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Assessment of the control measures for category A diseases of Animal Health Law: Contagious Caprine Pleuropneumonia

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Abstract

EFSA received a mandate from the European Commission to assess the effectiveness of some of the control measures against diseases included in the Category A list according to Regulation (EU) 2016/429 on transmissible animal diseases ('Animal Health Law'). This opinion belongs to a series of opinions where these control measures will be assessed, with this opinion covering the assessment of control measures for Contagious Caprine Pleuropneumonia (CCPP). In this opinion, EFSA and the AHAW Panel of experts review the effectiveness of: (i) clinical and laboratory sampling procedures, (ii) monitoring period, (iii) the minimum radius of the protection and surveillance zones and iv) 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. Several scenarios for which these control measures had to be assessed were designed and agreed prior to the start of the assessment. Different clinical and laboratory sampling procedures are proposed depending on the scenarios considered. The monitoring period of 45 days was assessed as effective in affected areas where high awareness is expected, and when the index case occurs in an area where the awareness is low the monitoring period should be at least 180 days (6 months). Since transmission kernels do not exist and data to estimate transmission kernels are not available, a surveillance zone of 3 km was considered effective based on expert knowledge, while a protection zone should also be developed to include establishments adjacent to affected ones. Recommendations, provided for each of the scenarios assessed, aim to support the European Commission in the drafting of further pieces of legislation, as well as for plausible ad hoc requests in relation to CCPP.

Keywords: Contagious Caprine Pleuropneumonia, Disease control measures, *Mycoplasma capricolum* subsp. *capripneumoniae*, sampling procedures, monitoring period, protection zone, surveillance zone

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Summary

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

- the clinical and laboratory examination in their capacity to detect disease (or estimate the disease prevalence within an establishment), either in suspect or confirmed animals in a single establishment, or in establishments within restriction zones (ToR 1);
- the effectiveness of the duration of the monitoring period (for different scenarios) in the control of suspected and confirmed outbreaks (ToR 2);
- the size and duration of the restriction 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 (EFSA, 2020).

Specific clinical and laboratory procedures for Contagious Caprine Pleuropneumonia (CCPP) for each scenario of ToR 1 have not been found in the EU legislation. Specific sampling procedures for clinical and laboratory examination have been provided for some scenarios.

To answer ToR 2, and to assess the minimum length of time measures should 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 with *Mycoplasma capricolum* subsp. *capripneumoniae* (*Mccp*) and the time of reporting of a suspicion by the competent authority. The average time to the reporting of a suspicion was then used to assess the effectiveness of the length of monitoring periods. For most of the scenarios, the existing length of the monitoring period for CCPP (45 days) was considered sufficient (90–100% certainty it would be effective). Recommendations were given for some of the relevant scenarios. To assess the effectiveness of the minimum length of time in which the measures should be applied in the protection and surveillance zones, the average and the longest time assessed via the ELS were used, respectively. In this regard, the minimum length of time of the protection zone (45 days) and the surveillance zone (45 days) that must be in place according to existing legislation were also considered effective (90–100% certainty).

To assess the effectiveness of the minimum radius to be implemented in the protection and surveillance zones (ToR 3.1), transmission kernels could not be used because they do not exist in the literature and data to develop them are not available. Taken into consideration that *Mccp* is mainly transmitted by direct contact between animals, the length of the radius of 3 km for the surveillance zone is considered effective for preventing transmission in 95 or more out of every 100 protection zones set (95–100% certainty). The protection zone should include at least all the adjacent (contiguous) premises to the affected establishment, in which case it would prevent transmission outside the zone in 95 or more out of every 100 protection zones set (90–100% certainty).

Nevertheless, transmission over longer distances cannot be excluded if infected animals are moved outside the zones.

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1. Introduction

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

Regulation (EU) 2016/429 on transmissible animal diseases ('Animal Health Law'), hereinafter referred to as AHL, requires the Commission to lay down detailed rules on the disease control measures against listed diseases as referred to in point (a), (b) and (c) of its Article 9 (Category A, B and C diseases). The Commission is empowered to adopt delegated acts supplementing the rules laid down in Part III of Regulation (EU) 2016/429 on transmissible animal diseases (Animal Health Law) on disease control measures for listed diseases as referred to in point (a), (b) and (c) of its Article 9 (Category A, B and C diseases). Therefore, the Commission has developed and adopted a Delegated Regulation laying down rules for the prevention and control of certain diseases ('the Delegated Regulation'). The rules laid down in the Delegated Regulation are in respect of terrestrial animals largely replicating the rules currently in force concerning the disease control measures in the event of animal diseases with serious effects on the livestock as they have proven to be effective in preventing the spread of those diseases within the Union. Consequently, many animal disease control measures laid down in existing Directives will be, to the extent that not already done by the Animal Health Law, replaced by the rules provided in the Delegated Regulation. At the same time, these rules have been aligned with the international standards from the World Organisation for Animal Health (OIE), wherever these existed. However, certain disease control measures proposed in the Delegated Regulation, in particular in its Annexes, were considered as outdated i.e. possibly not based on most recent scientific evidence at the time of development. Their review is considered as necessary. Moreover, for those Category A diseases for which rules were not established before or were not detailed enough, certain disease control and risk mitigating measures are, due to the lack of scientific basis, extrapolated from other diseases, for which rules existed in the past. Finally, for some other diseases the evidence and scientific knowledge, was not available to the Commission and to the Member States at the time of developing the Delegated Regulation due to the time constraints. The following diseases are examples of the later: infection with Rift Valley fever (RVF), infection with *Mycoplasma mycoides* subsp. *mycoides* SC (Contagious bovine pleuropneumonia) (CBPP), Contagious caprine pleuropneumonia (CCPP), Sheep pox and goat pox, infection with 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 examinations to ensure the detection of the relevant Category A disease during the performance of official investigations in establishments that are affected or suspected to be affected by Category A diseases and visits in establishments located in restricted zones in accordance with Articles 6(2), 12(3), 13(3)(c), 14(1), 26(2) of the Delegated Regulation.

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

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

ToR 1.5 Animals for laboratory examinations to ensure the detection of the relevant Category A disease before and after being introduced in the affected 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 Annexes 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:

- 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

- 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 manuscript is one of the 14 opinions covering ToRs 1, 2 and 3 for Contagious Caprine Pleuropneumonia (CCPP).
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 contractor were defined (Annex D). The assessment of the effectiveness of the monitoring period will be done by assessing its ability to ensure that specific actions can be carried out without posing a risk of disease spread, if the monitoring period is calculated backwards or forwards from a specific date. If the length of the monitoring period estimated by EFSA is longer than the existing monitoring periods, the existing monitoring period will be considered not effective. If the length of the monitoring period estimated by EFSA is shorter than the existing monitoring period, this existing monitoring period will be considered effective from a disease control point of view. No assessment of the plausible unnecessary economic burden that may be placed on the stakeholders as a result of an excessive length of the monitoring periods will be done by EFSA.
e) The assessment of the minimum duration and the length of the 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 manuscript; nonetheless, the limitations that this assumption may have in the control of certain diseases will, when relevant, be discussed.
f) The following scenarios of the ToR 1 of Annex B are not relevant for the CCPP, and therefore not included in the assessment of the current Opinion:
    i) scenario 7 because protection zone for CCPP is no greater than 3 km radius
    ii) scenarios 10, 11, 16 and 17 because they are referring to poultry.
g) The duration of the monitoring period for CCPP as described in Annex II of the Delegated Regulation is 45 days.
h) The minimum length of the radius of the protection zone and surveillance zone for CCPP as described in Annex V of the Delegated regulation are at the level of infected establishment and 3 km, respectively.
i) The minimum duration of the measures in the protection and surveillance zone for CCPP as described in Annexes X and XI of the Delegated Regulation is 45 days for both zones.

2. Epidemiology and geographical distribution of CCPP

2.1. Aetiology

Contagious caprine pleuropneumonia (CCPP) is a severe contagious respiratory disease affecting mainly goats, possibly sheep and some species of wild ruminants. The causative agent is *Mycoplasma capricolum* subsp. *capripneumoniae* (*Mccp*), a wall-less bacterium (Mollicutes) and a member of the family Mycoplasmataceae. It belongs to a cluster of genetically closely related mycoplasma (‘*mycoides*

cluster') including *Mycoplasma capricolum* subsp. *capricolum (Mcc)*, *Mycoplasma leachii (Ml)*, *Mycoplasma mycoides* subsp. *capri (Mmc)* and *Mycoplasma mycoides* subsp. *mycoides* (*Mmm*) (Thiaucourt, 2003; OIE, 2009; Spickler, 2015; EFSA AHAW Panel, 2017; Thiaucourt et al., 2018; Manso-Silván and Thiaucourt, 2019; OIE, 2019).

2.2. Epidemiology

CCPP is primarily a contagious respiratory disease of domestic goats, although some cases of clinical infection in sheep have been reported (Litamoi et al., 1990). Since 2007, it has been shown that wildlife such as wild goats, Laristan mouflons and several antelopes and gazelles are also susceptible to the disease (Arif et al., 2007). CCPP is not a zoonotic disease (OIE, 2009; Spickler, 2015; EFSA AHAW Panel, 2017; OIE, 2019).

Transmission of CCPP occurs by direct contact with infected animals through inhalation of aerosolised agent. Short distance airborne transmission has been reported, but no indirect transmission routes (fomites, vectors) are described. It is suspected that chronically infected animals may act as potentially carriers (OIE, 2009; Spickler, 2015; EFSA AHAW Panel, 2017; OIE, 2019; Yatoo et al., 2019).

CCPP has been described since the end of the 19th century in Africa, where now it is endemic in a large part of the continent, in the Middle East as well as in Asia (including Pakistan and China and suspected in other countries). It is not present in the EU, but there is scientific evidence that it is present in Western Turkey (Thrace region) near the borders (Thiaucourt, 2003; OIE, 2009; Spickler, 2015; EFSA AHAW Panel, 2017; Özdemir et al., 2018; OIE, 2019).

The main control measures in the event of an outbreak include stamping out of the animals in the affected establishments, restrictions on the movements of animals and products, as well as surveillance and tracing activities within and outside the restricted zones. In endemic areas, antimicrobial treatments (e.g. tetracyclines, macrolides or quinolones) are effective in reducing losses in infected flocks. Although antibiotic treatment appears to cure infected animals clinically, the animals may remain carriers.

Inactivated commercial vaccines are available in several countries (e.g. Kenya, Ethiopia, Jordan, Turkey and Saudi Arabia) and are claimed by manufacturers to provide a 1-year protection, though their quality and efficacy have been questioned. Thus, the control of some vaccine batch contents by mass spectrometry has shown that many did not contain, by far, what is expected from a properly manufactured vaccine as described in the OIE manual (Thiaucourt et al., 2018). Vaccination has been used in some countries to control outbreaks, but its use in disease-free countries is limited mainly because of the current absence of DIVA vaccine and the low quality standards of the commercially available vaccines (OIE, 2009; Spickler, 2015; EFSA AHAW Panel, 2017; OIE, 2019).

2.3. Clinical signs and diagnosis

CCPP is a contagious disease and in outbreaks the morbidity can reach 100% and mortality 50–80%, depending on the immune status of the animals and the use or not of antimicrobial treatment. Stress due to transport or climatic conditions (cold or wet season) can favour outbreaks (Thiaucourt, 2003; OIE, 2009; Spickler, 2015; EFSA AHAW Panel, 2017; Yatoo et al., 2019).

The incubation period is usually 6–10 days, but varies from 2 days to 4 weeks, while some experimentally infected goats did not develop clinical signs until up to 41 days after exposure (Thiaucourt, 2003; OIE, 2009; Spickler, 2015). CCPP is a respiratory disease with acute, peracute and chronic forms. In the acute form, the first signs are high fever (41°C), lethargy and anorexia, followed by severe respiratory signs (coughing and dyspnoea). The cough is productive and painful. Abortion is common in pregnant goats. In the final stages, animals are unable to move and typically stand with front legs apart and extended neck, with saliva drooling and nasal discharge. Death occurs after 7–10 days from respiratory failure due to unilateral or bilateral pneumonia and pleuritis, characterised at necropsy by a yellow sero-fibrinous exudate in the thoracic cavity. In the peracute form, death can occur within 1–3 days. The chronic form is characterised by intermittent cough and nasal discharge, progressive debilitation and, without treatment, death after several weeks (Thiaucourt, 2003; OIE, 2009; Spickler, 2015).

Detection of *Mccp* can be performed preferably on samples taken from lesions at necropsy (lung tissue, pleural fluid, lymph nodes). Culture and isolation of *Mccp* is time consuming and often unsuccessful; therefore, PCR tests are now preferred. Current commonly used serological tests, performed on blood or serum samples in the field, are latex agglutination test (pen-side test for first-line detection) and a competitive ELISA (c-ELISA), the latter being recommended due to its high

specificity, because other assays can provide false-positive results due to cross reactions with other mycoplasma from the *mycoides* cluster. However, all serological tests developed for *Mccp* have a low sensitivity at individual level and should be used and interpreted at flock level. Paired sera taken 3–8 weeks apart in an infected flock can be used to confirm the diagnosis. Antibodies can be absent in the terminal stage of acutely infected animals and decline after a few months in chronic infections or in surviving animals (Thiaucourt, 2003; OIE, 2009; Spickler, 2015; OIE, 2019; Yatoo et al., 2019; OIE, 2021).

2.4. Geographical distribution of Contagious Caprine Pleuropneumonia

The disease was first described by Thomas in 1873 in Algeria (Yatoo et al., 2019; OIE, 2021). *Mccp* known as F38 biotype was first isolated *in vitro* in 1976 and shown to cause CCPP in Kenya (Yatoo et al., 2019; OIE, 2021).

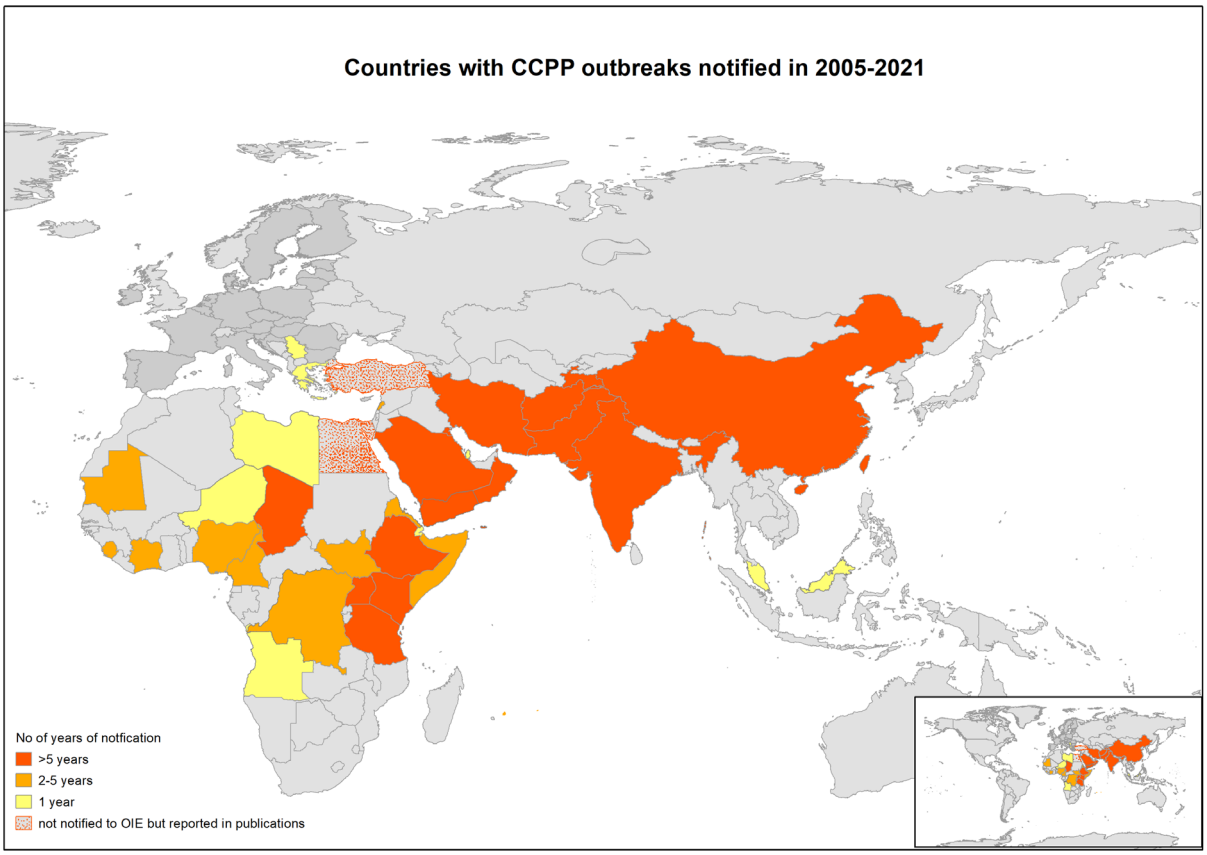

Figure 1: Countries that have notified to the OIE outbreaks of Contagious Caprine Pleuropneumonia (CCPP) in 2005–2021 according to the number of years of notification: more than 5 years of notification (red), from 2 to 5 years (orange) and only 1 year (yellow). Turkey and Egypt are included (red dots) in this map even if they have not reported outbreaks to the OIE, because there are scientific publications confirming the presence of the disease in their territory. Data sources: OIE and publications (Özdemir et al., 2005; Çetinkaya et al., 2009; Özdemir et al., 2018; Abd-Elrahman et al., 2019; Selim et al., 2021).

Maps based on official data from the OIE may not accurately reflect the geographical distribution of CCPP. Some countries declare CCPP outbreaks without proper confirmation of *Mccp* presence (e.g. Mauritania, Sierra Leone, Ivory Coast), while some others that experienced CCPP outbreaks did not report to the OIE, e.g. Egypt (Abd-Elrahman et al., 2019; Selim et al., 2021). Consequently, it is likely that geographical distribution of CCPP is more widespread in Africa, the Middle East and Central Asia (Figure 1).

In Europe, according to Stylianopoulos (1933), CCPP was demonstrated in Greece between 1920 and 1930 (EFSA AHAW Panel, 2017). The lack of available laboratory methods to differentiate the different types of mycoplasmas at that time raises questions if it was CCPP infection. CCPP has been

reported to the OIE by Greece in 2006 and by Serbia in 2009 (Greece OIE-WAHIS, 2006; Serbia OIE-WAHIS, 2009).

Although Turkey has never reported the disease to OIE WAHIS (which only collates data since 2005), they experienced an outbreak in 2002 and since then the disease may be considered endemic (Özdemir et al., 2005). A serological study conducted in 2014 suggested a seroprevalence of between 5.9% and 17.6% in goats in most provinces of Turkish Thrace and *Mccp* was identified by PCR in lung samples collected in 2013 and 2014 from the same area (Özdemir et al., 2018). In addition, from a survey conducted by Çetinkaya et al. (2009) in eastern Turkey from February 2006 to May 2007, *Mcpp* has been identified in cultures of 55.6% of samples (lungs, pleural fluid, nasal) and by PCR in 31.1% of samples from sheep and goats suspected for CCPP in the field or found with pneumonic lesions in slaughterhouse.

3. Data and methodologies

3.1. Methodologies

3.1.1. Methodology used in ToR 1

A qualitative assessment of the clinical and laboratory procedures was performed to answer ToR1. Estimation of sample size, when needed, was carried out using the RiBESS+ tool.[1]

To answer the 1st scenario of ToR 1 in the event of CCPP suspicion in an establishment, some additional calculations were needed.

The positive predictive value of the clinical examination ($PPV_{clinical}$, the probability that a selected animal clinically classified as positive is truly *Mccp* infected) at a certain design prevalence is given by the following equation:

$$PPV_{clinical} = \frac{P(\text{true positive})}{P(\text{true positive}) + P(\text{false positive})} = \frac{Se_{clinical} \cdot DP}{Se_{clinical} \cdot DP + (1 - DP) \cdot (1 - Sp_{clinical})}, \quad (1)$$

where $Se_{clinical}$ is the sensitivity of the clinical examination, DP is the design prevalence that needs to be detected and $Sp_{clinical}$ is the specificity of the clinical examination.

The overall probability to detect *Mccp* or antibodies by a laboratory test (PCR or c-ELISA) with a single sample from an animal with clinical signs would be

$$P_{detect} = PPV_{clinical} \cdot Se_{labtest}, \quad (2)$$

where $Se_{labtest}$ is the sensitivity of the laboratory test used.

The probability that at least one truly infected animal is detected is given by the equation:

$$Se_{overall} = 1 - [(1 - P_{detect})]^n. \quad (3)$$

Based on the $Se_{overall}$ to be achieved, the n (number of samples needed to be collected) can be calculated

$$n \cong \frac{\ln(1 - Se_{overall})}{\ln(1 - P_{detect})}. \quad (4)$$

3.1.2. Methodology used in ToR 2

To answer ToR 2, an extensive literature search (ELS) was outsourced by EFSA (OC/EFSA/ALPHA/2020/02 - LOT 2). The aim of this ELS was to answer the epidemiological question: 'what is the average, shortest and longest period of time (measured as the number of days from the earliest point of infection with CCPP to the time of declaration of a suspicion by the competent authority after the clinical investigation by an official veterinarian) for an outbreak of CCPP to be reported'. To answer this question, an ELS on case reports, papers describing outbreaks or epidemics of CCPP and any other relevant grey literature or data was carried out. For inclusion in the ELS, the earliest point of infection had to have been estimated through an epidemiological investigation. Papers and other sources of

[1] RiBESS+ tool https://efsa.openanalytics.eu/app/ribess

data were excluded, when the earliest point of infection was determined purely by subtracting a known incubation period from the date of the suspicion of the outbreak. 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. The general protocol used for the ELS is shown in Annex 5 of the Technical report on Methodology (EFSA, 2020). The ELS carried out for CCPP (see also Section 4.2) could not provide any objective conclusion on the current monitoring period for CCPP (45 days). Therefore, the assessment was based on the experts' knowledge using the maximum incubation period of (41 days) as reported in the OIE. To answer the scenario 5 of ToR 2 in relation to semen, an ELS was performed to determine the time of seroconversion as it can be identified by different laboratory methods. This work was outsourced by EFSA to an expert (EOI/EFSA/SCIENCE/2020/01 – CT 02 ALPHA).

3.1.3. Methodology used in ToR 3

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

No studies were identified which either estimated transmission kernels for the spread of CCPP between farms or provided data that could be used to estimate a kernel. Furthermore, no kernels or data were available for other diseases with similar transmission routes as CCPP. Accordingly, expert knowledge was used to assess the zone sizes for CCPP.

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 4.2.1 were used. Further details can be found in the Technical report on Methodology (EFSA, 2020).

Nevertheless, the ELS carried out for CCPP (see also Section 4.2) could not provide any objective conclusion on the current duration of the zones (45 days). Therefore, the assessment was based on the expert's knowledge using the maximum incubation period as reported in the OIE (41 days).

3.1.4. Uncertainty

A description of the methodology followed to deal with uncertainty is provided in a Methodology report published by EFSA (2020). For this opinion, the impact of the uncertainties identified in the assessment of ToRs 1 (scenarios 1, 2 and 3) were assessed collectively after transforming the objective of these ToRs into well-defined quantities of interest. Sources of uncertainty identified in the assessment are listed in Annex F.

For scenario 1 in ToR1, which aims to assess the effectiveness of existing or proposed sampling procedures to detect or rule out the presence of CCPP in kept animals in a suspect establishment based on clinical and laboratory examinations, it was agreed that a sampling strategy would be considered effective if it would allow the detection of the disease in at least 95% of the goat establishments in which it was applied. Two quantities of interest (QoI) were defined based on the reason triggering the suspicion (occurrence of clinical disease and CCPP-related mortality or other reasons in the absence of clinical disease and mortality, e.g. contact tracing with a previously CCPP-infected holding) and the sampling and diagnostic approach proposed:

- QoI 1a: Probability that in 95 (or more) out of every 100 **goat establishments suspected due to the occurrence of clinical disease and mortality with signs/lesions resembling to CCPP**, the presence of the disease would be detected based on **laboratory tests (PCR/culture) performed on dead animals with characteristic lesions if present, or clinical inspection involving testing in CAPRILAT at least 20 animals with clinical signs and the slaughter of at least five positive reactors for post-mortem inspection and PCR,**
- QoI 1b: Probability that in 95 (or more) out of every 100 **goat establishments suspected (and eventually confirmed) but in which no CCPP-compatible clinical signs/lesions have been found** (e.g. suspected due to contact tracing), the presence of the disease would be detected based on **c-ELISA performed on all animals in the establishment (for establishments with < 255 animals) or between 255 and 370 animals (including those with unspecific signs if present) depending on establishment size (see**

Table 3) **up to two times separated by 3 months in case no positive animals are detected in the first establishment test.**

For ToR2, which aims to assess the effectiveness of the length of the monitoring period under different scenarios, a given length was considered effective if it would serve its scenario-specific purpose in at least 95% of the cases in which it was implemented. In this case, four QoI were defined based on the scenarios among those listed in Annex D and whether the suspect establishment was the first case in a region or not:

- QoI 2a (scenarios 1, 2 and 4): Probability that, in 95 (or more) of every 100 **goat establishments suspected (and eventually confirmed) in a previously unaffected region or country**, the initial infection would have occurred within 45 days before the date of notification of the suspicion.
- QoI 2b (scenarios 1, 2 and 4): Probability that, in 95 (or more) of every 100 **goat establishments suspected (and eventually confirmed) in a region or country where CCPP cases have been already reported**, the initial infection would have occurred within 45 days before the date of notification of the suspicion.
- QoI 2c (scenario 3): Probability that, in 95 (or more) of every 100 of these **independent epidemiological units within CCPP-affected goat establishments that eventually become infected**, infection would have occurred within 45 days before the date of confirmation of infection in the establishment.
- QoI 2d (scenario 6): Probability that, in 95 (or more) out of every 100 **repopulated CCPP-affected goat establishments that become reinfected**, reinfection takes place in the 45 days following the introduction of the animals.

For ToR3, which aims at the assessment of the effectiveness of the minimum radii established in the protection and surveillance zones, a given radius was assumed to be effective if it would prevent transmission to outside of the zone in the 45 days following the setting up of these zones. In this case, two QoI were defined:

- QoI 3a: Probability that, in 95% or more of all protection zones established around an affected establishment, there is no transmission to outside the protection zone in the 45 days following their establishment.
- QoI 3b: Probability that, in 95% or more of all surveillance zones established around an affected establishment, there is no transmission to outside the surveillance zone in the 45 days following their establishment.

Members of the WG provided their judgements individually for each of the QoI, along with the rationale supporting them, using the probability scale of **Table 1** proposed in the EFSA uncertainty guidance (EFSA Scientific Committee, 2018).

Table 1: Approximate probability scale used for quantification of the uncertainty in the assessment

Probability term	Subjective probability range	Additional options	
Almost certain	99–100%	More likely than not: > 50%	Unable to give any probability: range is 0–100%
Extremely likely	95–99%		
Very likely	90–95%		
Likely	66–90%		
About as likely as not	33–66%		Report as 'inconclusive', 'cannot conclude', or 'unknown'
Unlikely	10–33%		
Very unlikely	5–10%		
Extremely unlikely	1–5%		
Almost impossible	0–1%		

Individual judgements and rationales were discussed during a meeting in order to elicit a consensus group judgement for each QoI. The outputs of this assessment are provided in the respective Sections of this Opinion.

4. Assessment

4.1. Assessment of sampling procedures

4.1.1. Assessment of sampling procedures in the event of suspicion or confirmation of Contagious Caprine Pleuropneumonia (CCPP)

4.1.1.1. In the event of a suspicion of CCPP in kept animals of listed species in an establishment

The purpose of this section is to assess the effectiveness of disease-specific sampling procedures of animals of listed species in a suspect establishment, based on clinical examination (ToR 1.1) and laboratory examination (ToR 1.2), in their ability to detect CCPP 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 Article 6(2) of the Delegated Regulation (EU) 2020/687
- Commission Implemented Regulation 2018/1882 on listed species

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

1) It concerns an event of suspicion of CCPP in an establishment of kept animals of listed species for CCPP;
2) The listed species for CCPP as provided in Commission Implemented Regulation 2018/1882 are those of *Ovis* ssp., *Capra* ssp., *Gazella* ssp.;
3) In the event of a suspicion of CCPP, the competent authority shall immediately conduct an investigation to confirm or rule out the presence of the CCPP;
4) On the day of the investigation, the official veterinarians must perform clinical examinations and collect samples for laboratory examinations.

Summary of sampling procedures

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

Information on clinical examination and laboratory methods have been described in the OIE Terrestrial Manual (OIE, 2021) and in EFSA Scientific Opinion on CCPP (2017).

The OIE manual states that as isolation of *Mccp* is so difficult, molecular techniques are preferred for identification of the agent. Samples to be taken from live animals are bronchoalveolar washings or pleural fluid obtained by puncture. Samples to be taken at necropsy are lung lesions, lymph nodes and pleural fluid. Several serological tests are available.

Assessment

Clinical examination and inspection of lesions

In the scenario of a suspicion of CCPP in an establishment, the purpose of the clinical examination[2] (including both the initial visual inspection of the flock and the individual examination of the animals) is to identify suspect cases and collect samples for further laboratory analysis.

No data on the sensitivity and specificity of clinical examination exist in the literature. Nevertheless, the specificity cannot be considered high since clinical signs of CCPP are similar to many common respiratory diseases (e.g. pasteurellosis and other mycoplasmoses). Most strains of mycoplasmas

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

species frequently observed in Europe, e.g. *Mmc* or *Mcc*, mainly cause arthritis, mastitis, keratitis, but only a few display an increased lung tropism where they create lesions and generate respiratory signs. Consequently, unilateral pleuropneumonia not accompanied by keratitis, arthritis and mastitis is rather typical in *Mcpp*-infected animals.

Lesions observed at necropsy and are supportive of CCPP are (see Figure 2 and Figure 3): (i) unilateral pleuropneumonia, (ii) presence of a straw-coloured exudate in the thoracic cavity, (iii) renal infarct and (iv) presence of enlarged regional lymph nodes. In contrast to CBPP, there are no '*sequestra*' formed in lungs with CCPP, but the lesions in affected lungs enter a necrotising process. Animals entering a chronic stage of the disease will be much more difficult to spot as clinical signs may wane.

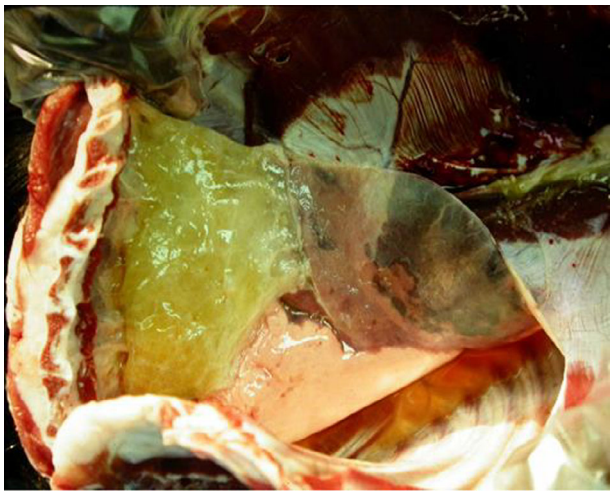

Figure 2: Thoracic cavity of a CCPP-infected kid showing the lesions in lungs, the accumulation of pleural fluid and the fibrin which starts to coagulate (Ethiopia 1991, François Thiaucourt, CIRAD and National Veterinary Institute Ethiopia)

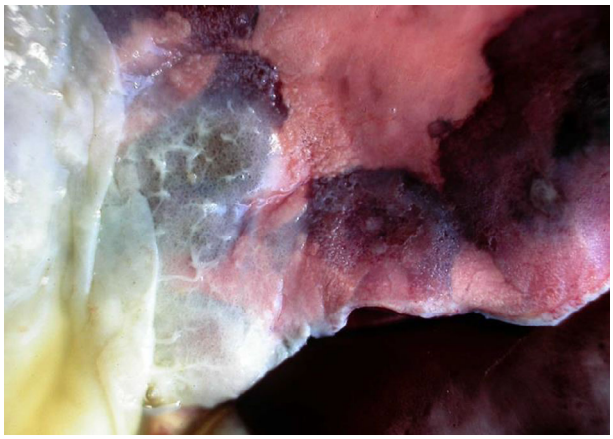

Figure 3: Detail of CCPP lung lesions in a goat: The picture shows the initial stages of pneumonic lesions, which are progressively extending, ultimately leading to the whole lung lobe being affected. The centres of the lesions are necrotising (grey point) and the active initial inflammatory process is observed at the periphery (Ethiopia 1991, François Thiaucourt, CIRAD and National Veterinary Institute Ethiopia)

Consequently, in non-affected areas and in areas not neighbouring affected ones or in apparently disease-free areas, clinical signs most likely will not trigger the suspicion of CCPP; other more common respiratory diseases will be suspected and animals will probably be treated with antimicrobials.

In Europe, it is unlikely that a CCPP suspicion would initially be raised upon the onset of respiratory signs, as goat flocks are very frequently infected by other mycoplasma species. Hence, antimicrobial treatments are frequently administered. Sheep are seldom affected by *Mccp* and generally less

affected by mycoplasmas of the *mycoides* cluster. The most frequent one in sheep is *M. agalactiae* (a species close to *Mycoplasma bovis* in cattle). Isolation of *Mccp* from sheep is rare but may occur in mixed sheep and goat flocks.

The suspicion may arise in case of establishments with listed species: (i) seropositive results of active surveillance performed in high-risk areas, (ii) mortality with the only lesions observed at necropsy being unilateral pleuropneumonia, (iii) when there is an epidemiological link with another affected establishment or area.

Laboratory examination

The preferred sample matrices for early detection and confirmation of CCPP are pleural fluid for *Mccp* DNA detection followed by affected lung tissue and regional lymph nodes.

PCR is the method of choice for the early detection and confirmation of *Mccp* (in the case of an acute outbreak). Pleural fluid samples contain high quantities of *Mccp* and can be stored at −20°C for very long periods to send aliquots to reference laboratories able to isolate *Mccp*.

Several PCR methods exist (Woubit et al., 2004; Lorenzon et al., 2008; Settypalli et al., 2016). For *Mccp*, the sensitivity of the real-time PCR seems greater compared to the one for *Mmm* (Lorenzon et al., 2008). Analytical sensitivity is not an issue with acute CCPP cases, because the mycoplasma concentration is huge in the pleural fluid.

The presence of pathogens of the genus *Mycoplasma* can be checked with a universal PCR targeting the 16S rDNA genes (van Kuppeveld et al., 1994). If positive, other PCR tests can be performed for the specific detection of *Mccp*. Alternatively, the amplified rDNA fragment can be sequenced to obtain an identification at the species level (not necessarily sufficient to distinguish between subspecies though).

Sequencing of *Mccp* genome could also be performed directly from pleural fluid as it contains very high quantities of *Mccp* (5 ml of pleural fluid can be centrifuged at 1,000 g for 15 min to remove inflammatory cells, the supernatant is then centrifuged at 12,000 g for 30 min and the pellet resuspended in 100 µL to perform DNA extraction before sequencing).

Isolation of *Mccp* is very difficult due to the fastidiousness of this mycoplasma. It requires very rich media and stereomicroscopes for observations since colonies are very small. Laboratories performing routine diagnostic procedures are usually not able to isolate *Mccp*.

A c-ELISA developed and validated at CIRAD also exists and is currently the only serological test commercially available (marketed by IDEXX[3]) that can lead to a specific detection of antibodies to *Mccp*. This method has been validated for goats (Peyraud et al., 2014). It has also been used for other species, e.g. gazelles (Lignereux et al., 2018) and sheep (Selim et al., 2021), but the performance of the test in sheep and gazelles is unknown.

Although paired sera taken 3–8 weeks apart in an infected flock is recommended by OIE (OIE, 2021), it is not considered necessary for c-ELISA as this test has been designed to be strictly specific. The sensitivity of the c-ELISA is low at the early stages of infection, when no or low amounts of antibodies exist but then *Mccp* can be detected by PCR in lesions. In addition, the sensitivity will decrease when the antibodies have waned and then repeating the test would not bring any added value.

There is also a latex agglutination test (LAT) based on latex beads sensitised with polysaccharides (CapriLAT, APHA diagnostics[4]). This pen-side test can be used to detect ongoing or recent outbreaks as it detects mostly IgM antibodies. The specificity of the LAT has not been properly evaluated but as it detects antibodies to *Mccp* polysaccharides, cross reactions are expected with the other mycoplasmas, members of the *mycoides* cluster, which are known to occur frequently in goats in Europe. *Mccp* shares the same polysaccharide at its surface with *Mcc* and with *Ml*. Therefore, the presence of such bacteria may lead to false-positive reactions. Examples of cross reactions have been observed in non-listed species in Poland (Dudek et al., 2016).

The complement fixation test (CFT) should not be used for CCPP as there are many cross reactions within the *M. mycoides* cluster species, or closely related species, that can be found in goats (*Mcc*, *Mmc*, *Ml*, *M. putrefaciens*, *M. ferriruminatoris*, etc.).

In a supposedly CCPP-free country, LAT and CFT will lead to many false-positive results due to the high number of mycoplasma species affecting goats, which share antigens with *Mccp*.

[3] C-ELISA by IDEXX is the only one available in the market.
[4] CapriLAT by APHA is the only one available in the market.

Development of new procedures

The sampling procedures for CCPP detection are related to the epidemiological conditions that may trigger the suspicion and, in case of EU countries, the suspicion may be raised: (i) at an establishment with clinical signs compatible to CCPP and mortalities where unilateral pleuropneumonia is observed at necropsy without any other lesions and no other mycoplasma species are isolated (taken into consideration that *Mmc* and *Mcc* grow easily), (ii) when animals of listed species with clinical signs are detected at an establishment located in an affected area or at an establishment epidemiologically linked with an affected one, and (iii) at an establishment without clinical signs that is epidemiologically linked with an affected establishment or area.

Clinical Examination

Although clinical examination has marked limitations for the diagnosis and confirmation of CCPP, it is an important tool to identify the animals with clinical signs or history of clinical signs to be sampled for further laboratory analyses.

The acute lesions (unilateral pleuropneumonia) identified in the lungs and pleural cavity of a high number of goats in an establishment, even though considered pathognomonic, are not enough alone to confirm CCPP and further laboratory analysis is necessary to confirm the disease. Therefore, in some suspect establishments, it is necessary to kill some animals to collect samples from the lesions.

The individual clinical examination should focus primarily on those animals identified by the owner as suspects for CCPP or identified by the veterinarians based on clinical signs resembling CCPP during the initial visual inspection of the flock (targeted sampling).

The health history of the establishment at least 45 days (monitoring period as defined in delegated Regulation) backwards from the day of the suspicion and subsequent visit by the veterinarian should be investigated during the interview with the farmers and the inspection document. Any evidence of respiratory symptoms, deaths or contacts with affected establishments and the use of antimicrobials as treatment of respiratory symptoms should be thoroughly investigated and the affected animals prioritised for clinical examination and sampling.

In case of mixed establishments with goats and sheep, clinical examination should be performed on goats since *Mcpp* affects the goats above other small ruminants. Clinical examination in an establishment with sheep only can be performed to identify sheep with respiratory signs or mortality if there is an adjacent affected establishment or an epidemiological link with an affected establishment.

Laboratory Examination

Suspicion at an establishment with clinical signs compatible with CCPP and mortalities where unilateral pleuropneumonia is observed at necropsy without any other lesions and no other mycoplasma species are isolated (taken into consideration that *Mmc* and *Mcc* grow easily).

The sampling for laboratory analysis should be initiated with those animals that are found dead and preferably those with a history of respiratory disease without receiving antimicrobial treatment.

In establishments with sheep and goats, the samples should be collected from goats. In establishments with sheep only, samples can be collected from sheep with respiratory clinical signs and dead sheep if there is an adjacent affected establishment or there is an epidemiological link with an affected establishment. Thorough inspection of the lungs and the pleural cavity should be implemented to identify the characteristic lesions of unilateral pleuropneumonia. Samples of lungs with lesions, regional lymph nodes and pleural fluid should be collected from the dead animals to be cultured and tested with PCR methods.

In addition to dead animals or if dead animals are not available for sampling, animals with clinical signs associated with CCPP should be killed for necropsy to identify the pathognomonic lesions and to collect samples to be tested by PCR.

The clinical examination is not specific for CCPP diagnosis, and its positive predictive value ($PPV_{clinical}$) which indicates the probability that a selected animal clinically classified as CCPP positive is truly *Mcpp* infected, is expected to be low. Nevertheless, in combination with LAT, it will increase the likelihood that an *Mcpp*-infected animal will be identified by laboratory tests and will reduce the number of animals to be tested (Figure 4 and Table 2).

To justify the procedure proposed, the following assumptions were made:

i) A specificity of clinical examination of 80%, to take into account the existence of another respiratory disease in the establishment since unilateral pleuropneumonia is typical for CCPP,

ii) A design prevalence in an establishment where CCPP is suspected is assumed to be 10% as the infection may have been present for several months, and
iii) A sensitivity of clinical examination of 90% in naive susceptible species, since veterinarians will easily identify respiratory distress in an animal like coughing, dyspnoea, lacrimation.

Based on the above assumptions, the $PPV_{clinical}$ would be 33% (see equation 1 in Section 3.1.1). Consequently, the prevalence of animals infected by CCPP in each selected group of animals with clinical signs is 33%, which requires at least eight animals to be killed, necropsied and tested by PCR alone (and not LAT) to achieve a confidence level of 95% for confirmation of infection in the flock (Figure 4 and Table 2).

To reduce the number of animals to be killed, necropsied and sampled for PCR, an additional step is introduced; the LAT is implemented in the field to blood samples collected from at least 20 animals classified as CCPP positive based on clinical examination. The LAT is proposed here only to support the selection of animals to be killed for necropsy and not for the confirmation of CCPP. The probability that animals that are both clinically suspected and LAT positive being CCPP infected is higher than that in animals that are only clinically suspected, so fewer animals have to be submitted to necropsy for reliable detection.

For the LAT, the sensitivity is considered 70% and the specificity is 70% because of possible cross reactions with other mycoplasmas. With a design prevalence of 33% (positive predictive value of the clinical examination), the positive predictive value following LAT increases to 54% (see equation 1 in Section 3.1.1).

The overall probability to detect CCPP by PCR with sensitivity of 94% with a single sample from lesions from a culled animal with clinical signs that tested positive to LAT would be 51% (equation 2 in Section 3.1.1). In this case, at least five animals should be killed, to detect the CCPP by PCR in lesions with confidence level of 95% (Figure 4 and Table 2).

Consequently, to detect an outbreak with at least 95% confidence, and taken into consideration the assumptions and the uncertainty, it is recommended to collect blood samples from up to 20 animals with clinical signs and test them first with LAT in the field. From those animals that test positive to LAT, five should be killed and samples from the lesions should be tested by PCR (Figure 4 and Table 2).

In the event that all 20 samples are negative by LAT, it can be considered that the animals are in the later stages of infection and no more IgM is present. In that case, there will be some c-ELISA positives. If both the LAT and c-ELISA are negative, it is very, if not extremely unlikely that the clinical signs are caused by *Mccp*. To further increase the certainty of the absence of CCPP, a random sample of animals (according to Table 3) could be tested by c-ELISA (which will detect 'older infections').

In the event that none of the targeted animals are positive for LAT, restrictions on the establishment are maintained until negative testing with c-ELISA and further clinical examination of the animals can resolve the suspicion. The visit to the establishment and the sampling procedures should be repeated after a period of 45 days to have a very high certainty of the absence of the infection.

Based on the available evidence and considering the existing uncertainty regarding the performance of the diagnostic tests, **it was concluded with a 90–100% certainty that the proposed sampling strategy** (post-mortem examination and testing on dead animals with lesions if present or LAT testing of at least 20 animals with signs and slaughter of at least five LAT-reactors for post-mortem inspection and PCR) **would be able to detect the infection in 95 or more out of every 100 CCPP-affected establishments in which suspicion was triggered due to the occurrence of clinical signs (given that there is an epidemiological link with affected establishment or area) or due to findings at slaughterhouse or dead animals resembling CCPP**. The 90–100% certainty range was due to the potential for increased difficulty detecting infection in the case of smaller flocks in which sample size would be necessarily more reduced, and therefore, the limited sensitivity of the diagnostic tests could lead to increased uncertainty regarding the detection of the infection. Importantly, this judgement assumes that the diagnostic techniques are already set up and optimised in laboratories conducting the testing.

Table 2: Minimum number of animals with clinical signs needed: (i) to be killed in order to collect samples for PCR without and with LAT testing and (ii) to be sampled and tested with c-ELISA in order to detect or rule out the CCPP in the establishment with confidence level 95% and 99% assuming a design prevalence in the establishment of 10%. Se: sensitivity of the test and Sp: specificity of the test

Target population			**Minimum number of animals needed for sampling**	
Animals found positive in clinical examination Design prevalence DP = 10% Clinical examination Se = 90%	**Sample matrices**	**Laboratory method**	**95% confidence**	**99% confidence**
Animals to be killed for necropsy	Lung Lesions, pleural fluid, lymph nodes	PCR (Se = 94%)	8	13
Animals found positive to LAT to be killed for necropsy	Lung lesions, pleural fluid, lymph nodes from killed animals with clinical signs and positive to LAT (BoviLAT)8	LAT (Se = 70%, Sp = 70%) and PCR (Se = 94%) to those animals found positive to LAT	5	7
Live animals	Blood from live animals with clinical signs	c-ELISA (Se = 70%)	12	18

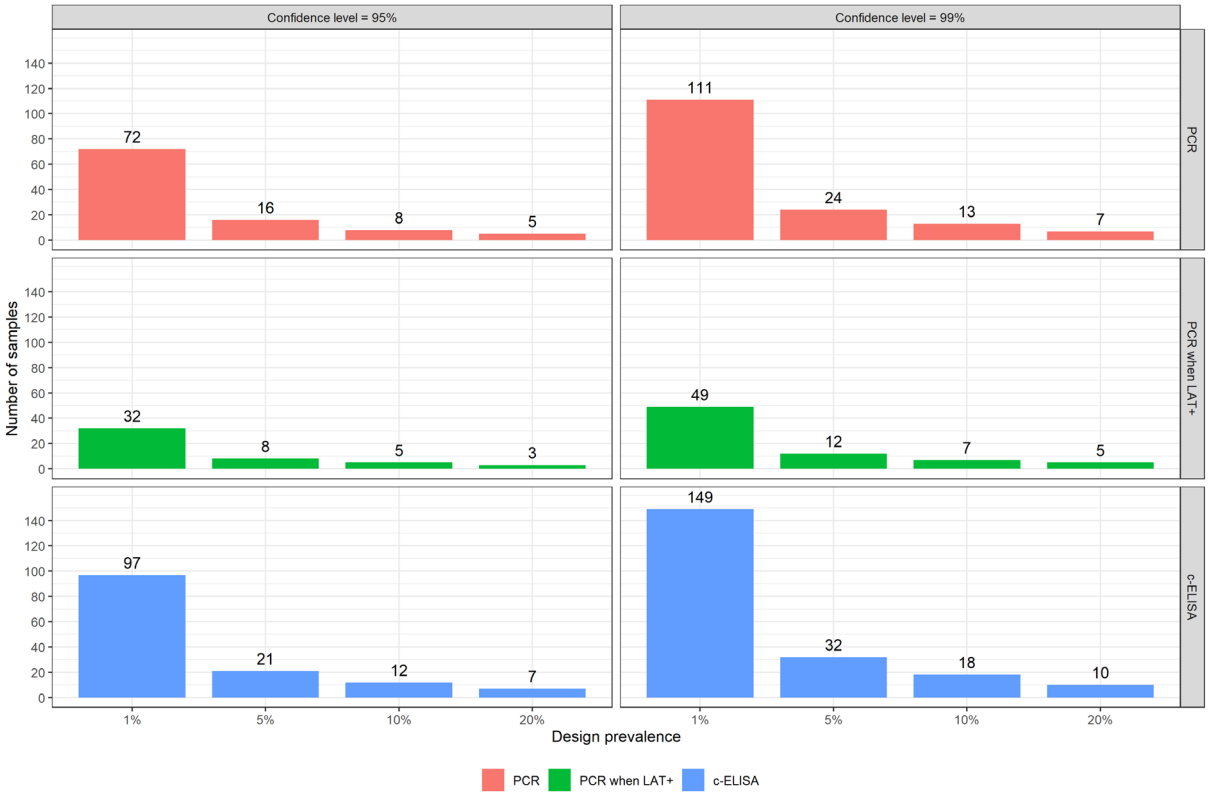

Figure 4: Minimum sample size (animals) needed to achieve 95% and 99% confidence level accordingly in detecting one infected animal with clinical signs, assuming different values for design prevalence (1%, 5%, 10%, 20%) by using: (i) directly PCR to samples from killed animals, (ii) PCR to samples from killed animals that have been previously positive to LAT test and (iii) c-ELISA to samples from live animals

Suspicion at an establishment with animals without clinical signs: in an establishment epidemiologically linked with affected establishment or affected areas and in establishment located in affected areas or close to affected areas.

In the absence of animals with clinical signs or dead animals, blood samples are collected from live animals according to Table 3 to be examined by c-ELISA (IDEXX) assuming prevalence of 1% in the establishment. In addition, a low design prevalence is assumed as there are no clinical signs indicating a low prevalence should the disease be present. c-ELISA can detect IgG antibodies from infected and recovered animals even if they have been treated by antimicrobials. The IgG antibodies can be detected for several months although the exact duration cannot be ascertained with confidence. Here, the LAT is not recommended, because of the low sensitivity in later stages of infection and the low specificity given the absence of the clinical signs.

Table 3 and Figure 5 demonstrate that, using a test such as c-ELISA with low sensitivity of 70% in establishments where low (1%) prevalence is expected, it is not possible to detect or rule out the CCPP with a confidence level of 95%, when the size of the establishment is n < 255 animals, even if all the animals are tested.

Table 3: Minimum sample size for 95% confidence level (probability to detect CCPP-infected animals) achieved in an establishment as a function of the flock size, assuming a target (design) prevalence (DP) of 1% and 10%, and using two different values of the sensitivity of the c-ELISA Se = 70%

	c-ELISA (Se = 70%) Examples of sampling calculations using different design prevalence of 1% and 10%					
	DP = 1%			**DP = 10%**		
Flock size	**Design prevalence**	**Sample size**	**Confidence**	**Design prevalence**	**Sample size**	**Confidence**
10	10%*	10	69%	10%*	10	69%
20	5%*	20	69.5%	10%	20	91.4%
50	2%*	50	69.8%	10%	32	95%
70	2%*	70	70%	10%	34	95%
100	1%	100	70%	10%	36	95%
200	1%	200	91%	10%	39	95%
250	1%	250	91%	10%	40	95%
255	1%	230	95%	10%	39	95%
300	1%	271	95%	10%	40	95%
350	1%	315	95%	10%	40	95%
500	1%	322	95%	10%	41	95%
750	1%	334	95%	10%	41	95%
1,000	1%	369	95%	10%	41	95%

*: The minimum number of animals with clinical signs in a flock is one it cannot be lower. Therefore, the values provided here for the design prevalence are the result of the ratio between 1 and the flock size rounded to an integer.

Values in red: The confidence level of 95% cannot be reached even if all the animals in the establishment are tested.

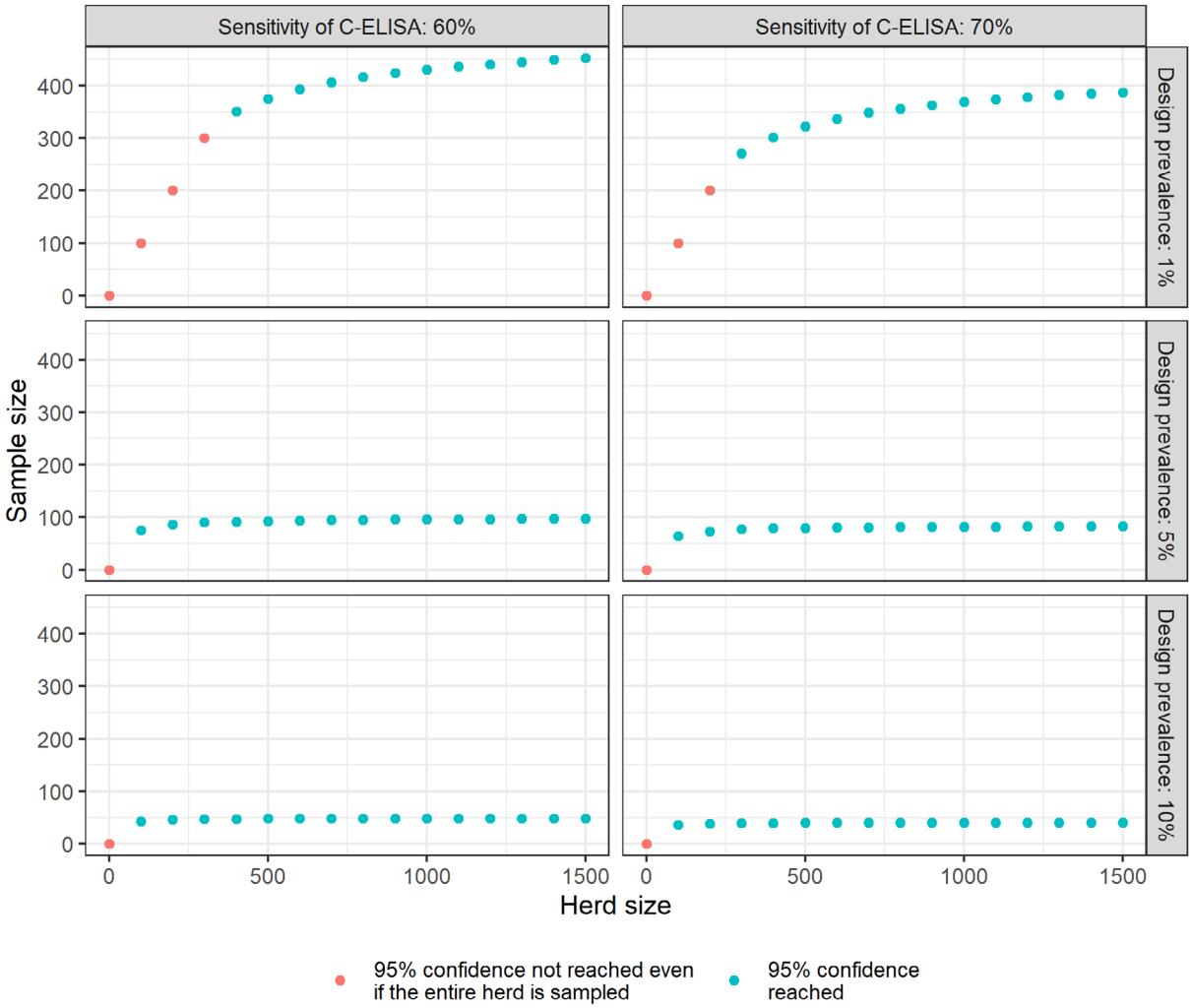

Figure 5: Minimum sample size, to detect animals with CCPP with confidence level of 95% and 95%, assuming design prevalence of 1%, 5% and 10% using c-ELISA with different sensitivity levels (Se: 60%, 70%)

In case of negative or inconclusive results, based on the epidemiological situation and the risk assessment conducted at national level, the sampling procedures should be repeated at least 45 days later (monitoring period in Delegated Regulation). If the establishment is infected, the prevalence will increase during this period and the likelihood of detection will also increase (Table 3 and Figure 5).

Overall, and considering the uncertainties regarding the sensitivity of the serological tests depending on the stage of infection of tested animals and the possible stage in which affected establishments may be when sampling takes place (e.g. in an early stage of infection with many animals in the incubation period, or in a more advanced stage with more animals in a chronic stage of infection), **it was concluded with a 90–100% certainty that the proposed sampling strategy** (c-ELISA of all animals for establishments with < 255 animals or 255/369 animals depending on flock size up to two times separated by 3 months if no reactors are detected in the first flock test) **would be able to detect the infection in 95 or more out of every 100 CCPP-affected establishments in which the suspicion is raised in the absence of clinical signs or CCPP-related mortality**. Some uncertainty exists due to the possible existence of animals in early stages of infection (whose proportion should nevertheless be low in the second sampling), the presence of very low antibody titres in infected animals due to the circulation of low virulence strains, and the involvement of small flocks in which available sample sizes will be reduced and therefore limit the potential of the proposed sampling strategy to detect infected establishment at low prevalence levels. Again, this judgement is based on an adequate performance of the diagnostic techniques, which may not be always expected if testing procedures are not well standardised in the laboratories conducting the testing.

Given the limitations of knowledge on the quantitative characteristics of the laboratory diagnostic methods, the confidence for the CCPP diagnosis can be increased by: (i) targeted sampling from animals with clinical signs or from lesion in carcasses or animals epidemiologically linked to the affected ones (closest animals or with common origins) that will increase the sensitivity, (ii) implementing a combination of laboratory methods in different samples, (iii) using experienced and trained veterinarians able to recognise the characteristic lesions of CCPP and (iv) training on sampling collection and transport.

In addition, the nomination of a European Union Reference Laboratory (EURL) for CCPP would increase the preparedness and the capacity of the National Reference Laboratories (NRL) to early detect CCPP in case it enters the EU territory. An EURL may drive studies and test validations adjusted to the needs of EU countries that are mainly focused on highly sensitive and specific tests able to detect the disease at early stages.

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 CCPP

The purpose of this section is to assess the effectiveness of disease-specific sampling procedures, based on laboratory examination (ToR 1.2), in their ability to detect the disease in the event of preventive killing, and in their ability to support with the epidemiological investigation (disease detection, prevalence estimation, agent 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 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 should be 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) The competent authority shall collect samples for laboratory examination;
4) The purposes of the sampling are:

   a) to support the epidemiological enquiry:

      i) to identify the likely origin of the disease;
      ii) to calculate the likely length of time that the disease has been present;
      iii) 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; and
      iv) to obtain information on the likely spread of the listed disease in the surrounding environment, including the presence and distribution of disease vectors.

   b) to confirm/rule out disease in the event of preventive killing.

Summary of sampling procedures

No specific guidelines on sampling procedures for clinical or laboratory examination were found for the 2nd scenario.

Assessment

To support the epidemiological investigation when an affected establishment is officially confirmed, disease-specific sampling procedures based on laboratory examination should be performed.

When CCPP has been officially confirmed in an establishment, further sampling procedures will support the needs of the epidemiological enquiry to obtain information on the origin of the disease, the length of time that the disease is present.

In addition, in case preventive killing is applied in establishments where the disease has not yet been confirmed, sampling procedures as described below will confirm or rule out the disease.

Development of new procedures

Estimate the prevalence of animals with clinical signs within the affected establishment

With CCPP, it is difficult to estimate the prevalence of infected animals in an establishment. Information on clinically affected animals may be collected during the epidemiological enquiry. Serological tests may help but they may underestimate the situation due to limited sensitivity.

Estimate the length of time that the disease has been present in the establishment

The source of infection will be direct contact with infected animals therefore the length of time since infection was introduced will be obtained by the epidemiological investigation and interview of the owner on the health history of the establishment and animal movements. It is not possible to use a laboratory analysis alone to estimate the time of introduction.

Collect samples for isolation and to identify the likely origin of the disease

Identifying the origin of disease, in the absence of evidence from the examination of movement records, whole genome sequencing can be used to identify the likely origin of *Mccp*. Because the disease has been confirmed in the establishment, and assuming this has not been done during the investigation of the suspicion, additional samples (pleural fluid, lungs with lesions, lymph nodes) may be needed for *Mccp* detection according to the instructions provided by the laboratory (see also Laboratory Examination in Section 4.1.1.1).

Sequencing *Mccp* genome is much easier than for *Mmm* because *Mccp* genomes are not riddled with mobile genetic elements leading to large DNA fragments' duplications and rearrangements. *Mccp* genomes are all collinear and can be distinguished by single nucleotide polymorphism (SNPs) and possibly some deletions. The mutation rate *in vivo* has been evaluated at 10^{-6} per base per year (hence one SNP per year and per genome as it contains roughly 10^6 bases (Loire et al., 2020).

Confirm the disease in case preventive killing is decided

In the Delegated Regulation, preventive killing may be implemented for the animals of listed species for CCPP (*Ovis* ssp., *Capra* ssp., *Gazella* ssp.) in three cases: (i) in an establishment suspect of CCPP, (ii) in the establishments in temporary restricted zones (article 9 of Delegated regulation) and (iii) in the establishments of the restricted zone (that is the protection and surveillance zones and further restricted zones).

Where preventive killing is applied, all the animals in the establishment should be subjected to individual clinical examination to identify animals with clinical signs and the whole procedure as described in the 1st scenario in Section 4.1.1.1.

In the absence of clinical signs, and given that the animals are going to be culled, the confirmation of CCPP in the establishments will be based on one or a combination of the followings:

i) Detection of lung lesions in culled animals (acute lesions may be pathognomonic);
ii) PCR from lung lesions and regional lymph nodes;
iii) Blood sampling for c-ELISA as described in Table 3 can be undertaken. In some cases, serological tests might be positive even though cultivation and PCR yield negative results.

4.1.1.3. For granting a specific derogation from killing animals of the categories of article 13.2 of the Delegated Regulation in a CCPP-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 procedures**
- ToR 1.1 and ToR 1.2 in accordance with Article 13(3)c of the Delegated Regulation (EU) 2020/687

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

1) It concerns an affected establishment where infection is officially confirmed;
2) In the establishment there are kept animals of listed species of the following specific categories animal categories based on article 13(2):
    a) animals kept in a confined establishment;
    b) animals kept for scientific purposes or purposes related to conservation of protected or endangered species;
    c) animals officially registered in advance as rare breeds;
    d) animals with a duly justified high genetic, cultural or educational value.
3) The competent authority may grant specific derogation from killing all the animals of listed species belonging to any of the above categories in an affected establishment, provided that specific conditions are fulfilled;
4) The animals should be subjected to clinical surveillance, including laboratory examinations;
5) Sampling procedures should ensure that the animals do not pose a risk of transmission of the category A disease if left alive.

Summary of sampling procedures

No specific guidelines on sampling procedures for clinical or laboratory examination were found for the 3rd scenario.

Assessment

In a CCPP-affected establishment, the following should be considered when designing derogations from killing animals of listed species:

i) The lack of specificity of clinical examination;
ii) Animals without clinical signs may be incubating CCPP, which cannot be detected by laboratory tests (the incubation period is usually 6–10 days, but varies from 2 days to 4 weeks);
iii) Some animals may become carriers following their exposure and may remain a source of the *Mccp*;
iv) The length of infectious period is not known;
v) Data on sensitivity and specificity of diagnostic tests are sparse, complicating interpretation of test results and estimates of predictive values;
vi) Identification of infectious animals is often not possible; and
vii) Airborne transmission may occur over short distances.

Consequently, sampling procedures (clinical and laboratory) cannot provide a high level of confidence that these animals do not pose a risk for transmission if they are kept alive.

Development of new procedures

All animals intended for derogation from killing should be subjected to thorough individual clinical examination and samples for laboratory examination with serological tests (c-ELISA, LAT) should be collected from all the animals irrespective of clinical signs.

Regular clinical examination should be carried out at least weekly (the incubation period is usually 6–10 days) for up to the first 45 days, to detect early the onset of clinical signs and proceed with the laboratory examinations and then every 45 days. Sampling for laboratory examination can be repeated every 45 days together with the clinical examination (monitoring period as defined in the Delegated Regulation) from all the animals in the establishment. This procedure should be carried out for at least 6 months calculated forwards from the day of confirmation of the latest case within the establishment.

The animals with clinical signs and/or those found positive to serological tests should be immediately culled and samples from carcasses can additionally be examined by PCR to detect or rule out the presence of *Mcpp*.

Sampling procedures for laboratory examinations in order to detect or rule out the presence of *Mccp* should follow the procedures described in Section 4.1.1.2.

However, even with these new procedures, the EFSA AHAW Panel considers that given the currently available laboratory tests it will be very difficult to state with enough confidence that the animals from an affected establishment without clinical signs and with negative results in serological tests do not pose a risk of transmission, and therefore, this practice should be discouraged.

4.1.1.4. For the animals of non-listed species kept in a CCPP-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 agent if it is present in these species. For further details, see Annexes B and C.

- **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 (*Ovis* ssp., *Capra* ssp., *Gazella* ssp.)

The following elements of the scenario should be taken into consideration 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 agent 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 agent in these species.

Summary of sampling procedures

No specific guidelines on sampling procedures for clinical or laboratory examination were found for the 4th scenario.

Assessment

Non-listed species which are susceptible to CCPP include *Oryx* spp. This group includes the Arabian oryx (*Oryx leicoryx*), the Scimitar oryx (*Oryx dammah*), the East African oryx (*Oryx beisa*) and the Gemsbok (*Oryx gazella*), which are likely to be present in approved establishments as captive animals, but are not kept as domesticated food-producing animals in the EU (Chaber et al., 2014). CCPP has also been detected in the Tibetan antelope (*Pantholops hodgsonii*) (Yu et al., 2014).

Previously the genera *Eudorcas* and *Nanger* were taken as subgenera of *Gazella*. Now those two subgenera and *Procapra* (Asian gazelles) are three different genera and considered separately. However, they should also be considered as non-listed species to rule out infection in an establishment where CCPP has been detected.

The clinical manifestation of CCPP in *Oryx* spp. is very similar to that found in goats (Lignereux et al., 2018) based on the observations in the United Arab Emirates by the OIE expert Thiaucourt François (personal communication with the expert).

Development of new procedures

In the scenario where non-listed species are kept in an establishment affected by CCPP, they should be monitored for clinical signs. Where clinical signs or deaths are reported, samples should be collected for laboratory analysis following the procedures of the 1st scenario, Section 4.1.1.1.

The lack of information on the performance of laboratory tests (sensitivity, specificity) for animal species other than goats along with the lack of validation of the diagnostic methods in them will increase the uncertainty on the reliability of the sampling strategy.

Nevertheless, both LAT and c-ELISA do not depend on the species being sampled and could be used for serology in wildlife or zoo species. The difficulty, in that case, would be the harvesting of sera in such animals. Hence, the recognition of CCPP in wildlife or captive non-livestock animals is mostly dependent on the detection of *Mccp* DNA in suspicious samples.

Where there is no contact with domestic or wild listed species, and disease was not already present in the region/country, an epidemiological investigation should be undertaken to ascertain whether the infection was introduced through an import during the previous 6 months.

4.1.1.5. For wild animals of the listed species within the CCPP-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 agent, if the agent is present in these wild species. For further details, see Annexes B and C.

- **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 should be taken into consideration for the. assessment:

1) It concerns an affected establishment officially confirmed;
2) They may exist wild animals of listed species within the establishment and in the surroundings of the establishment;
3) As listed in Commission Implementing Regulation (EU) 2018/1882 for CCPP; the wild animals of listed species animals are those of *Ovis* ssp.*, Capra* ssp.*, Gazella* ssp.*;*
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 agent, if the agent is present in these wild species.

Summary of sampling procedures

No specific guidelines on sampling procedures for clinical or laboratory examination were found for the 5th scenario.

Assessment

Listed species include those animals of *Ovis* ssp.*, Capra* ssp. and *Gazella* ssp. Therefore, the wild Alpine ibex (*Capra ibex ibex*) or the Iberian ibex/Iberian wild goat (*Capra pyrenaica*) would be included in this group of listed wild animals. Feral goats without owner may be present in areas around captive animals or kept livestock and should be considered as wild.

In terms of wild animals of *Ovis* spp. the European mouflon, *Ovis aries musimon* is present in several European Countries, but *Ovis* spp. are generally less susceptible to CCPP and are seldom affected. Therefore, it is unlikely that there is a need for testing such wild *Ovis* spp. unless known contact with an infected establishment of domestic or captive species.

For *Gazella* spp., there are no known wild herds in the EU.

Wild *Ovis* ssp.*, Capra* ssp. (including stray or feral animals) could be infected as a result of close contact with infected goats (e.g. absence of fences, free ranging flocks) and therefore may play a role in the spread or maintenance of CCPP. For the purpose of the CCPP control around an affected establishment, the presence of wild or feral animals of *Ovis* ssp.*, Capra* ssp. must, therefore, be considered.

Development of new procedures

If there is known contact with an affected establishment, based on an epidemiological investigation, it may be appropriate to isolate the animals for monitoring testing. In this circumstance, the testing protocols of Section 4.1.1.1 are considered appropriate.

The detection of CCPP in wild animals is more complicated than in kept animals, because of the practical difficulties and limitations of surveillance and monitoring activities of wildlife in the natural environment.

The surveillance of wild animals (including stray or feral animals) of listed species around an affected establishment may include: (i) visual inspection of these animals from a distance, (ii) clinical examination of trapped animals and (iii) thorough examination of animals found dead or hunted to identify lesions compatible with CCPP and sampling for laboratory analysis by PCR.

In the scenario where wild animals of *Ovis* ssp.*, Capra* ssp., are living in the surrounding area of the affected establishment, and the risk assessment carried out by the Competent Authority may conclude that sampling live animals is necessary, then blood samples may be collected for laboratory analysis with c-ELISA. Wildlife population health experts would be able to provide additional advice in these circumstances.

Nonetheless, the lack of information on the performance of laboratory tests (sensitivity, specificity) in animals other than goats, along with the lack of validation of the diagnostic methods in them, will increase the uncertainty on the reliability of the sampling strategy.

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

Summary of sampling procedures

No specific guidelines on sampling procedures for a clinical or laboratory examination were found for the 6th scenario.

Assessment

In the case of CCPP, according to the Delegated Regulation, the protection zone is at the affected establishment level only, while the minimum radius for the surveillance zone is 3 km (Annex V of the Delegated Regulation). This means there is no protection zone as defined for other diseases and only the affected establishment was considered as a protection zone, with no other establishments included, not even those that are neighbouring the affected one.

The absence of a protection zone is not considered effective as explained in Section 4.3.1. The reason is that animals in adjacent establishments can have contact over the fence and the causative agent can be transmitted by air over short distances.

Development of new procedures

It is advised to implement a protection zone including the establishments adjacent to the infected establishment (e.g. 1 km zone depending on the local situation).

Clinical inspection of animals in establishments neighbouring the infected ones is recommended, and in addition to goats in establishments with pastures or yards adjacent to the infected establishment or pastures thereof. Animals should be clinically inspected for signs pointing at CCPP.

Moreover, the farmer should be asked which animals have shown such signs during the last 45 days, and the farmer should present information on the use of antimicrobials considered effective against CCPP in this period. In case of animals showing signs suggestive of acute CCPP, sampling to detect the pathogen should be pursued as described in 1st scenario of Section 4.1.1.1.

In the absence of animals with clinical manifestation of typical signs, blood should be collected from the animals in the establishment according to Table 3 (to detect a 1% seroprevalence with 95% confidence), including all animals with a clinically suspect history.

In case of negative or inconclusive results, based on the epidemiological situation in the protection zone, the sampling procedures should be repeated after 45 days, aiming to detect a seroprevalence higher than 1%, e.g. 5%, 10%. The protection zone can be lifted if all samples prove negative.

Increased awareness should be raised in the protection zone, in order to enhance passive surveillance and immediate reporting of signs suggestive for CCPP. Animals brought to slaughterhouse (scenario 9) should be thoroughly examined for lung lesions followed by sampling according to scenario 9.

In establishments with sheep and goats, the clinical and laboratory examination should performed on goats. Establishments with sheep only that are adjacent to the affected ones should be visited to identify respiratory signs and mortalities in sheep. In case of sheep with clinical signs suggestive of acute CCPP, sampling to detect the pathogen should be pursued as described in 1st scenario in Section 4.1.1.1. c-ELISA theoretically can be applied also to sheep, but it is not recommended since it has not been validated for sheep.

4.1.1.7. For non-affected establishment 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 agent is present in establishments within the surveillance zone. For further details, see Annexes B and C.

- **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 should be taken into consideration during 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 specific guidelines on sampling procedures for a clinical or laboratory examination were found for the 8th scenario.

Assessment

According to the Delegated Regulation, the minimum radius for the surveillance zone is 3 km (Annex V of the Delegated Regulation).

Development of new procedures

Because *Mccp* is mainly transmitted by direct contact between animals and air transmission is not expected to be over a long distance, for the surveillance zone, it is recommended that the efforts will be allocated to enhance immediate notification and passive surveillance by increasing awareness in all establishments, industry and public.

In addition, the awareness of the veterinarians at the slaughterhouses should be high during the ante-mortem animal inspection and post-mortem inspection of the pleural cavity. Animals from establishments located in the surveillance zone should be thoroughly examined at slaughterhouse for CCPP-like lesions followed by sampling in case of suspicion according to the procedures described in Section 4.1.1.1 (1st scenario).

Any establishment where more generic signs of the disease such as fever, lethargy, lost appetite and even changes in feed intake and productivity are reported should be visited, the animals should be clinically examined and samples should be collected following the procedures described in Section 4.1.1.1.

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

In establishments with sheep and goats, the clinical and laboratory examination should be performed on goats. Establishments with sheep only should be visited if they are epidemiologically

linked with the affected establishments or the establishments in the protection zone. In case of mortalities and sheep with respiratory signs, samples should be collected following the procedures described in Section 4.1.1.1. c-ELISA theoretically can be applied also to sheep, but it is not recommended since it has not been validated for sheep.

Given the limited transmission, a 3-km zone is considered effective and the zone should be implemented for 45 days according to the incubation period of the disease (see Section 4.3.2) and not be lifted before the sampling of all the establishment in the protection zone has been completed with negative results.

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 examinations of the animals of an establishment in a protection zone, in order to grant a derogation from prohibitions in the movement of animals, and allow for the animals to be moved to a slaughterhouse located within the protection zone or in the surveillance zone or outside the restricted zone (Art29). For further details, see Annexes B and C.

- **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 should be taken into consideration during 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 specific guidelines on sampling procedures for clinical or laboratory examination were found for the 9th scenario in EU legislation.

Assessment

This scenario includes three different subscenarios: (a) the need to transfer animals of listed species for CCPP kept in establishments located in the protection zone to a slaughterhouse located within the protection zone; (b) the need to transfer animals of listed species for CCPP located in the protection zone to a slaughterhouse located within the surveillance zone; and (c) the need to transfer animals of listed species for CCPP located within the protection zone to a slaughterhouse located outside the restricted zone.

During a CCPP outbreak, the following considerations should be taken into account when designing animal movement derogations:

i) The lack of specificity of clinical examination;
ii) Animals without clinical signs may be incubating CCPP which cannot be detected by laboratory tests (the incubation period is usually 6–10 days, but varies from 2 days to 4 weeks);
iii) Some animals may become 'carriers' following their exposure and may remain a source of the *Mccp*;
iv) The length of infectious period is not known;
v) Data on sensitivity and specificity of diagnostic tests are sparse, complicating interpretation of test results and estimates of predictive values;
vi) Identification of infectious animals is often not possible and
vii) Airborne transmission can occur over short distances.

Consequently, sampling procedures (clinical and laboratory) cannot provide a high level of confidence that these animals do not pose a risk for transmission if moved to slaughterhouses.

The highest risk of spread due to movement of undiagnosed animals is associated with subscenario c, then b and finally a. Nevertheless, the fact that the destination of these animals is the slaughterhouse, all biosecurity measures are implemented and given that the animals should be slaughtered within 24 h reduces the risk. In addition, animal slaughtering from the establishments in the protection zone could have beneficial effect resulting in the reduction of the number of potential hosts for the further spread of CCPP.

Development of new procedures

All animals in the establishment of origin should be clinically examined before their movement, following the procedures described in Section 4.1.1.1 and a thorough investigation of the health history of the establishment for at least 45 days backwards should be performed to identify any sign compatible with CCPP. In an establishment where the number of animals is large, the individual clinical examination of all the animals may not be feasible; in that case the individual clinical examination can be restricted to those animals that are intended to be moved and the whole establishment should be visually inspected for clinical signs of the respiratory system.

In case clinical signs compatible with CCPP are identified, the establishment is considered suspect and the procedures for the laboratory confirmation that are described in Section 4.1.1.1 should be followed and any movements should be prohibited.

At the slaughterhouse, a thorough post-mortem inspection should be routinely performed on those animals coming from the protection zone to identify the lesions of CCPP. Any suspect lesion attributable to CCPP should be further investigated with laboratory examinations to rule out the presence of CCPP following the procedures described in Section 4.1.1.2.

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

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

- **12th scenario of sampling procedures**
- ToR 1.4 in accordance with article 28(5) and article 37 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;
2) To grant derogation for movement of kept animals of listed species from a nonaffected establishment in the protection zone;
3) The animals to be moved to a plant approved for processing or disposal of animal by-products in which the kept animals are immediately killed;
4) Clinical examinations and laboratory examinations of animals kept in the establishment, including those animals to be moved.

Summary of sampling procedures

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

Assessment

This scenario is very similar to the 9th scenario of Section 4.1.2.1, and therefore, the assessment is the same.

Development of new procedures

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

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

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

- **13th scenario of sampling procedures**
- ToR 1.4 in accordance with article 43(5) and article 44 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 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 specific guidelines on sampling procedures for clinical or laboratory examination were found for the 13th scenario in EU legislation.

Assessment

This scenario includes three different subscenarios: (a) the need to transfer animals of listed species for CCPP kept in establishments located in the surveillance zone to a slaughterhouse located within the surveillance zone; (b) the need to transfer animals of listed species for CCPP located in the surveillance zone to slaughterhouse located outside the surveillance zone; and (c) the need to transfer animals of listed species for CCPP located outside the surveillance zone to slaughterhouse located within the surveillance zone. The highest risk of spread is associated with the subscenario (b) where animals move from a higher risk zone to a lower risk zone.

The same considerations as described in the 9th scenario should be included in the assessment when designing animal movement derogations.

Development of new procedures

This scenario is similar to the 9th scenario of Section 4.1.2.1 and therefore, the procedure is the same.

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

The purpose of this section is to assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations of kept ungulates of listed species in order to grant a derogation and allow the animals to be moved from an establishment in the surveillance zone to pastures situated within the surveillance zone. For further details, see Annexes B and C.

- **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 should be taken into consideration during 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 specific guidelines on sampling procedures for clinical or laboratory examination were found for the 14th scenario in EU legislation.

Assessment

The same considerations as described in the 9th scenario should be included in the assessment when designing animal movement derogations.

Consequently, sampling procedures (clinical and laboratory) are not able to ensure with high level of confidence that animal movements to pastures do not pose a risk for transmission.

Development of new procedures

The animal movements from the establishments located in the surveillance zone to pastures within the surveillance zone should be allowed once the first clinical inspection of the establishments in the protection zone have been completed and the results of the initial laboratory tests in these establishments are negative.

All the animals in the establishment of origin should be clinically examined before their movement, following the procedures described in Section 4.1.1.1 and a thorough investigation of the health history of the establishment for at least 45 days backwards should be performed to identify any sign compatible to CCPP. In an establishment where the number of animals is large, the individual clinical examination of all the animals may not be feasible; in that case the individual clinical examination can be restricted to those animals that are intended to be moved and the whole establishment should be visually inspected for clinical signs from respiratory system.

In case clinical signs compatible with CCPP are identified, the establishment is considered suspect and the procedures for the laboratory confirmation that are described in Section 4.1.1.1 should be followed and any movements should be prohibited.

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

The purpose of this section is to assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations of kept ungulates of listed species in order to grant derogation and allow 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. For further details, see Annexes B and C.

- **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 should be taken into consideration during for the assessment:

1) It concerns the surveillance zone;
2) Grant derogation for movement of kept animals of listed species from the surveillance zone;
3) 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;
4) Clinical examinations and laboratory examination of animals kept in the establishment, including those animals to be moved.

Summary of sampling procedures

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

Assessment

During CCPP outbreak, the same considerations as described in the 9th scenario should be included in the assessment when designing animal movement derogations.

Taking into consideration the above-mentioned limitations, it is very difficult to develop sampling procedures that will provide a high level of confidence that the disease will not spread if live animals of listed species are allowed to be moved while the zones are in place.

However, it is noteworthy that allowing movements from an establishment in a surveillance zone to an establishment belonging to the same supply chain, outside the surveillance zone will increase the risk of CCPP expansion.

Development of new procedures

The animal movements from the establishments located in the surveillance zone to an establishment belonging to the same supply chain should be allowed once the first clinical inspection of the establishments in the protection zone has been completed and the results of the initial laboratory tests in these establishments are negative.

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.

In an establishment where the number of animals is large, the individual clinical examination of all the animals may not be feasible. In that case then clinical inspection of the whole establishment and thorough investigation of the health history of the establishment for at least 45 days months backwards should be performed to identify any symptom compatible to CCPP.

In case clinical signs compatible with CCPP are identified, the establishment is considered suspect and the procedures for the laboratory confirmation as described in Section 4.1.1.1 should be followed and any movements should be prohibited.

In addition to clinical examination, a minimum sample of animals (including all animals to be moved) should be tested with c-ELISA as described in Section 4.1.1.1 based on the total number of animals in the establishment before the movement.

Additional measures are recommended also for the establishment of destination where the animals should be tested again with c-ELISA 45 days after their introduction in the establishment of destination. Moreover, during that period, animal movements from the establishments of destination, slaughterhouses excluded, should not be allowed.

Nevertheless, EFSA AHAW Panel considers that given the current available laboratory tests, it is very difficult to state with confidence that live animals without clinical signs and with negative results in serological tests do not pose a risk of transmission, and therefore, live animal movements from the surveillance zone outside the restricted zone should be discouraged.

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

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

- **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 should be taken into consideration during 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

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

Assessment

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

The same considerations as described in the 9th scenario should be included in the assessment when designing animal movement derogations.

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

Development of new procedures

Sampling procedures should be implemented as described in Sections 4.1.2.1, 4.1.2.2, 4.1.2.3, 4.1.2.4 and 4.1.2.5.

4.1.3. Assessment of sampling procedures for repopulation purposes

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

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

- **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 should be taken into consideration during assessment:

1) It concerns the repopulation of a previously affected establishment;
2) Animals intended to repopulation shall be sampled prior to their introduction into establishment of destination;
3) The samples shall be collected from a representative number of animals to 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) The purpose of sampling procedures is to rule out the presence of the disease.

Summary of sampling procedures

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

Assessment

For animals kept for repopulation, clinical examination and sampling should be used as standard procedures to ensure that the animals do not pose a risk of CCPP 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 pathogen before entry and, consequently, negative test results are expected.

When designing the sampling procedures for repopulation, the following elements should be taken into consideration:

i) the lack of specificity of clinical examination;
ii) animals without clinical signs may be incubating CCPP which cannot be detected by laboratory tests (the incubation period is usually 6–10 days, but varies from 2 days to 4 weeks);
iii) some animals may become 'carriers' following their exposure and may remain a source of the *Mccp*;
iv) the length of infectious period is not known;
v) data on sensitivity and specificity of diagnostic tests are sparse, complicating interpretation of test results and estimates of predictive values;
vi) identification of infectious animals is often not possible and
vii) airborne transmission can occur over short distances.

Development of new procedures.

All the animals in the establishment of origin should be clinically examined before their movement, following the procedures described in Section 4.1.1.1. In an establishment where the number of animals is large, the individual clinical examination of all the animals may not be feasible. In that case clinical inspection of the whole establishment and thorough investigation of the health history of the establishment for at least 45 days backwards should be performed to identify any symptom compatible to CCPP.

In case clinical signs compatible with CCPP are identified, the establishment is considered suspect 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.

In case the animals originate from establishments located in areas outside the restricted zones, there is no need for laboratory examination if there are no other reasons based on the authorities risk assessment to recommend it (e.g. epidemiological link with an affected establishment or with an affected or high-risk area). Clinical examination as described above would be enough.

When animals originate from restricted areas established around different index cases, in addition to clinical examination, a minimum sample of animals (including all animals to be moved) should be tested with c-ELISA as described in Section 4.1.1.1 based on the total number of animals in the establishment before the movement.

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

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

- **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 should be taken into consideration during 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 specific guidelines on sampling procedures for laboratory examination were found for the 20th scenario.

Assessment

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

Development of new procedures

In the event of animals with clinical signs compatible with CCPP, as they have been described in Section 4.1.1.1, being identified in an establishment during the repopulation, the establishment is considered suspect. The repopulation should be stopped and the procedures for the laboratory confirmation as described in Section 4.1.1.1 should be followed.

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

4.1.3.3. For animals that have been repopulated

The purpose of this section is to assess the effectiveness of disease-specific sampling procedures based on laboratory examinations of the animals that have been repopulated, on the last day of the monitoring period calculated forwards 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 forwards from the last day in which the last animal is introduced in the establishment. For further details, see Annexes B and C.

- **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 should be taken into consideration during for the assessment:

1) It concerns the repopulated establishment;
2) Animals that have been used for repopulation;
3) The purpose of sampling procedures is to rule out the presence of the disease.

Summary of sampling procedures

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

Assessment

During the repopulation of an establishment previously affected by CCPP, 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 laboratory examination in order to rule out the presence of the disease.

Development of new procedures

Animals must be subjected to weekly clinical inspection up to 45 days (monitoring period as defined in Delegated Regulation) after re-introduction. The last day of the monitoring period following the latest day of animals' introduction, all the animals should be subjected to thorough clinical examination as described in Section 4.1.1.1 and should be sampled for laboratory examination in accordance with the procedures described in Section 4.1.1.2.

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 has been introduced as a management tool for the investigation and control of suspect and confirmed outbreaks of Category A diseases in terrestrial animals. This tool aims to standardise the methodology by which relevant authorities respond to suspect 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).

Annex D in this Opinion describes the seven scenarios, for which an assessment of the length of the monitoring period for CCPP had been requested.

For the assessment of this ToR, the methodology described in Section 2.3 of the Technical Report on Methodology published by EFSA (EFSA, 2020) was followed. In essence, in order to assess the length of the monitoring period, the purpose of this monitoring period for each of the scenarios was ascertained.

To answer all scenarios except scenario 5, an extensive literature search (ELS) on the average, shortest and longest period of time between the earliest point of infection of an animal with CCPP, and the time of reporting of a suspicion by the competent authority, was carried out. The time period between reporting of a suspicion and the notification of the disease was also assessed. Several outcomes were designed for the ELS as shown in the protocol, and the results are presented below.

To answer scenario 5, a literature search was conducted by EFSA on the seroconversion period, as well as the earliest time of antibody detection in blood, with the outputs being discussed with relevant experts.

4.2.1. Results

Extensive Literature Search

A search was carried out on 21/5/2021, identifying 48 unique references published after 1/1/2000. As no references were available for outbreak data from the EU/EEA, the search was extended to data from the rest of the world and to simulation data. Among the 48 references, three were selected to be included in the qualitative review. The full selection process is displayed in Figure 6.

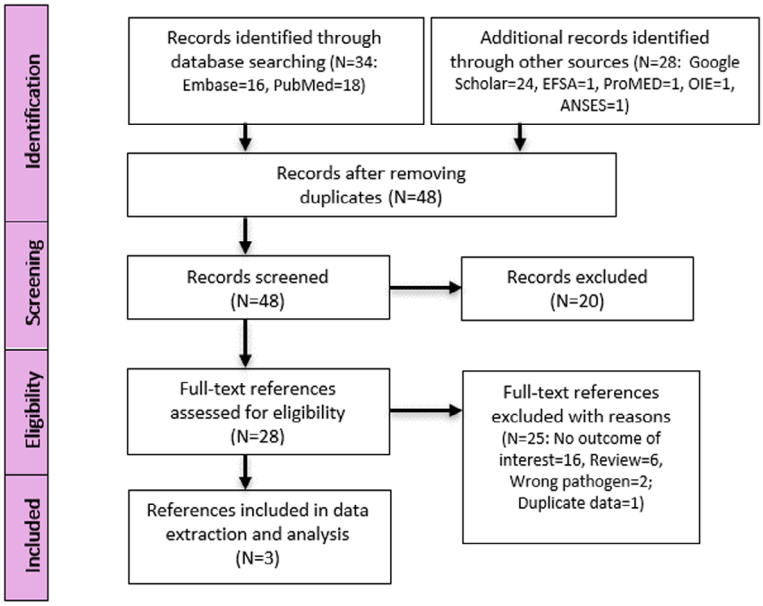

Figure 6: PRISMA diagram CCPP monitoring period ELS

One of the three references reported dates instead of periods; therefore, the dates were used to calculate the different periods of interest (as described in Section 2.1 – PICOS table). No data was retrieved for the main outcome of interest, i.e. the period between the earliest point of infection and the suspicion report. The extracted data for other periods that are included in the outbreak reporting process (i.e. the other outcomes) are summarised in Table 4.

Table 4: Periods (days) in the CCPP outbreak reporting process

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

(1): Based on first observed clinical signs of CCPP.
(2): Based on the date of the first necropsies presenting CCPP-compatible lesions and of biosecurity measures implementation.
(3): CCPP already existed in the area before the outbreak, therefore the suspicion was raised as soon as the lesions were noticed.

As described in Table 4, 7 days occurred between the introduction of infected goats in a farm in Tanzania and the first clinical signs of CCPP in goats from two other units of the same farm (Kusiluka et al., 2000).

It is also noteworthy that CCPP appeared to have disseminated widely within the Thrace region in Turkey before the disease was suspected in 2003, more or less 1 year after the first cases of respiratory disease with high morbidity and mortality had been noticed (Özdemir et al., 2005).

In addition, we reconstructed the period between the earliest point of infection and the suspicion report by adding together the incubation period (OIE, 2009) and the period between the first suspicion and suspicion report found in the context of the captive sand gazelle outbreak which took place in 2013 in the United Arab Emirates (Lignereux et al., 2018):

2.1. Average period = mean incubation period (22 days), plus period between first suspicion and suspicion report (2 days) = 24 days.
2.2. Shortest period = min incubation period = 3 days.
2.3. Longest period =max incubation period (41 days), plus period between first suspicion and suspicion report (2 days) = 43 days.

However, since no data was available in the literature with respect to the period between the earliest point of infection and the suspicion report, it is not possible to provide an objective conclusion on the current monitoring period for CCPP (45 days) based only on the evidence found by ELS.

Seroconversion in animals

Several publications describing experimental infection with CCPP were consulted (Table 5) and the time of seroconversion after infection/inoculation and contact was retrieved from the serological results described. Nevertheless, these studies were not designed to estimate the time between infection and seroconversion (first time when antibodies can be detected) and they can only provide a broad estimation. The knowledge about CCPP pathogenesis is limited, mainly due to the small number of experimental trials and the lack of a robust challenge model (Liljander et al., 2019; OIE, 2021).

Table 5: Range of days for seroconversion and latest detected day of antibody presence in goats after experimental infection with *Mycoplasma capricolum subsp. capripneumoniae*

Laboratory method	Infection	Blood collection	Range of days for seroconversion (dpi(1))		Latest day of antibodies detection/end of experiment	Reference
			Earliest day of seroconversion	Latest day of seroconversion		
CFT	In-contact with infected animals	NS	21 days post-contact		NS	Ozdemir et al. (2005)
c-ELISA	IN + TTN	Twice per week	11 dpi	14 dpi	31 dpi (end of experiment)	Liljander et al. (2019)
i-ELISA	IT	Every 10 days	10 dpi	40 dpi	85 dpi (end of experiment)	Wesonga et al. (2004)
	In-contact with infected animals	Every 10 days	11 dpi (only 1 animal challenged)		85 dpi (end of experiment)	Wesonga et al. (2004)

CFT: complement fixation test; c-ELISA: competitive ELISA; EBI: endobronchial inoculation; IN: intranasal; IT: intratracheal; TTN: transtracheal by needle puncture; NS: not specified.
(1): dpi: days post infection/inoculation.

In experimental studies (Table 5), where non-vaccinated naive goats were experimentally infected, the latest day of seroconversion was: (i) 14 days after intranasal and transtracheal by needle puncture infection identified by c-ELISA and (ii) 40 days after intratracheal infection identified by i-ELISA.

In experimental studies (Table 5), where non-vaccinated naïve goats were infected through direct contact with infected animals, the latest day of seroconversion identified was 21 days post contact by CFT (Özdemir et al., 2005) and 11 dpi by i-ELISA (Wesonga et al., 2004). It should be highlighted that, in the experimental infection by contact, the day of infection remains unknown.

The latest day of antibody detection found in experimental studies was 85 dpi by i-ELISA (Wesonga et al., 2004) which coincides with the end of the follow-up period of the trials.

However, not all challenged animals seroconverted and some remained seronegative for the entire period of study, as detected with c-ELISAs (Wesonga et al., 2004). Therefore, CCPP serological test results should be interpreted at establishment basis and not to individual animals (OIE, 2021).

4.2.2. Assessment

Considering the results presented above, an assessment of the effectiveness of the monitoring period for CCPP, depending on the purpose of that period in the different scenarios shown in Annex D, was carried out. For CCPP, the length of the monitoring period as defined in Annex II of the Delegated Regulation is 45 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 CCPP outbreak

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 CCPP 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 CCPP outbreak in an epidemiological unit in which the disease has not been confirmed, in order to provide derogations from killing the animals in this unit, if this unit has been completely separated, and handled by different personnel during this monitoring period

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

The length of the monitoring period should then dictate how far, backwards or forwards 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 and remain undetected in an establishment, and due to the regular activities carried out in this establishment, could have spread to other epidemiological units.

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

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

The ELS carried out and presented above did not find evidence corroborating the current monitoring period for CCPP (45 days).

Information is available about the incubation period of CCPP, which is usually 6–10 days, but can vary from 2 days to 4 weeks while some experimentally infected goats did not become ill until up to 41 days after exposure (Thiaucourt, 2003; OIE, 2009; Spickler, 2015).

According to the expert knowledge, and based on the longest incubation period (41 days), **it was concluded with a 90–100% certainty that 95 out of every 100 CCPP-infected goat**

establishments in an already affected region, infection would have occurred within the 45 days prior to the suspicion report (QoI 2b), and therefore, the 45-day monitoring period as defined in the Delegated Regulation is considered effective. This is due to the expected efficiency detecting new outbreaks in areas where awareness is high given the described lengths of the incubation period, assuming compliance with the control measures set by the veterinary authorities. However, in previously unaffected regions, there could be a significantly longer delay in detecting CCPP infection in affected establishments given the expected lack of awareness, and therefore, the 45-day period was not considered effective in this context. **In the case of the first case in a previously unaffected region, it was concluded with a 50–100% certainty that in 95 out of every CCPP goat flocks suspected and eventually confirmed infection would have occurred within the previous 6 months before the suspicion report (QoIa), and therefore, this is the recommended monitoring period. Large uncertainty remains due to the difficulties assessing the potential delay in detecting the disease when awareness is low, particularly in cases where antibiotic treatments may also be applied thus further complicating clinical diagnosis**.

In the case of independent epidemiological units within CCPP-affected goat establishments that eventually become infected (QoIc), the certainty of the efficacy of the 45-day monitoring period as defined in the Delegated Regulation depends on whether these units are present in the first or in subsequent affected establishments in a region. **For establishments in an already affected region, it was concluded with a 90–100% certainty that 95 or more out of every 100 independent epidemiological units within the CCPP-affected goat establishments that eventually become infected, infection would have occurred within the 45 days prior to the date of suspicion, and thus, the monitoring period would be effective**. **In case the independent epidemiological unit was located in the first affected establishment in a region a much longer monitoring period, to be determined by the veterinary authorities considering the specific situation, would be required** given the potential for the disease to remain undetected in a goat establishment when awareness is low and appropriate diagnostic tests are not carried out.

Scenario 4

4th scenario of monitoring period

- ToR 2 in accordance with article 27(3)c 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 CCPP outbreak in the protection zone. Products or other materials likely to spread the disease, must had been obtained or produced, before this time period in order to be exempted from prohibitions of movements

The main purpose of the monitoring period in scenario 4 is to ensure that certain products or materials, likely to spread the disease, that have been produced in a non-affected establishment located in the protection zone of an affected establishment, can be moved safely and without posing a risk of disease spread. In this scenario, and in contrast with the previous three scenarios, the establishment of concern is neither a suspect nor an affected establishment, but restrictions are still in place, for establishments in the protection zone.

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).

When disease has already been detected in the area, and high awareness is expected, the length of the monitoring period of 45 days is considered effective in this scenario. A longer monitoring period of at least 180 days (6 months) is recommended for the early phases of the outbreak in the area where the awareness is low (e.g. if the index case was in a slaughterhouse and the epidemiological enquiry is taking time).

Because the assessment of the effectiveness of the proposed alternative monitoring period is subjected to the same uncertainties described for scenarios 1, 2 and 3, the same certainty regarding its effectiveness was reached for scenario 4.

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 the non-affected establishments (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.

There is no evidence found in the scientific literature to demonstrate that *Mccp* can be detected in the semen of infected animals or that the disease can be transmitted through the contaminated semen.

Nonetheless, in this scenario, where the semen might have been contaminated the latest at the date of collection from an infected donor without clinical signs or with mild clinical signs that remained unnoticed, a serological test would indicate if the donor has ever been exposed to and therefore if the semen could be contaminated.

The latest date of seroconversion for non-vaccinated, naive animals infected through contact with already infected animals was identified as 40 days post IT infection by i-ELISA as reported by Wesonga et al. (2004).

Taken into consideration that the results of serological tests for CCPP should be interpreted at a flock basis and not at individual animals, using c-ELISA at the establishment from where the donor is coming from (45 + 7) days after semen collection as foreseen in the Delegated Regulation is considered effective to detect antibodies in the flock, given that the infection may have occurred at the latest on the day of semen collection.

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 forwards 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 forwards from the date the first animal was introduced for the purpose of repopulation, during this monitoring period, all animals of the listed species intended for repopulation should be introduced

In scenarios 6 and 7, the monitoring period is used in the context of repopulation.

In scenario 6, the monitoring period is used to ensure that the repopulation process is not put at risk due to the disease still being present unknowingly in establishments within the surrounding area of the establishment to be repopulated (if an establishment tested positive to *Mccp* at a distance equal or lower than the radius of the surveillance zone, the repopulation process could not take place).

Repopulation can only take place after a period equal to the monitoring period has elapsed, since the final cleaning, and disinfection of the affected establishment.

In this regard, the number of days of the monitoring period for CCPP, counted from the day of the final cleaning and disinfection, must ensure enough time for any potentially affected surrounding establishment to be reported as a suspicion. Considering the results presented in Section 4.1.2, and taking into account that a high level of awareness is expected due to the disease having been present in the area, the EFSA AHAW Panel considers the existing length of the monitoring period (45 days) effective, as it would allow for the identification of any potentially affected establishment in the surrounding area prior to the repopulation is taking place.

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

The aim of the monitoring period in this scenario is to ensure the early detection of any potentially recently infected animal intended for repopulation once all animals 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 an animal introduced into the repopulated establishment is the day when it is moved, and considering that the maximum incubation period is 41 days, it would be likely that some clinical signs would be present in animals if this visit is carried out 45 days after the last introduction. **Based on the available evidence, it was concluded with a 90–100% certainty that 95 or more out of all repopulated CCPP-affected goat establishments that become reinfected would be infected within the 45 days following the introduction of the animals**. The EFSA AHAW Panel thus considers the existing length of the monitoring period (45 days) effective, as it would allow for early detection of potentially infected animal 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 CCPP outbreak

4.3.1. Assessment of the minimum radius

The purpose of this section is to assess the effectiveness to control the spread of CCPP of the minimum radius of the protection and surveillance zones as set out in Annex V of the Delegated Regulation for CCPP. According to this regulation, protection zone is at the level of establishment and the minimum radius for the surveillance zone for CCPP is 3 km (Annex V of the Delegated Regulation).

Results

No transmission kernels either specific for CCPP or for diseases that have similar transmission routes to CCPP were found in the literature, nor were data suitable to estimate kernels identified. Accordingly, the zone sizes for CCPP were assessed using expert knowledge.

Assessment

Since transmission kernels are not available to allow an estimation of CCPP transmission beyond an affected establishment, given that the transmission occurs, the assessment of the effectiveness of the length of the radius of the surveillance zone and the fact that only the affected establishment constitutes the protection zone (in fact, there is no protection zone), cannot be quantified. Based on the WG expert opinion, the absence of a protection zone is not considered effective. The reason is that animals in adjacent establishments can have contact over the fences and the causative agent can be transmitted.

It is advised to develop a protection zone including the establishments adjacent to the infected establishment or establishments with pastures or yards adjacent to the infected one (e.g. 1 km zone depending on the local situation and the farms distribution). All the establishments in the protection zone should be visited and clinical inspection of the animals is recommended. **It was concluded**

with a 90–100% certainty that in 95 or more out of every 100 protection zones built as proposed, transmission would not occur beyond the zone, and therefore, it would be considered effective.

Taken into consideration that *Mccp* is mainly transmitted by direct contact between animals and indirect transmission is limited, **it was concluded with a 95–100% certainty that in 95 or more out of every 100 surveillance zones, transmission would not occur beyond a 3-km radius, and therefore, the length of the radius of the surveillance zone is considered effective**.

Nevertheless, transmission across longer distances cannot be excluded if infected animals are moved outside the zones.

4.3.2. Assessment of the minimum period

The purpose of this section is to assess the effectiveness to control the spread of CCPP of the minimum periods during which the competent authority should apply the restriction measures in the protection and surveillance zones as set out in Annexes X and XI for the CCPP. The minimum period for the protection zone and the surveillance zone is 45 days.

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

The ELS carried out and presented above did not identify published evidence corroborating the period between the earliest point of infection and the notification of suspicion.

Information that is available is about the incubation period of CCPP, which is usually 6–10 days, but can vary from 2 days to 4 weeks, while some experimentally infected goats did not become ill until up to 41 days after exposure (Thiaucourt, 2003; OIE, 2009; Spickler, 2015).

Based on expert knowledge, it was concluded with a 90–100% certainty 45 days would allow the detection of 95 or more out of every 100 CCPP-affected establishments due to infections starting before control measures were implemented since the maximum incubation period of the disease can be 41 days, and thus, the duration of the protection and surveillance zones of 45 days as defined in the Delegated Regulation is considered effective.

4.3.3. Uncertainty analysis

Several sources of uncertainty were identified during the scientific assessment (see Annex F), and their impact on the outputs of the assessment was quantified for scenario 1 in ToR1 and ToRs 2 and 3.

5. Conclusions and Recommendations

Sampling procedure	Laboratory guidelines based on Council Directive 2003/85/EC if not stated otherwise	Conclusions	Recommendations
ToR 1: In the event of suspicion or confirmation			
1st scenario Section 4.1.1.1 In the event of a suspicion of CCPP in an establishment where animals of the listed species are kept		Clinical examination and Inspection of lesions Acute clinical signs associated with CCPP but are similar to very common respiratory diseases in goats. In the chronic phase, the clinical signs are very mild and cannot be easily detected. The acute lesions (unilateral pleuropneumonia) identified in the lungs and pleural cavity of are considered pathognomonic and can play a crucial role to the diagnosis since they contain a large amount of *Mccp*. In case of antimicrobial treatment, typical lesions may not be observed, and the results of the laboratory examinations may be affected. In non-affected areas, clinical signs most likely will not trigger the suspicion of CCPP; other more common respiratory diseases will be suspected and probably treated with antimicrobials. The suspicion is usually triggered at the slaughterhouses during post-mortem inspection of the lungs and the thoracic cavity or during necropsy of dead animals submitted to post-mortem examination. In affected areas, where awareness is higher, clinical signs may raise a suspicion of CCPP. No data on the sensitivity and specificity of clinical examination exist in the literature: (i) the specificity cannot be considered high since the clinical signs are not pathognomonic to CCPP and (ii) the sensitivity decreases when the animals enter the chronic phase. The sensitivity of clinical examination is considered 90% and the specificity 80%. Laboratory examination For the laboratory methods for CCPP, there are no proper validation studies to estimate the	Clinical examination is recommended to identify animals most suitable for sampling for further laboratory examinations. Samples (lungs with lesions, regional lymph nodes and pleural fluid when available) from dead animals with a history of respiratory disease (preferably without receiving antibiotic treatment) should be collected for culture or PCR. In addition to dead animals or if dead animals are not available for sampling, animals with clinical signs associated with CCPP, are recommended to be killed for further examinations: (i) up to 20 animals to be tested in LAT and c-ELISA, and (ii) at least five animals positive in LAT should be killed and submitted for post-mortem inspection, to identify the pathognomonic lesions and to collect samples to be tested by PCR, to detect an outbreak with at least 95% confidence. If LAT is not used, 8 animals with clinical signs should be killed, to collect samples to be tested with PCR. In the event that all 20 samples are negative by LAT it can be considered that the animals are in the later stages of infection and no more IgM is present. In that case there will be some c-ELISA positives. If both the LAT and c-ELISA are negative, it is very, if not extremely unlikely that the clinical signs are caused by Mccp. To further increase the certainty of absence of CCPP a random sample of animals (according to Table 3) could be tested by c-ELISA (which will detect 'older infections').

Sampling procedure	Laboratory guidelines based on Council Directive 2003/85/EC if not stated otherwise	Conclusions	Recommendations
		performance of these methods (sensitivity, specificity) in conditions similar to EU countries (free from the disease) where the prevalence of CCPP in the establishments is expected zero or very low (in case of occurrence). c-ELISA is highly specific (Sp > 99.5%) and the sensitivity can be considered 70%. The quality of the samples and the conditions of their transport to the laboratory, may affect the final diagnosis.	In the event that none of the targeted animals are positive for LAT, restrictions on the establishment are maintained until negative testing with c-ELISA and further clinical examination of the animals can resolve the suspicion. The visit to the establishment and the sampling procedures should be repeated after a period of 45 days to have a very high certainty of the absence of the infection. It was concluded with a 90–100% certainty that the proposed sampling strategy would be able to detect the infection in 95 or more out of every 100 CCPP-affected establishments in which suspicion was triggered due to the occurrence of clinical signs or dead animals resembling CCPP. In the absence of clinical signs collecting serum samples to be tested by c-ELISA allowing the detection of a 1% design prevalence with 95% confidence, is recommended. In case of negative or doubtful results, based on the epidemiological situation and the risk assessment contacted at national level, the sampling procedures should be repeated at least 45 days later. It was concluded with a 90–100% certainty that the proposed sampling strategy would be able to detect the infection in 95 or more out of every 100 CCPP-affected establishments in which the suspicion is raised in an establishment in the absence of clinical signs or CCPP-related mortality. Additional actions that will increase the level of confidence to CCPP diagnosis: (i) the validation of the performance of the existing laboratory methods for goats and sheep, (ii) the development of alternative to c-ELISA and LAT serological methods, (iii) the nomination of EURL for CCPP, in order to support the preparatory activities of the NRLs of the EU Countries.

Sampling procedure	Laboratory guidelines based on Council Directive 2003/85/EC if not stated otherwise	Conclusions	Recommendations
2nd scenario Section 4.1.1.2 For the purposes of the epidemiological enquiry as referred to Article 57 of Regulation (EU) 2016/429 in a CCPP officially confirmed establishment		Epidemiological enquiry Due to the difficulties with determining the age of lesions or the true prevalence on an affected establishment initial enquiry should investigate movement records and an interview with the owner. Molecular methods such as whole genome sequencing may be used to determine the geographical origin of the pathogenic agent. Preventive Killing Confirm and rule out the disease in case of preventing killing will be based on clinical and laboratory examination of the animals	Epidemiological enquiry Additional samples for c-ELISA can be collected in a confirmed affected establishment to investigate the distribution of infected animals in the establishment. Sequencing is recommended to determine the origin of the *Mccp* and to perform a retrospective study. Preventive Killing In case of preventive killing, all animals should be subjected to clinical examination and in case of clinical signs the procedures described in the 1st scenario should be followed. In case of no clinical signs: i) detection of lung lesions in culled animals (acute lesions may be pathognomonic); ii) PCR from lung lesions and regional lymph nodes; iii) blood sampling for c-ELISA as described in Table 3 can be undertaken. In some cases, serological tests might be positive even though cultivation and PCR yield negative results.
3rd scenario Section 4.1.1.3 For granting a specific derogation from killing animals of the categories of article 13.2 of the Delegated Regulation in a CCPP-affected establishment	No specific guidelines on sampling procedures for clinical or laboratory examination were found for the 3rd scenario.	In a CCPP-affected establishment, the following considerations should be taken into account when designing derogations from killing animals: i) the lack of specificity of clinical examination; ii) animals without clinical signs may be incubating CCPP which cannot be detected by laboratory tests (the incubation period is usually 6–10 days, but varies from 2 days to 4 weeks); iii) some animals may become 'carriers' following their exposure and may remain a source of the Mccp; iv) the length of infectious period is not known; v)data on sensitivity and specificity of diagnostic tests are sparse, complicating interpretation of test results and estimates of predictive values;	All the animals intended for derogation from killing should be subjected to thorough individual clinical examination and samples for laboratory examination with serological tests (c-ELISA, LAT) should be collected from all the animals irrespective of the presence of clinical signs. Any animal testing positive to c-ELISA and LAT should be killed and samples from carcases should be examined by PCR. Regular clinical examination should be carried out at least weekly for the first 45 days and then every 45 days to detect early the onset of clinical signs and proceed with the laboratory examinations. In case clinical signs or deaths occurred, samples should be collected for further laboratory

Sampling procedure	Laboratory guidelines based on Council Directive 2003/85/EC if not stated otherwise	Conclusions	Recommendations
		vi) identification of infectious animals is often not possible and vii) airborne transmission can occur over short distances. Consequently, sampling procedures (clinical and laboratory) cannot provide a high level of confidence that these animals do not pose a risk for transmission if they are kept alive.	examinations following the procedures of the 1st scenario. Sampling for laboratory examination can be repeated every 45 days together with clinical examination from all the animals in the establishment for at least 6 months calculated forwards from the day of confirmation of the latest case within the establishment. The EFSA AHAW Panel considers that, given the current available laboratory tests, it will be very difficult to state with enough confidence, that the animals from an affected establishment without clinical signs and with negative results in serological tests taken during this one year period do not pose a risk of transmission and therefore this practice should be discouraged.
4th scenario Section 4.1.1.4 For the animals of non-listed species kept in a CCPP-affected establishment.	No specific guidelines on sampling procedures for clinical or laboratory examination were found for the 4th scenario.	Non-listed susceptible species include *Oryx* spp., such as the Arabian oryx and Gazelles, and the Tibetan antelope, *Pantholops hodgsonii*. *Gazella* spp. and *Procapra* spp. all of which are likely to be present in approved establishments as captive animals but are not kept as domesticated food-producing animals in the EU. Validity of the tests in animals other than goats has not been done, therefore there is uncertainty regarding the performance of tests in these non-listed species.	Where non-listed species are kept in an establishment affected by CCPP, they should be monitored for clinical signs. Where clinical signs or deaths are reported, samples should be collected for laboratory analysis following the procedures of the 1st scenario, Section 4.1.1.1.
5th scenario Section 4.1.1.5 For wild animals of the listed species within the CCPP-affected establishment and its surroundings.	No specific guidelines on sampling procedures for clinical or laboratory examination were found for the 5th scenario.	Wild *Ovis* ssp., *Capra* ssp. (including stray or feral animals) may play a role in the spread or maintenance of CCPP, following contact with infected goats. Isolation of animals for monitoring and testing in according with Section 4.1.1.1.	The surveillance of wild animals (including stray or feral animals) of listed species around an affected establishment may include: (i) visual inspection of these animals from a distance, (ii) clinical examination of trapped animals and (iii) thorough examination of animals found dead or hunted to identify lesions compatible with CCPP and sampling for laboratory analysis by PCR.

Sampling procedure	Laboratory guidelines based on Council Directive 2003/85/EC if not stated otherwise	Conclusions	Recommendations
		Validation of the tests in wild *Ovis* spp. or wild *Capra* spp. has not been done, therefore there is uncertainty about the performance of such tests	In the scenario where wild animals of Ovis ssp., Capra ssp., are living in the surrounding area of the affected establishment, and the risk assessment carried out by the Competent Authority may conclude that sampling live animals is necessary, then blood samples may be collected for laboratory analysis with c-ELISA. Wildlife population health experts can provide advice about the most suitable way to take samples, safely, from such animals. Investigation of development and validation of non-invasive diagnostic procedures by using alternative sample matrices (e.g. faeces, chewing baits) to detect antibodies.
6th scenario Section 4.1.1.6 For animals of listed species in the non-affected establishments located in a protection zone	No specific guidelines on sampling procedures for a clinical or laboratory examination were found for the 6th scenario.	*Mccp* may be transmitted by air over short distance and therefore CCPP can be transmitted to adjacent establishments. The absence of a protection zone and consequently visits and sampling procedures to establishments adjacent to the affected one, is not considered effective.	A protection zone including establishments adjacent to the infected establishment is recommended. Upon implementation clinical inspection and laboratory testing should take place in all establishments in the protection zone according to the 1st scenario (based on the presence or not of clinical signs or deaths). In case results are negative, serological sampling (aiming to detect seroprevalence higher than 1%, e.g. 5%, 10%) should be performed after 45 days (duration of the protection zone as recommended by EFSA AHAW Panel see Section 4.3.2) and the protection zone can be lifted if all samples prove negative.

Sampling procedure	Laboratory guidelines based on Council Directive 2003/85/EC if not stated otherwise	Conclusions	Recommendations
8th scenario Section 4.1.1.7 For non-affected establishments located in a surveillance zone	No specific guidelines on sampling procedures for a clinical or laboratory examination were found for the 8th scenario.	*Mccp* may be transmitted by air over short distance and therefore CCPP can be transmitted to adjacent establishments. Given the limited transmission, a 3 km zone is considered effective and the zone should be implemented for 45 days according to the incubation period of the disease (see Section 4.3.2) and not be lifted before the sampling of all the establishment in the protection zone has been completed with negative results.	For the surveillance zone, it is recommended that the efforts will be allocated to enhance immediate notification and passive surveillance by increasing awareness in all establishments, industry and public. High awareness at the slaughterhouses during the ante-mortem animal inspection and post-mortem inspection of the pleural cavity. Animals from establishments located in the surveillance zone should be thoroughly examined CCPP like lesions followed by sampling in case of suspicion according to the procedures described in Section 4.1.1.1 (1st scenario). Any establishment where more generic signs of the disease such as fever, lethargy, lost appetite, feed intake and productivity are reported should be visited, the animals should be clinically examined and samples should be collected following the procedures described in Section 4.1.1.1. Establishments in the surveillance zone epidemiologically linked to an affected establishment or to any other establishment in the protection zone should be also visited; the animals should be clinically examined, and samples should be collected following the procedures described in Section 4.1.1.1. The zone should not be lifted before the second negative test (45 days after the initiation of the zone and the first sampling) of the establishments in the protection zone.
ToR 1: To grant derogations for animal movements			
9th scenario Section 4.1.2.1 From non-affected establishments located in the protection zone to slaughterhouses	No specific guidelines on sampling procedures for clinical or laboratory examination were found for the 9th scenario in EU legislation.	During a CCPP outbreak the following considerations should be taken into account when designing derogations animal movements: i) the lack of specificity of clinical examination; ii) animals without clinical signs may be incubating CCPP which cannot be detected by laboratory	All the animals in the establishment of origin should be clinically examined before any movement, to identify animals with respiratory signs. In case clinical signs compatible with CCPP are identified, the establishment is considered suspect and the procedures for the laboratory confirmation

Sampling procedure	Laboratory guidelines based on Council Directive 2003/85/EC if not stated otherwise	Conclusions	Recommendations
located within the protection zone or in the surveillance zone or outside the restricted zone		tests carried out (incubation period varies from 2 days to 4 weeks) iii) some animals may become 'carriers' following their exposure and may remain a source of the *Mccp*; iv) the length of infectious period is not known; v) data on sensitivity and specificity of diagnostic tests are sparse, complicating interpretation of test results and estimates of predictive values; vi) identification of infectious animals is not always possible; vii) airborne transmission can occur over short distances. The fact that the destination of these animals is the slaughterhouse, all biosecurity measures are implemented and given that the animals should be slaughtered within 24 h reduces the risk. Animal slaughtering from the establishments in the protection zone could have beneficial effect encompassing the reduction of the number of potential hosts for the further spread of CCPP agent. Since the lesions in pleural cavity are pathognomonic for CCPP diagnosis, post-mortem inspection at slaughterhouse is crucial for the detection of the disease.	that are described in Section 4.1.1.1 should be followed and any movements should be prohibited. At slaughterhouses, a thorough post-mortem inspection should be performed for each animal, to identify lesions of CCPP. Any suspect lesion attributable to CCPP should be further investigated with laboratory examinations to rule out the presence of *Mccp* following the procedures described in Section 4.1.1.1.
12th scenario Section 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	No specific guidelines on sampling procedures for clinical or laboratory examination were found for the 12th scenario in EU legislation.	This scenario is very similar to the 9th scenario of Section 4.1.2.1.	This scenario is very similar to the 9th scenario of Section 4.1.2.1; therefore, the same procedures will be followed for this scenario as well.

Sampling procedure	Laboratory guidelines based on Council Directive 2003/85/EC if not stated otherwise	Conclusions	Recommendations
13th scenario Section 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	No specific guidelines on sampling procedures for clinical or laboratory examination were found for the 13th scenario in EU legislation.	This scenario is very similar to the 9th scenario of Section 4.1.2.1.	This scenario is very similar to the 9th scenario of Section 4.1.2.1; therefore, the same procedures will be followed for this scenario as well.
14th scenario Section 4.1.2.4 From an establishment in a surveillance zone to pastures situated within the surveillance zone	No specific guidelines on sampling procedures for clinical or laboratory examination were found for the 14th scenario in EU legislation.	The same considerations as described in the 9th scenario should be included in the assessment when designing animal movement derogations to pastures. Consequently, sampling procedures (clinical and laboratory) are not able to ensure with high level of confidence that animal movements to pastures do not pose a risk for transmission.	The animal movements from the establishments located in the surveillance zone to pastures within the surveillance zone should be allowed once the first clinical inspection of the establishments in the protection zone have been completed and the results of the initial laboratory tests in these establishments are negative. All the animals in the establishment of origin should be clinically examined before their movement, following the procedures described in Section 4.1.1.1 and a thorough investigation of the health history of the establishment for at least 45 days backwards should be performed to identify any sign compatible to CCPP. In an establishment where the number of animals is large, the individual clinical examination of all the animals may not be feasible; in that case the individual clinical examination can be restricted to those animals that are intended to be moved and the whole establishment should be visually inspected for clinical signs from respiratory system. In case clinical signs compatible with CCPP are identified, the establishment is considered suspect and the procedures for the laboratory confirmation that are described in Section 4.1.1.1 should be followed and any movements should be prohibited.

Sampling procedure	Laboratory guidelines based on Council Directive 2003/85/EC if not stated otherwise	Conclusions	Recommendations
15th scenario Section 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	No specific guidelines on sampling procedures for clinical or laboratory examination were found for the 15th scenario in EU legislation.	The same considerations as described in the 9th scenario should be included in the assessment when designing animal movement derogations. Taken into consideration the above-mentioned limitations it is very difficult to develop sampling procedures that will ensure with high level of confidence that the disease will not spread if live animals are allowed to be moved. Consequently, it is noteworthy that allowing movements from establishment in a surveillance zone to an establishment belonging to the same supply chain, located outside the surveillance zone increases the risk of CCPP expansion.	The animal movements from the establishments located in the surveillance zone to an establishment belonging to the same supply chain should be allowed once the first clinical inspection of the establishments in the protection zone have been completed and the results of the initial laboratory tests in these establishments are negative. In case clinical signs compatible with CCPP are identified or evidence of clinical signs the last 3 months, the establishment is considered suspect and the procedures for the laboratory confirmation as described in Section 4.1.1.1 should be followed and any movements should be prohibited. In addition to clinical examination a minimum sample of animals (including all animals to be moved) should tested with c-ELISA as described in Section 4.1.1.1 based on the total number of animals in the establishment and should be negative before moving the animals. Additional measures are recommended also for the establishment of destination where the animals should be tested again with c-ELISA 45 days after their introduction in the establishment of destination. Moreover, during that period, animal movements from the establishments of destination, slaughterhouses excluded, should not be allowed. The EFSA AHAW Panel considers that given the current available laboratory tests, it cannot be assessed with high confidence that live animals without clinical signs and with negative results in serological tests do not pose a risk of transmission. Therefore, live animal movements from the surveillance zone outside the restricted zone should be discouraged.

Sampling procedure	Laboratory guidelines based on Council Directive 2003/85/EC if not stated otherwise	Conclusions	Recommendations
18th scenario Section 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	No specific guidelines on sampling procedures for clinical or laboratory examination were found for the 18th scenario.	Same conclusions as described in Sections 4.1.2.1, 4.1.2.3, 4.1.2.4 and 4.1.2.5.	The same sampling procedures, according to different scenarios, should be implemented as those described in Sections 4.1.2.1, 4.1.2.3, 4.1.2.4 and 4.1.2.5.
ToR 1: For repopulation purposes			
19th scenario Section 4.1.3.1 For the animals that are kept for the repopulation prior to their introduction	No specific guidelines on sampling procedures for laboratory examination were found for the 19th scenario.	The following elements should be taken into consideration in case animals intended to be used for repopulation: i) the lack of specificity of clinical examination; ii) animals without clinical signs may be incubating CCPP which cannot be detected by laboratory tests (the incubation period is usually 6–10 days, but varies from 2 days to 4 weeks); iii) some animals may become 'carriers' following their exposure and may remain a source of the *Mccp*; iv) the length of infectious period is not known; v) data on sensitivity and specificity of diagnostic tests are sparse, complicating interpretation of test results and estimates of predictive values; vi) identification of infectious animals is often not possible and vii) airborne transmission can occur over short distances.	All the animals in the establishment of origin should be clinically examined before their movement, following the procedures described in Section 4.1.1.1. In an establishment where the number of animals is large, the individual clinical examination of all the animals may not be feasible. In that case then clinical inspection of the whole establishment and thorough investigation of the health history of the establishment for at least 45 days backwards should be performed to identify any symptom compatible to CCPP. In case clinical signs compatible with CCPP are identified, the establishment is considered suspect 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. In case the animals originate from establishments located in outside the restricted zones, there is no need for laboratory examination if there are no other reasons based on the authorities' risk assessment to recommend it (e.g. epidemiological link with an

Sampling procedure	Laboratory guidelines based on Council Directive 2003/85/EC if not stated otherwise	Conclusions	Recommendations
			affected establishment or with an affected or high-risk area). Clinical examination as described above would be enough. When animals originate from restricted areas established around different index cases in addition to clinical examination a minimum sample of animals (including all animals to be moved) should tested with c-ELISA as described in Section 4.1.1.1 based on the total number of animals in the establishment before the movement.
20th scenario Section 4.1.3.2 In the event of unusual mortalities or clinical signs being notified during the repopulation	No specific guidelines on sampling procedures for laboratory examination were found for the 20th scenario.	In the case of unusual mortalities or clinical signs compatible with CCPP notified during the repopulation, it is important to rule out the presence of the disease.	In the event that animals with clinical signs compatible with CCPP (see Section 4.1.1.1) are identified in an establishment during repopulation, the establishment is considered suspect. Repopulation should be stopped and the procedures for confirmation should be followed (see Section 4.1.1.1). In addition, the establishments from where the suspect animals originate should be considered as suspect and confirmation procedures followed (see Section 4.1.1.1).
21st scenario Section 4.1.3.3 For animals that have been repopulated		Following restocking, animals should be thoroughly examined clinically and by laboratory examinations in order to rule out the presence of the disease.	Animals must be subjected to weekly clinical inspection up to 45 days (monitoring period as proposed by EFSA AHAW Panel) after re-introduction. The last day of the monitoring period following the latest day of animals' introduction, all the animals should be subjected to a thorough clinical examination as described in Section 4.1.1.1. Laboratory examination is not recommended if there are no other reasons based on the authorities' risk assessment to recommend. If clinical signs are identified, then the procedures for the laboratory confirmation that are described in Section 4.1.1.1 should be followed.

ToR 2

Description	Conclusions	Recommendations
Section 4.2 Assessment of the length of the monitoring period of CCPP	Scenarios 1, 2, 3, 4, 6 and 7 The ELS carried out did not find evidence corroborating the current monitoring period for CCPP (45 days). Information is available about the incubation period of CCPP which is usually 6–10 days, but can vary from 2 days to 4 weeks while some experimentally infected goats did not become ill until up to 41 days after exposure (Thiaucourt, 2003; OIE, 2009; Spickler, 2015. According to the expert knowledge and based on the longest incubation period (41 days), it was concluded with a 90–100% certainty that 95 out of every 100 CCPP-infected goat establishments in an already affected region, infection would have occurred within the 45 days prior to the suspicion report, and therefore, the length of the monitoring period of 45 days as defined in the Delegated Regulation is considered effective in case the disease has already been detected in the area, and high awareness is expected. Scenario 5 Based on the results of the scientific publications as presented in Table 5 in Section 4.2.1, the latest date of seroconversion was 21 days post contact by CFT. The length of the monitoring period of 45 days, as defined in the Delegate Regulation is considered effective in areas where the disease has been confirmed and high awareness is in place.	Scenarios 1,2,3,5,6,7 A monitoring period of at least 180 days (6 months) is recommended for the index case in the area where the awareness is low since it is concluded with a 50–100% certainty that 95 or more out of every 100 affected CCPP establishments will have become infected within the previous six months. Scenario 4 A longer monitoring period of at least 180 days (6 months) is recommended for the early phases of the outbreak in the area where the awareness is low (e.g. if the index case was in a slaughterhouse and the epidemiological enquiry is taking time).

ToR 3

Description	Conclusions	Recommendations
Section 4.3.1 Assessment of the minimum radius	No transmission kernels either specific for CCPP or for diseases that have similar transmission routes to CCPP were found in the literature, nor were data suitable to estimate kernels identified. Accordingly, the zone sizes for CCPP were assessed using expert's knowledge. The causative agent can be transmitted by air, and therefore, animals in adjacent establishments can be infected. Based on the WG expert opinion, the absence of a protection zone is not considered effective while the defined minimum radii of 3 km of the	A protection zone including the establishments adjacent to the infected establishment or establishments with pastures or yards adjacent to the infected one (e.g. 1 km zone depending on the local situation and the farms distribution) since this would prevent disease spread (90–100% certainty). All the establishments in the protection zone should be visited and clinical inspection of animals is recommended (see Section 4.3.1). Taken into consideration the local epidemiological situation, the density of the establishments and the commercial activities different

ToR 2		
	surveillance zone, is considered effective (95–100% certainty) to restrain the spread of CCPP.	combinations of radii in the protection and the surveillance zones may be selected to further decrease the
Section 4.3.2 Assessment of the minimum period	The results of the ELS are inconclusive. The OIE reports an incubation period which varies from 2 days to 4 weeks, while some experimentally infected goats become ill up to 41 days. The minimum period of 45 days indicated in the Delegated Regulation for the restriction measures in the protection and surveillance zone is considered effective to detect affected establishments and to prevent the movement of infected animals from the zones.	None

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Abbreviations

ASF	African swine fever
AHS	African horse sickness
c-ELISA	Competitive enzyme linked immunosorbent assay
CFT	Complement Fixation Test
CSF	Classical swine fever
CBPP	Contagious bovine pleuropneumonia
CCPP	Contagious caprine pleuropneumonia
CO	Cut-off (of a diagnostic test)
dpi	days post inoculation/infection
ELISA	enzyme-linked immunosorbent assay
ELS	extensive literature search
HPAI	Highly Pathogenic Avian Influenza
OIE	World Organisation for Animal Health
PCR	polymerase chain reaction
QoI	quantities of interest
RP	rinderpest virus
RVFV	Rift Valley fever virus
SPGP	Sheep pox and goat pox
ToR	Terms of Reference

Annex A – Definitions in EU legislation

Terms	Definitions
Clinical examination	The clinical examination comprises: (i) an initial general evaluation of the animal health status of the establishment which comprises all the animals of listed species kept in the establishment; and (ii) an individual examination of the animals included in the sample referred to in point (a). The sampling of animals for clinical examination is carried out in accordance with point A.1 of Annex I for terrestrial animals (Delegated Regulation article 3).
Confined establishment	Means any permanent, geographically limited establishment, created on a voluntary basis and approved for the purpose of movements, where the animals are: (a) kept or bred for the purposes of exhibitions, education, the conservation of species or research; (b) confined and separated from the surrounding environment; and (c) subject to animal health surveillance and biosecurity measures; (AHL: Regulation 2016/429 article 4(48)).
Epidemiological unit	Means a group of animals with the same likelihood of exposure to a disease agent; (AHL: Regulation 2016/429 article 4(39)).
Establishment	Means any premises, structure, or, in the case of open-air farming, any environment or place, where animals or germinal products are kept, on a temporary or permanent basis, except for: (a) households where pet animals are kept; (b) veterinary practices or clinics; (AHL: Regulation 2016/429 article 4(27)).
Health status	Means the disease status as regards the listed diseases relevant for a particular listed species with respect to: (a) an animal; (b) animals within: (i) an epidemiological unit; (ii) an establishment; (iii) a zone; (iv) a compartment; (v) a Member State; (vi) a third country or territory; (AHL: Regulation 2016/429 article 4(34)).
Infected zone	Means a zone in which restrictions on the movements of kept and wild animals or products and other disease control and biosecurity measures may be applied with the view to preventing the spread of a category A disease in the event of official confirmation of the disease in wild animals. (Delegated Regulation article 2(15)).
Kept animals	Means animals which are kept by humans, including, in the case of aquatic animals, aquaculture animals; (AHL: Regulation 2016/429 article 4 (5)).
Outbreak	Means the officially confirmed occurrence of a listed disease or an emerging disease in one or more animals in an establishment or other place where animals are kept or located; (AHL: Regulation 2016/429 article 4 (40).
Protection zone	Means a zone around and including the location of an outbreak, where disease control measures are applied in order to prevent the spread of the disease from that zone; (ahl: regulation 2016/429 article 4(42).)
Listed diseases	Means diseases listed in accordance with article 5(1); (ahl: regulation 2016/429 article 4 (18)). List of the diseases (ahl: regulation 2016/429, annex ii).
Listed species	Means an animal species or group of animal species listed in accordance with article 8(2), or, in the case of emerging diseases, an animal species or group of animal species which meets the criteria for listed species laid down in article 8(2); (ahl: regulation 2016/429 article 4(20)). List of species and groups of species (commission implemented regulation 2018/1882).
Monitoring periods	It is appropriate to follow a single approach for the measures to apply in the event of a category a disease. However, the epidemiology of diseases should be taken into account to establish the appropriate moment for the competent authority to apply control measures and to carry out investigations if there is suspicion or confirmation of those diseases. Therefore 'monitoring periods' should be provided, as reference time frames for each category a disease affecting terrestrial animals based on incubation periods and other relevant elements that may affect the spread of the disease. (delegated regulation, whereas 10).

Terms	Definitions
Restricted zone	Means a zone in which restrictions on the movements of certain animals or products and other disease control measures are applied, with a view to preventing the spread of a particular disease into areas where no restrictions are applied; a restricted zone may, when relevant, include protection and surveillance zones; (ahl: regulation 2016/429 article 4(41)).
Surveillance zone	Means a zone which is established around the protection zone, and where disease control measures are applied in order to prevent the spread of the disease from the protection zone; (ahl: regulation 2016/429 article 4(43)).
Wild animals	Means animals which are not kept animals; (ahl: regulation 2016/429 article 4(8)).
Zone	Means: (a) for terrestrial animals, an area of a member state, third country or territory with a precise geographical delimitation, containing an animal subpopulation with a distinct health status with respect to a specific disease or specific diseases subject to appropriate surveillance, disease control and biosecurity measures; (ahl: regulation 2016/429 article 4 (35)).

Annex B – Scenarios of ToR 1

ToRs	Legislation	Scenario	Description of the Scenario	Elements of the Scenario
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 suspect establishment, based on clinical examination (TOR 1.1) and laboratory examination (TOR 1.2), in their ability to detect a category A disease in kept animals if the disease is present in that establishment, or to rule it out if not present (Art. 6 (2)).	• event of suspicion of a category A disease • in an establishment • kept animals of listed species • the competent authority shall immediately conduct an investigation to confirm or rule out the presence of the suspected listed disease • official veterinarians perform clinical examinations and collect samples for laboratory examinations
ToR 1.2	Art. 12(3), Art. 7 (4) (Preventive killing) of the Delegated Regulation, and Art. 57 Reg.2016/429	2nd scenario	To assess the effectiveness of disease-specific sampling procedures, based on laboratory examination (ToR 1.2), in their ability to detect the disease in the event of preventive killing and in their ability to support with the epidemiological investigation (disease detection, prevalence estimation, agent identification, etc.) in kept animals of listed species in an affected establishment, before or when they are killed or found dead. The purposes of the epidemiological enquiry are described in Article 57 of Regulation (EU)2016/429.	• affected establishment officially confirmed • kept animals of listed species found dead or before/ when they are killed • competent authority collects samples for laboratory examinationfor the purposes of: a) supporting the epidemiological enquiry: – to identify the likely origin of the disease – to calculate the likely length of time that the disease is present – to identify establishments where the animals could have contracted the disease and movements from the affected establishment that could have led to the spread of the disease – to obtain information on the likely spread of the listed disease in the surrounding environment, including the presence and distribution of disease vectors b) confirming/ruling out disease in the event of preventive killing
ToR 1.1 ToR 1.2	Article 13(3)c of the Delegated Regulation	3rd scenario	To assess the effectiveness of disease-specific sampling procedures based on clinical (ToR 1.1) and laboratory (ToR 1.2) examinations of the animals of listed species belonging to the categories described in article 13(2)) of an affected establishment, in order to grant a specific	• affected establishment officially confirmed • kept animals of listed species of specific categories • animal categories based on article 13(2): a) animals kept in a confined establishment

ToRs	Legislation	Scenario	Description of the Scenario	Elements of the Scenario
			derogation from killing these animals, while ensuring that they do not pose a risk for the transmission of the disease.	b) animals kept for scientific purposes or purposes related to conservation of protected or endangered species c) animals officially registered in advance as rare breeds d) animals with a duly justified high genetic, cultural or educational value • the competent authority may grant specific derogation from killing all the animals of listed species belonging to any of the above categories in an affected establishment, provided that specific conditions are fulfilled • the animals should be subjected to clinical surveillance, including laboratory examinations • sampling procedures should ensure that the animals do not pose a risk of transmission of the category A disease if left alive
ToR 1.1 ToR 1.2	Article 14(1) of the Delegated Regulation Art. 57 Reg.2016/429	4th scenario	To assess the effectiveness of disease-specific sampling procedures based on clinical (ToR 1.1) and laboratory (ToR 1.2) examinations of the animals of non-listed species kept in an affected establishment, in their ability to ensure the detection of the agent if the agent is present in these species.	• kept animals of non-listed species of epidemiological relevance for the control of the disease • animals of non-listed species are those animals that are not listed in Commission Implementing Regulation (EU) 2018/1882 for each of the category A diseases • animal species acting purely as mechanical carriers of the agent will not be covered • The competent authority is not obliged to carry out the sampling of non-listed species, but they may establish it in addition to other measures • sampling procedures to ensure detection of the agent in these species
ToR 1.1 ToR 1.2	Article 14(1) of the Delegated Regulation Art. 57 Reg.2016/429	5th scenario	To assess the effectiveness of disease-specific sampling procedures based on clinical (ToR 1.1) and laboratory (ToR 1.2) examinations of the wild animals of listed species within the affected establishment and in its surroundings. The purpose of the sampling procedures is to ensure the detection of the agent, if the agent is present in these wild species	• affected establishment officially confirmed • wild animals of listed species within the establishment and in the surroundings of the establishment • the competent authority may establish these sampling procedures in addition to other measures

ToRs	Legislation	Scenario	Description of the Scenario	Elements of the Scenario
				• sampling procedures in wild animals of listed species to ensure the detection of the agent, if the agent is present in these wild species
ToR 1.1 ToR 1.2	Article 26(2) of the Delegated Regulation	6th scenario	To assess the effectiveness of disease-specific sampling procedures based on clinical (ToR 1.1) and laboratory (ToR 1.2) examinations of the animals of listed species in establishments located in the protection zone. The purpose of the sampling procedures is to ensure the detection of the agent, if the agent is present in these animals.	• protection zone with radius up to 3 km • non-affected establishments with kept animals of listed species • all the non-affected establishments within the protection zone • official veterinarians must visit at least once all the establishments • among others, they must perform a clinical examination of kept animals of listed species and if necessary, collection of samples for laboratory examination • sampling procedures to confirm or rule out the presence of a category A disease
ToR 1.3	Article 26(5) of the Delegated Regulation point A.3 of Annex I	7th scenario	To assess the effectiveness of disease-specific sampling procedures, based on clinical (ToR 1.1) and laboratory (ToR 1.2) examinations of the animals of listed species, for the sampling of establishments located in a protection zone when the radius is larger than 3 km. The purpose of the sampling procedure is to ensure disease detection of the agent if the agent is present in establishments within the protection zone	• protection zone with radius larger than 3 km • non-affected establishments of kept animals of listed species • sample of the non-affected establishments in the protection zone • in a protection zone with a radius equal to 3 km, official veterinarians must carry inspections in all establishments within the 3 km • in case of a radius larger than 3 km, official veterinarians may not visit all establishments, but a sample of those. EFSA is requested to assess how many of these establishments should be inspected, in order to ensure the detection of the agent, if the agent is present in animals in these establishments • among others perform clinical examination of kept animals of listed species and if necessary, collection of samples for laboratory examination • sampling procedure to ensure the detection of the disease if the disease is present in any of these establishments

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 agent is present in establishments within the surveillance zone	• surveillance zone • establishments of kept animals of listed species • sample of the establishments in the surveillance zone • official veterinarians carry out visits to a sample of the establishments • among others perform clinical examination of kept animals of listed species and if necessary, collection of samples for laboratory examination • sampling procedure to ensure the detection of the disease if the disease is present in any of the establishments
Derogations to allow animal movements				
ToR 1.4	Article 28(5) of the Delegated Regulation Article 29 of the Delegated Regulation	9th scenario	To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations of the animals of an establishment in a protection zone, in order to grant a derogation from prohibitions in the movement of animals, and allow for the animals to be moved to a slaughterhouse located within the protection zone or in the surveillance zone or outside the restricted zone (Art29)	• protection zone • kept animals of listed species • grant derogation for movement from a non-affected establishment in the protection zone • to be moved to a slaughterhouse located within the protection zone or in the surveillance zone or outside the restricted zone • clinical examinations and laboratory examination of animals kept in the establishment, including those animals to be moved
ToR 1.4	Article 28(5) and Article 30(1) of the Delegated Regulation	10th scenario	To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations, to grant a derogation from prohibitions in the movement of day-old-chicks located in the protection zone and hatched from eggs originating in the restricted zone or outside the restricted zone. The sampling procedures should ensure that the movement of these day-old-chicks to an establishment located in the same Member State but if possible, outside the restricted zone	• protection zone • grant derogation for movement from a non-affected establishment in the protection zone • day-old-chicks from non-affected establishment located in the protection zone, hatched from eggs originating in or outside the restricted zone • to be moved to an establishment located in the same Member State but if possible, outside the restricted zone • clinical examinations and laboratory examination of animals kept in the establishment, including those animals to be moved

ToRs	Legislation	Scenario	Description of the Scenario	Elements of the Scenario
ToR 1.4	Article 28(5) and Article 30(2) of the Delegated Regulation	11th scenario	To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations, to grant a derogation from prohibitions in the movement of ready-to-lay poultry located in the protection zone to establishments located in the same MS and if possible within the restricted zone.	• protection zone • ready-to-lay poultry • grant derogation for movement from a non-affected establishment in the protection zone • to be moved to an establishment located in the same Member State and if possible, within the restricted zone • clinical examinations and laboratory examination of animals kept in the establishment, including those animals to be moved
ToR 1.4	Article 28(5) and Article 37 of the Delegated Regulation	12th scenario	To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations of the animals of an establishment in a protection zone, in order to grant derogation from prohibitions in the movement of these animals to a plant approved for processing or disposal of animal by-products in which the kept animals are immediately killed (Art37)	• protection zone • kept animals of listed species • grant derogation for movement from a non-affected establishment in the protection zone • to be moved to a plant approved for processing or disposal of animal by-products in which the kept animals are immediately killed • clinical examinations and laboratory examinations of animals kept in the establishment, including those animals to be moved
ToR 1.4	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 examinations of the animals of listed species in order to grant derogation from prohibitions and allow for these animals to be moved: a) from an establishment in a surveillance zone to a slaughterhouse located within or outside the restricted zone, b)from an establishment outside the surveillance zone to a slaughterhouse situated in the surveillance zone	• surveillance zone • kept animals of listed species • grant derogation for movement from an establishment in the surveillance zone to be moved to a slaughterhouse within the restricted zone or outside the restricted zone • grant derogation for movement from an establishment outside the surveillance zone to a slaughterhouse situated in the surveillance zone • clinical examinations and laboratory examination of animals kept in the establishment, including those animals to be moved
ToR 1.4	Article 43(5) and Article 45(1) of the Delegated Regulation	14th scenario	To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations of kept ungulates of listed species in order to grant a derogation and allow for the animals to be moved	• surveillance zone • kept ungulates of listed species • grant derogation for movement from an establishment in the surveillance zone

ToRs	Legislation	Scenario	Description of the Scenario	Elements of the Scenario
			from an establishment in the surveillance zone to pastures situated within the surveillance zone	• to be moved to pastures situated within the surveillance zone • clinical examinations and laboratory examination of animals kept in the establishment, including those animals to be moved
ToR 1.4	Article 43(5) and Article 45(2) of the Delegated Regulation	15th scenario	To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations of kept ungulates of listed species in order to grant derogation and allow to be moved from an establishment in the surveillance zone to an establishment belonging to the same supply chain, located in or outside the surveillance zone, in order to complete the production cycle before slaughter	• surveillance zone • kept animals of listed species • grant derogation for movement from the surveillance zone • to be moved to an establishment belonging to the same supply chain, located in or outside the surveillance zone, to complete the production cycle before slaughter • clinical examinations and laboratory examination of animals kept in the establishment, including those animals to be moved
ToR 1.4	Article 43(5) and Article 46(1) of the Delegated Regulation	16th scenario	To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations to grant derogation of movements of day-old-chicks hatched from establishment located in the surveillance zone, from eggs originating within the surveillance zone and eggs originating outside the restricted zone, to an establishment located in the same Member State where they were hatched	• surveillance zone • kept birds of listed species • grant derogation for movement of day-old-chicks hatched from establishment located in the surveillance zone, from eggs originating from establishment within the surveillance zone or eggs originating from outside the restricted zone • to be moved to an establishment located in the same Member State • clinical examinations and laboratory examination of animals kept in the establishment, including those animals to be moved
ToR 1.4	Article 43(5) and Article 46(2) of the Delegated Regulation	17th scenario	To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations, to grant a derogation from prohibitions in the movement of ready-to-lay poultry located in the surveillance zone to establishments located in the same MS.	• surveillance zone • ready-to-lay poultry • to be moved to an establishment located in the same Member State • clinical examinations and laboratory examination of animals kept in the establishment, including those animals to be moved

ToRs	Legislation	Scenario	Description of the Scenario	Elements of the Scenario
ToR 1.4	Article 56(1)c of the Delegated Regulation	18th scenario	To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations of the animals of an establishment located in the restricted zone of an outbreak in order to allow their move within the restricted zone, when restriction measures are maintained beyond the period set out in Annex XI	• restricted zone when restriction measures are maintained beyond the period set out in Annex XI • kept animals of listed species • grant derogation for movement from an establishment within the restricted zone • clinical examinations and laboratory examination of animals kept in the establishment, including those animals to be moved
Repopulation				
ToR 1.5	Article 59(2),(3) of the Delegated Regulation	19th scenario	To assess the effectiveness of disease-specific sampling procedures based on laboratory examinations of the animals that are kept for the repopulation prior to their introduction to rule out the presence of the disease.	• repopulation of a previous affected establishment • kept animals of listed species • Animals intended to repopulation shall be sampled prior to their introduction into the establishment of destination • samples shall be collected from a representative number of animals to be introduced of each consignment from each establishment or from a representative number of animals of each consignment (if animals are all to be introduced at different times or from different establishments of origin) • laboratory examinations • sampling procedures to rule out the presence of the disease
ToR 1.5	Article 59(9) of the Delegated Regulation	20th scenario	To assess the effectiveness of disease-specific sampling procedures based on laboratory examinations of the animals that have been repopulated, in the event of unusual mortalities or clinical signs being notified during the repopulation; to rule out the presence of the disease.	• repopulated establishment • unusual mortalities or clinical signs during the repopulation • the official veterinarians shall without delay collect samples for laboratory examination • sampling procedures to rule out the presence of the disease
ToR 1.5	Article 59(5) of the Delegated Regulation	21st scenario	To assess the effectiveness of disease-specific sampling procedures based on laboratory examinations of the animals that have been repopulated, on the last day of the monitoring period calculated forwards from the date on which the animals were placed in the repopulated	• repopulated establishment • kept animals of listed species • Animals that have been used for repopulation • Laboratory examinations

ToRs	Legislation	Scenario	Description of the Scenario	Elements of the Scenario
			establishment. In case the repopulation takes place in several days, the monitoring period will be calculated forwards from the last day in which the last animal is introduced in the establishment.	• Sampling procedures to rule out the presence of the disease

Annex C – Existing sampling procedures for CCPP

Laboratory and clinical guidelines as described in the relevant documents

Scenario	Description of the Scenario	Clinical guidelines	Laboratory guidelines
1st	**To assess the effectiveness of disease-specific sampling procedures of animals of listed species in a suspect establishment, based on clinical examination (TOR1.1) and laboratory examination (TOR1.2), in their ability to detect a category A disease in kept animals if the disease is present in that establishment, or to rule it out if not present (Art. 6 (2))**.	No specific guidelines described in legislation ***Notes:*** ***OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (OIE, 2018):*** A. Introduction : Differential diagnosis may be difficult in the field as goats may be infected with a number of mycoplasma species that may induce similar signs. However, CCPP may be suspected when lesions are restricted to the respiratory tract, affect only one lung and when animals present a conspicuous pleurisy with profuse effusion of pleural fluid. CCPP could also be confused with peste des petits ruminants or pasteurellosis. ***CFSPH factsheet on CCPP (CFSPH, 2015):*** Clinical Signs: Contagious caprine pleuropneumonia is strictly a respiratory disease. Peracute, acute and chronic forms may be seen in endemic areas. Peracutely affected goats can die within 1–3 days with minimal clinical signs. In acute disease, the initial signs are a very high fever (41–43°C; 106–109°F), lethargy and anorexia, followed by coughing and laboured respiration. The cough is frequent, violent and productive. In the final stages of disease, the goat may not be able to move, and stands with its front legs wide apart, and its neck stiff and extended . . . ***Foreign animal diseases (USAHA, 2008):*** CHAPTER 15: CONTAGIOUS CAPRINE PLEUROPNEUMONIA 9. Diagnosis a. Field diagnosis A highly contagious disease occurring in goats and characterised by pyrexia of 41C and above, severe respiratory distress, high mortality and post-mortem lesions of fibrinous	***OIE Terrestrial Code (OIE, 2019):*** Article 14.3.7. Recommendations for importation from countries considered infected with CCPP For domestic goats Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the animals: 1) showed no clinical sign of CCPP on the day of shipment; 2) were subjected to a complement fixation test for CCPP with negative results, on two occasions, with an interval of not less than 21 days and not more than 30 days between each test, the second test being performed within 14 days prior to shipment (under study); *Notes:* ***OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (OIE, 2018):*** B. Diagnostic technique Table 1: Test methods available for the diagnosis of CCPP and their purpose: purpose of 'confirmation of clinical cases': – Confirmation of the agent [1]: *in vitro* culture [2], molecular tests (PCR) (recommended method) – Detection of immune response: CFT, latex agglutination (recommended method), c-ELISA [1] A combination of agent identification methods applied on the same clinical sample is recommended. [2] Organisms isolated should be subjected to confirmatory molecular, biochemical or immunological methods as described below. 1. Serological tests Serology has not been widely applied to identifying the cause of outbreaks of pleuropneumonia in goats and sheep. Three methods are currently available: CFT, the

Scenario	Description of the Scenario	Clinical guidelines	Laboratory guidelines
		pleuropneumonia with pronounced hepatisation and pleural adhesions warrants a field diagnosis of CCPP.	latex agglutination test and the competitive enzyme-linked immunosorbent assay (ELISA) with a specific MAb (c-ELISA). Goats are frequently infected by mycoplasmas of the *mycoides* cluster, which may induce cross reactions with tests such as the CFT that use crude antigenic preparations. Seroconversion to Mccp in experimentally infected animals is observed by the CFT to start 7–9 days after the appearance of clinical signs, to peak between days 22 and 30, and to decline rapidly thereafter. These various observations indicate that serology should be applied on a herd, not an individual basis, and that whenever possible, paired serum samples collected 3–8 weeks apart, should be examined. ***EFSA Scientific opinion on CCPP (EFSA, 2017):*** 3.1.1.8. Article 7(a)(viii) The existence of diagnostic and disease control tools Diagnostic tools Parameter 1 – Existence of diagnostic tools Direct detection of Mccp: • Isolation of Mccp is very difficult due to the fastidiousness of this mycoplasma. Isolation requires very rich media which are not in routine use. Colonies are very small, especially upon primary isolation, and require stereomicroscopes for observations. Consequently, labs which perform routine diagnostic procedures are not able to isolate Mccp. Specific PCR and quantitative PCR (Q-PCR): A specific PCR was developed in 2004 (Woubit et al., 2004). Another PCR was developed earlier, but it required a digestion of the amplified product to achieve identification (Bascunana et al., 1994). A Q-PCR was then developed based on the same primers (Lorenzon et al., 2008). However, sensitivity

Scenario	Description of the Scenario	Clinical guidelines	Laboratory guidelines
			is not an issue when acute CCPP cases are found, as the mycoplasma concentration is huge in the pleural fluid. A multiplex PCR was developed to detect Mccp as well as other goat pathogens (Settypalli et al., 2016). . . . Indirect detection: The complement fixation test (CFT) should not be used for CCPP as there are many cross reactions within the *mycoides* cluster species, or closely related species, that can be found in goats (*M. capricolum* subsp. *capricolum*, *M. mycoides* subsp. *capri*, *M. leachii*, *M. putrefaciens*, *M. ferriruminatoris*, etc.). There is an agglutination test based on latex beads sensitised with polysaccharides (CapriLAT, APHA diagnostics). This test can be used to detect ongoing or recent outbreaks as it detects mostly IgMs. However, Mccp shares the same polysaccharide at its surface with M. capricolum subsp. Capricolum and also *M. leachii*. There are therefore risks of false positive reactions. There is now a specific c-ELISA test developed and validated at CIRAD (Validation dossier accepted by the French Committee of Accreditation for CIRAD to be accredited ISO 17025 for this technique) (Thiaucourt et al., 1994). . . . This test is marketed by IDEXX: Part Number:99-56231. . . . 3.1.4. Article 7(d) The feasibility, availability and effectiveness of the following disease prevention and control measures 3.1.4.1. Article 7(d)(i) Diagnostic tools and capacities Availability Parameter 1 – Officially/internationally recognised diagnostic tool, OIE certified Complement fixation test, latex agglutination and c-ELISA are not yet recognised as OIE certified tests. CFT should be

Scenario	Description of the Scenario	Clinical guidelines	Laboratory guidelines
			abandoned as it is not specific. The c-ELISA is now produced by IDEXX (Part Number: 99-56231) and all batches are quality assured by CIRAD before release. Effectiveness Parameter 2 – Se and Sp of diagnostic test The cut-off of the c-ELISA has been set at 55 PI to obtain a very high specificity (99.9%) when performed under quality assurance. This high specificity is detrimental to individual sensitivity. The test is, therefore, conceived as a herd test. In any case, herds are considered the most appropriate epidemiological unit to control CCPP. ***CFSPH factsheet on CCPP (CFSPH, 2015):*** Diagnostic Tests Because *M. capripneumoniae* is so fastidious and cultures can be overgrown with other mycoplasmas, it may not be isolated from clinical samples, particularly if the sample has not been conserved adequately. This organism has not been found in lesions from animals with chronic disease. PCR is more likely to be successful than culture and can be used to identify *M. capripneumoniae* directly in tissue samples or pleural fluid…. Cross reactions can be an issue in antigen detection tests. Serological tests to detect antibodies to *M. capripneumoniae* include complement fixation, latex agglutination (which can identify early IgM antibodies) and competitive enzyme-linked immunosorbent assays (ELISA). Animals with acute CCPP rarely develop measurable titres before death; antibodies usually become detectable 7–9 days after the first clinical signs. Whenever possible, paired serum samples should be collected 3–8 weeks apart. Serological tests are generally used on a herd basis and not for individual diagnosis. These tests do not identify all reactors, and cross-reactivity is an issue. A more specific

Scenario	Description of the Scenario	Clinical guidelines	Laboratory guidelines
			competitive binding ELISA, described in 2014, was reported not to cross-react with other Mycoplasma found in goats. ***Foreign animal diseases (USAHA, 2008):*** 9. Diagnosis b. Laboratory diagnosis i. Samples From a dead animal that has had severe clinical disease, the best specimens to submit are affected lungs, swabs of major bronchi and tracheobronchial or mediastinal lymph nodes. ***Technical paper about CCPP surveillance in France (Gaurivaud et al., 2017):*** • **Le diagnostic de certitude en laboratorie, qui impose I'isolement en culture de l'agent étiologue (au sens de I'OIE) [18], reste déllcat pour la PPCC.** En effect, *M. capricolum* subsp. capripneumonia montre une croissance difficile dans les milieux classiques utilisés à I'heure actuelle pour les mycoplasmes. Il n'a été isolé pour la premiére fois qu'en 1976. • De plus, les traitements antibiotiques souvent utilisés par les éleveurs reduisent beaucoup les chances d'isoler I'agent pathogene. **N.B.: L'obtention d'un mycoplasme en culture à partir d'une suspicion de PPCC n'est pas suffisante pour établir un diagnostic**. D'autres mycoplasmes à croissance plus rapide, et génétiquement proches de *M. capricolum* subsp. capripneumoniae, telsque *M. mycosides* subsp. capri, *M. capricolum* subsp. capricolumn et *M. putrefaciens*, qui sont responsables de l'agalactie contagieuse chez les caprins, peuvent être isolés. Des tests molécularies spécifiques developpés en 1994 [4] et 2004 [32]

Scenario	Description of the Scenario	Clinical guidelines	Laboratory guidelines
			permettent alors d'identifier précisément le mycoplasme en question. ***Contagious caprine pleuropneumonia – a comprehensive review (Iqbal Yatoo et al., 2019*):** 5. Diagnosis 5.1. Sampling Nasal swabs, pleural fluid and lung samples (from necropsied animals) are collected from goats showing typical signs of CCPP. Blood or serum samples are essential for serology and discharges, exudates, blood and tissues for culture or isolation and gene/DNA-based studies. Nasal swabs are collected after proper cleaning of the external nares and are placed in universal transport media. Lung samples are aseptically collected at necropsy from the interface between affected and non-affected parts.
2nd	**To assess the effectiveness of disease-specific sampling procedures, based on laboratory examination (ToR1.2), in their ability to detect the disease in the event of preventive killing, and in their ability to support with the epidemiological investigation (disease detection, prevalence estimation, agent identification, etc.) in kept animals of listed species in an affected establishment, before or when they are killed or**	No specific guidelines described in legislation ***CFSPH factsheet on CCPP (CFSPH, 2015):*** Post Mortem Lesions The lesions of contagious caprine pleuropneumonia are limited to the respiratory system. Acute disease is characterised by unilateral or bilateral pneumonia and serofibrinous pleuritis with straw-coloured fluid in the thorax. … Varying degrees of lung consolidation or necrosis can be seen, and the regional (bronchial) lymph nodes are enlarged. Some long-term survivors have chronic pleuropneumonia or chronic pleuritis, with encapsulation of acute lesions and numerous adhesions to the chest wall.	No specific guidelines described in legislation ***Note:*** ***OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (OIE, 2018):*** 1.4. Isolation of mycoplasmas 1.4.1. Selection of samples The necropsy samples of choice are lung lesions, particularly from the interface between consolidated and unconsolidated areas, pleural fluid and mediastinal lymph nodes. If microbiological examination cannot be performed immediately, samples or whole lungs can be stored at –20°C for considerable periods (months) with little apparent loss of mycoplasma viability. During transport, samples should always be kept as cool as possible, as mycoplasma viability diminishes rapidly with increasing temperature. Lung samples can be dispatched to other laboratories in frozen form.

Scenario	Description of the Scenario	Clinical guidelines	Laboratory guidelines
	found dead. The purposes of the epidemiological enquiry are described in Article 57 of Regulation (EU)2016/429.		
3rd	**To assess the effectiveness of disease-specific sampling procedures based on clinical (ToR1.1) and laboratory (ToR1.2) examinations of the animals of listed species belonging to the categories described in article 13(2)) of an affected establishment, in order to grant a specific derogation from killing these animals, while ensuring that they do not pose a risk for the transmission of the disease**.	No specific guidelines described in legislation	No specific guidelines described in legislation
4th	**To assess the effectiveness of disease-specific sampling procedures, based on clinical (ToR1.1) and laboratory (ToR1.2) examinations of the animals of non-listed species kept in an affected establishment, in their ability to ensure the detection of the agent if the agent 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 (ToR1.1) and laboratory (ToR1.2) examinations of the wild animals of listed species within the affected establishment and in its surroundings. The purpose of**	No specific guidelines described in legislation ***Notes:*** ***COMMISSION IMPLEMENTING REGULATION (EU) 2018/1882 of 3 December 2018*** *According to the table in Annex of this EU regulation, the listed species for CCPP are:* *Ovis* ssp., *Capra* ssp., *Gazella* ssp.	No specific guidelines described in legislation ***Note:*** ***EFSA Scientific opinion on CCPP (EFSA, 2017):*** 3.1.1.7. Article 7(a)(vii) The absence or presence and distribution of the disease in the Union, where the disease is not present in the Union, the risk of its introduction into the Union . . .

Scenario	Description of the Scenario	Clinical guidelines	Laboratory guidelines
	the sampling procedures is to ensure the detection of the agent, if the agent is present in these wild species.	***CFSPH factsheet on CCPP (CFSPH, 2015):*** Clinical signs in wild or captive wild ungulates have been similar to cases in goats.	Importing wildlife for zoos from infected zones (Asia, Africa; Middle East, etc.) should be followed with great care. This risk is considered very unlikely, as these animals are seldom in contact with infected goats and that distance transmission of CCPP is not frequent. The risk could be mitigated by performing a serological test either at the individual level or better at the herd level at the origin of import. The c-ELISA is not officially validated for species other than goats but as it is based on a competition, it can detect antibodies in infected animals other than goats. It has been used successfully in sand gazelles. If wild/zoo animals have been properly vaccinated, they should become serologically positive, provided that a correct vaccine has been used.
6th	**To assess the effectiveness of disease-specific sampling procedures based on clinical (ToR1.1) and laboratory (ToR1.2) examinations of the animals of listed species in establishments located in the protection zone. The purpose of the sampling procedures is to ensure the detection of the agent, if the agent is present in these animals**.	NA	NA
7th	**To assess the effectiveness of disease-specific sampling procedures, based on clinical (ToR1.1) and laboratory (ToR1.2) examinations of the animals of listed species, 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 agent if the**	NA	NA

Scenario	Description of the Scenario	Clinical guidelines	Laboratory guidelines
	agent is present in establishments within the protection zone.		
8th	**To assess the effectiveness of disease-specific sampling procedures, based on clinical (ToR1.1) and laboratory (ToR1.2) examinations of the animals of listed species, for the sampling of the establishments located within the surveillance zone. The purpose of the sampling procedure is to ensure disease detection if the agent is present in establishments within the surveillance zone.**	NA	NA
Derogations to allow animal movements			
9th	**To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations of the animals of an establishment in a protection zone, in order to grant a derogation from prohibitions in the movement of animals, and allow for the animals to be moved to a slaughterhouse located within the protection zone or in the surveillance zone or outside the restricted zone (Art29).**	NA	NA
10th	**To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations, to grant a**	NA	NA

Scenario	Description of the Scenario	Clinical guidelines	Laboratory guidelines
	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.		
11th	**To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations, to grant a derogation from prohibitions in the movement of ready-to-lay poultry located in the protection zone, to establishments located in the same Member State and if possible within the restricted zone.**	NA	NA
12th	**To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations of the animals of an establishment in a protection zone, in order to grant derogation from prohibitions in the movement of these animals to a plant approved for processing or disposal of animal by-products**	NA	NA

Scenario	Description of the Scenario	Clinical guidelines	Laboratory guidelines
	in which the kept animals are immediately killed (Art37).		
13th	**To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations of the animals of listed species in order to grant derogation from prohibitions and allow for these animals to be moved : 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.**	NA	NA
14th	**To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations of kept ungulates of listed species in order to grant a derogation and allow for the animals to be moved from an establishment in the surveillance zone to pastures situated within the surveillance zone.**	NA	NA
15th	**To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations of kept ungulates of listed species in**	NA	NA

Scenario	Description of the Scenario	Clinical guidelines	Laboratory guidelines
	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.		
16th	**To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations to grant derogation of movements of day-old-chicks hatched from establishment located in the surveillance zone, from eggs originating within the surveillance zone and eggs originating outside the restricted zone, to an establishment located in the same Member State where they were hatched.**	NA	NA
17th	**To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations, to grant a derogation from prohibitions in the movement of ready-to-lay poultry located in the surveillance zone to establishments located in the same Member State.**	NA	NA

Scenario	Description of the Scenario	Clinical guidelines	Laboratory guidelines
18th	**To assess the effectiveness of disease-specific sampling procedures based on clinical and/or laboratory examinations of the animals of an establishment located in the restricted zone of an outbreak in order to allow their move within the restricted zone, when restriction measures are maintained beyond the period set out in Annex XI.**	NA	NA
Repopulation			
19th	**To assess the effectiveness of disease-specific sampling procedures based on laboratory examinations of the animals that are kept for the repopulation prior to their introduction to rule out the presence of the disease.**	NA	NA
20th	**To assess the effectiveness of disease-specific sampling procedures based on laboratory examinations of the animals that have been repopulated, in the event of unusual mortalities or clinical signs being notified during the repopulation; to rule out the presence of the disease.**	NA	NA

Scenario	Description of the Scenario	Clinical guidelines	Laboratory guidelines
21st	**To assess the effectiveness of disease-specific sampling procedures based on laboratory examinations of the animals that have been repopulated, on the last day of the monitoring period calculated forwards 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 forwards from the last day in which the last animal is introduced in the establishment.**	NA	NA

Annex D – Scenarios of ToR 2

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

ToRs	Legislation	Scenario	Description of the Scenario	Elements of the Scenarios
				• time period before the suspicion, during which the pathogenic agent was introduced in the establishment and during which it could have spread outside the establishment. • the aim of the epidemiological enquire is the same as above.
ToR 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.	• event of confirmation of a category A disease • in an affected establishment with kept animals of listed species • non-affected epidemiological units kept separated • to provide derogation from killing for animals in non-affected separated epidemiological units • to exclude any possible contact between the affected establishment and the separated epidemiological units as per the epidemiological enquiry • time period calculated backwards from the date of the confirmation • time period before the confirmation, during which the pathogenic agent may have been introduced in the separated non-affected epidemiological units of the affected establishment.
ToR 2	Article 27(3)c of the Delegated Regulation Annex II of the Delegated Regulation	4th scenario	To assess the effectiveness of the length of the monitoring period, as the time period calculated backwards from the date of notification of the suspicion of the latest outbreak of a category A disease in the protection zone. Products or other materials likely to spread the disease, must had been obtained or produced, before this time period in order to be exempted from prohibitions of movements.	• protection zone • non-affected establishments • Products or other materials likely to spread the disease, obtained or produced, before the start of the monitoring period of the affected establishment that originated the protection zone • time period calculated backwards from the date of suspicion of the latest outbreak in the protection zone • time period before the notification of the suspicion, during which the products and materials produced in the non-affected establishments of a protection

ToRs	Legislation	Scenario	Description of the Scenario	Elements of the Scenarios
				zone may have been contaminated by the pathogenic agent of the disease.
ToR 2	Article 32(c) of the Delegated Regulation Article 48(c) of the Delegated Regulation Annex II of the Delegated Regulation	5th scenario	To assess the effectiveness of the length of the monitoring period, as the time period calculated forwards from the date of semen collection from animals of listed species kept in approved germinal product establishments in the protection or in the surveillance zone, to prove that the donor animal has tested favourable on a sample taken not earlier than 7 days after the monitoring period.	• protection or surveillance zone • non-affected approved germinal establishments • semen from kept animals (donor) of listed species • semen collected after the estimated date of the earliest infection of the earliest affected establishment that originated the protection zone/surveillance zone (if belonging to more than one protection or surveillance zones) • to take samples from the donor for laboratory analysis at least 7 days after the end of the monitoring period • to authorise movements of semen from approved germinal product establishments located in the protection or surveillance zones in case of favourable laboratory results • time period calculated forwards from the date of semen collection • time period after the semen collection, during which the animal donor if infected could be detected by the relevant diagnostic test.
ToR 2	Article 57(1)b of the Delegated Regulation Annex II of the Delegated Regulation	6th scenario	To assess the effectiveness of the length of the monitoring period, as the appropriate time period calculated forwards from the date after the final cleaning and disinfection and when relevant control of insects and rodents was carried out in an affected establishment, after which the repopulation of the establishment may be allowed by the competent authority.	• repopulation of a previous affected establishment • kept animals of listed species • to allow the repopulation of an affected establishment • time period calculated forwards from the date of the final cleaning and disinfection of the establishment • time period to ensure that the repopulation exercise is not put at risk due to the disease being unknowingly present in an establishment in the surrounding area.
ToR 2	Article 59(4)b of the Delegated Regulation	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	• repopulation of a previous affected establishment • kept animals of listed species to be repopulated

ToRs	Legislation	Scenario	Description of the Scenario	Elements of the Scenarios
	Annex II of the Delegated Regulation		which all the animals of listed species intended for repopulation should be introduced.	• the animals may not be introduced at the same time • time period calculated forwards from the date when the first animal was introduced • time period during which animals intended for repopulation, should be introduced and the process of repopulation be completed.

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

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 (CCPP)	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 *Mycoplasma mycoides* subsp. *mycoides* SC (Contagious bovine pleuropneumonia) (CCPP)	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 *Burkholderia mallei* (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	There is limited data on the performance of the diagnostic tests considered in the assessment, particularly regarding the sensitivity and specificity of clinical examination, in the different species.	The effectiveness of the sampling strategies could be over or underestimated.
ToR 2 and ToR 3	2	Information on the period elapsed between the earliest point of infection and the suspicion report could only be retrieved from to references obtained in countries in Africa where the disease was already present and therefore a higher awareness was expected	The effectiveness of the proposed monitoring period based on the limited available evidence could be overestimated.
	3	The two references originated from countries in Africa where surveillance systems may perform very differently, and therefore, data may not be representative for other regions/periods due to differences in production systems affecting the effectiveness of surveillance systems.	The effectiveness of the proposed monitoring period could be over or underestimated.