time that the listed disease has been present</li> <li>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</li> <li>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</li> <li>e) obtain information on the likely spread of the listed disease in the surrounding environment, including the presence and distribution of disease vectors</li> </ol> </li> </ul>
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	<ul style="list-style-type: none"> <li>• event of confirmation of a category A disease</li> <li>• in an establishment with kept animals of listed species</li> <li>• time period calculated backwards from the date of the notification of the suspicion</li> </ul>

ToRs	Legislation	Scenario	Description of the Scenario	Elements of the Scenarios
			of the epidemiological enquiry in the event of confirmation of the disease	<ul style="list-style-type: none"> <li>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.</li> <li>The aim of the epidemiological enquiry is the same as above.</li> </ul>
ToR 2	Article 13(b) of the Delegated Regulation Annex II of the Delegated Regulation	3rd scenario	To assess the effectiveness of the length of the Monitoring Period, as the time period 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"> <li>event of confirmation of a category A disease</li> <li>in an affected establishment with kept animals of listed species</li> <li>non-affected epidemiological units kept separated</li> <li>to provide derogation from killing for animals in non-affected separated epidemiological units</li> <li>to exclude any possible contact between the affected establishment and the separated epidemiological units as per the epidemiological enquiry</li> <li>time period calculated backwards from the date of the confirmation</li> <li>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.</li> </ul>
ToR 2	Article 27(3) 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 have been obtained or produced, before this time period in order to be exempted from prohibitions of movements	<ul style="list-style-type: none"> <li>protection zone</li> <li>non-affected establishments</li> <li>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</li> <li>time period calculated backwards from the date of suspicion of the latest outbreak in the protection zone</li> <li>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.</li> </ul>

ToRs	Legislation	Scenario	Description of the Scenario	Elements of the Scenarios
ToR 2	<p>Article 32(c) of the Delegated Regulation</p> <p>Article 48(c) of the Delegated Regulation</p> <p>Annex II of the Delegated Regulation</p>	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"> <li>• protection or surveillance zone</li> <li>• non-affected approved germinal establishments</li> <li>• semen from kept animals (donor) of listed species</li> <li>• 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)</li> <li>• to take samples from the donor for laboratory analysis at least 7 days after the end of the monitoring period</li> <li>• to authorise movements of semen from approved germinal product establishments located in the protection or surveillance zones in case of favourable laboratory results</li> <li>• time period calculated forwards from the date of semen collection</li> <li>• time period after the semen collection, during which the animal donor if infected could be detected by the relevant diagnostic test.</li> </ul>
ToR 2	<p>Article 57(1 of the Delegated Regulation)</p> <p>Annex II of the Delegated Regulation</p>	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"> <li>• repopulation of a previous affected establishment</li> <li>• kept animals of listed species</li> <li>• to allow the repopulation of an affected establishment</li> <li>• time period calculated forwards from the date of the final cleaning and disinfection of the establishment</li> <li>• 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.</li> </ul>
ToR 2	<p>Article 59(4 of the Delegated Regulation)</p> <p>Annex II of the Delegated Regulation</p>	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"> <li>• repopulation of a previous affected establishment</li> <li>• kept animals of listed species to be repopulated</li> <li>• the animals may not be introduced at the same time</li> <li>• time period calculated forwards from the date when the first animal was introduced</li> <li>• time period during which animals intended for repopulation, should be introduced and the process of repopulation be completed.</li> </ul>

## Annex E – 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	Cross-reactivity between PPR and RP VNT	Specificity of the VNT is lowered in the presence of PPR and the effectiveness of the sample size recommended may be overestimated
	2	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). Furthermore, the parameters were estimated for outbreaks in Africa and differences in host (e.g. animal breed, husbandry practices) and virus (e.g. virulence) factors may affect the model predictions	The effectiveness of the sampling strategies could be over- or underestimated
ToR 2	3	The diagnostic test (PCR) is assumed to have 100% Sensitivity and 100% Specificity. Although this is a reasonable assumption given the evidence retrieved there may be instances in which test performance may not be perfect	The effectiveness of the sampling strategies could be overestimated
	4	Few references for seroconversion and detection have been identified	The estimate of the time lag between infection and reporting of a rinderpest suspicion might be under- or overestimated
	5	Very few references available to estimate the time from infection to suspicion, and no data obtained from EU	The effectiveness of the proposed monitoring period could be over- or underestimated
ToR 3	6	The kernel is based on analysis of a single epidemic (Pakistan in 1994) and may not be representative of transmission in other regions due to differences in farm density, management practices, etc	The effectiveness of the proposed zone size could be over- or underestimated