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Assessment of listing and categorisation of animal diseases within the framework of the Animal Health Law (Regulation (EU) No 2016/429): porcine reproductive and respiratory syndrome (PRRS)

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Abstract

Porcine reproductive and respiratory syndrome (PRRS) has been assessed according to the criteria of the Animal Health Law (AHL), in particular criteria of Article 7 on disease profile and impacts, Article 5 on the eligibility of PRRS to be listed, Article 9 for the categorisation of PRRS according to disease prevention and control rules as in Annex IV and Article 8 on the list of animal species related to PRRS. The assessment has been performed following a methodology composed of information collection and compilation, expert judgement on each criterion at individual and, if no consensus was reached before, also at collective level. The output is composed of the categorical answer, and for the questions where no consensus was reached, the different supporting views are reported. Details on the methodology used for this assessment are explained in a separate opinion. According to the assessment performed, PRRS can be considered eligible to be listed for Union intervention as laid down in Article 5(3) of the AHL. The disease would comply with the criteria as in Sections 4 and 5 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in points (d) and (e) of Article 9(1). The animal species to be listed for PRRS according to Article 8(3) criteria are domestic pigs and wild boar.

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1. Introduction

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

The background and Terms of Reference (ToR) as provided by the European Commission for the present document are reported in Section 1.2 of the scientific opinion on the ad hoc methodology followed for the assessment of the disease to be listed and categorised according to the criteria of Article 5, Annex IV according to Article 9, and Article 8 within the Animal Health Law (AHL) framework (EFSA AHAW Panel, 2017).

1.2. Interpretation of the Terms of Reference

The interpretation of the ToR is as in Section 1.2 of the scientific opinion on the ad hoc methodology followed for the assessment of the disease to be listed and categorised according to the criteria of Article 5, Annex IV according to Article 9, and 8 within the AHL framework (EFSA AHAW Panel, 2017).

The present document reports the results of assessment on porcine reproductive and respiratory syndrome (PRRS) according to the criteria of the AHL articles as follows:

- Article 7: PRRS profile and impacts
- Article 5: eligibility of PRRS to be listed
- Article 9: categorisation of PRRS according to disease prevention and control rules as in Annex IV
- Article 8: list of animal species related to PRRS.

2. Data and methodologies

The methodology applied in this opinion is described in detail in a dedicated document about the ad hoc method developed for assessing any animal disease for the listing and categorisation of diseases within the AHL framework (EFSA AHAW Panel, 2017).

3. Assessment

3.1. Assessment according to Article 7 criteria

This section presents the assessment of PRRS according to the Article 7 criteria of the AHL and related parameters (see Table 2 of the opinion on methodology (EFSA AHAW Panel, 2017)), based on the information contained in the fact-sheet as drafted by the selected disease scientist (see section 2.1 of the scientific opinion on the ad hoc methodology) and amended by the AHAW Panel.

3.1.1. Article 7(a) Disease Profile

3.1.1.1. Article 7(a)(i) Animal species concerned by the disease

Susceptible animal species

Parameter 1 – Naturally susceptible wildlife species (or family/orders)

Eurasian wild boar (*Sus scrofa*): Natural infections reported from many EU Member States (MSs) (Bonilauri et al., 2006; Vengust et al., 2006; Reiner et al., 2009; Montagnaro et al., 2010; Wu et al., 2011b; Boadella et al., 2012; Touloudi et al., 2015; Vilcek et al., 2015; Stankevicius et al., 2016).

Also present in wild boar/feral pigs in Asia and Americas (Gipson et al., 1999; Wu et al., 2011a, 2012; Choi et al., 2012; Cano-Manuel et al., 2014; McGregor et al., 2015).

Parameter 2 – Naturally susceptible domestic species (or family/orders)

Domestic pig (*Sus scrofa domesticus*) (Albina, 1997).

Parameter 3 – Experimentally susceptible wildlife species (or family/orders)

Eurasian wild boar (*Sus scrofa*): In Europe, the course of disease is assumed the same as for PRRS in domestic pigs, although a study with highly pathogenic (HP) Type 2 strain of Porcine reproductive and respiratory syndrome virus (PRRSV) did result in more severe disease in wild pigs, compared to domestic pigs (Do et al., 2015b).

Early experiments of infection in bird species initially claimed productive infection in Mallard ducks (*Anas platyrhynchos*) (Zimmerman et al., 1997). Later work (Trincado et al., 2004) failed to reproduce the work and the claims of (Zimmerman et al., 1997) are now considered flawed.

Parameter 4 – Experimentally susceptible domestic species (or family/orders)

Domestic pig (*Sus scrofa domesticus*) (Albina, 1997).

Reservoir animal species

Parameter 5 – Wild reservoir species (or family/orders)

Eurasian wild boar (*Sus scrofa*).

Natural infections and serological evidence of exposure in wild boar have been widely reported throughout Europe (Albina, 1997; Zupancic et al., 2002; Bonilauri et al., 2006; Vengust et al., 2006; Reiner et al., 2009; Boadella et al., 2012; Touloudi et al., 2015; Vilcek et al., 2015; Stankevicius et al., 2016) and also in Asia, although fewer studies have been carried out (Wu et al., 2011a, 2012; Choi et al., 2012).

Parameter 6 – Domestic reservoir species (or family/orders)

Domestic pig (*Sus scrofa domesticus*). The virus may persist for some weeks after apparent recovery. In smaller herds, the virus is likely to be eventually eliminated, but in larger herds (> 250 sows), there is a greater likelihood of virus persistence within the herd (Evans et al., 2008). There is evidence that boars may excrete virus via semen for up to 90 days (Christopher-Hennings et al., 1995) and some claims have been made of a 'carrier' status, with virus persisting in tissues for more than 100 days (Horter et al., 2002) but is unclear whether such animals are infectious to in-contact animals.

3.1.1.2. Article 7(a)(ii) The morbidity and mortality rates of the disease in animal populations

Morbidity

Parameter 1 – Prevalence/ Incidence

A survey of veterinary practitioners in European countries (de Paz et al., 2015) was undertaken to assess PRRS prevalence in European pig holdings based on the farmers' perceptions. Swine veterinary practitioners (515 veterinarians in 11 countries) were asked to estimate the percentage of the animals under his or her supervision that were PRRS-positive. On average, PRRS was estimated to be present in 71% of sows and in 68% of weaned or growing pigs. While on average, clinical cases of the disease were estimated to occur in 17% of sows and in 23% of weaned or growing pigs. However, the prevalence of clinical signs due to PRRSV in sows in particular varied widely by country, from a high of 47% reported from Italy to just 4% for Russia.

An early Dutch study demonstrated that 23% of 8–9 week-old pigs were PRRSV seropositive (Nodelijk et al., 1997) and a more recent seroprevalence study in Spain revealed that the percentage of PRRSV seropositive herds was over 85% for sows, around 80% for fatteners and around 50% for boar studs (Lopez-Soria et al., 2010).

Parameter 2 – Case-morbidity rate (% clinically diseased animals out of infected ones)

The case-morbidity rate can vary greatly and a number of factors may be involved. These include the age of the pigs, the strain of the virus and the presence of other pathogens (Done and Paton, 1995; Solano et al., 1998; Brockmeier et al., 2001; Opriessnig et al., 2011).

In piglets, there is often an increase in neonatal diarrhoea and respiratory infections such as Glässer's disease. In weaners and growing pigs, the only clinical signs may be a period of slight inappetence, perhaps with coughing and some wasting. Sometimes, disease is inapparent. In sows, there may be inappetence, mild fever, abortions and respiratory signs, and in a small percentage of animals, they may show a transient 'blueing' of the ears. Around 10–15% of sows may farrow slightly early and there may also be an increase in delays in returning to heat (Meredith, 1995). Weak-born and still-born piglets, with associated pre- and post-weaning mortalities are often a predominant sign and losses can exceed 75%, particularly in large farms (Pejsak et al., 1997; Goldberg et al., 2000). In boars, sneezing and coughing, depression, low-grade fever and inappetence, and occasionally blueing of ears in a small percentage of affected animals occur. There are no reports of loss of libido, but some reduction in ejaculate volume has been recorded (Meredith, 1995). A table of morbidity rates and clinical signs is provided in Table 1, based on early studies of the disease in the UK (Meredith, 1995).

Table 1: Acute PRRS: clinical signs and effects based on European data

Clinical sign or effect	% of farms affected	% of animals affected on affected farm
Primary influenza-like illness		
Fever	50	1–10
Blue extremities	69	1–5
Also: inappetence, conjunctivitis, eyelid oedema, depression, respiratory signs, haemorrhage, bruising		
Secondary effects		
Pre-weaning mortality	100	10–40
Post-weaning mortality	100	1–10
Sudden death	44	1–2
Pneumonia (growers)	50	1–30
Reproductive effects		
Abortions	44	1–2
Premature litters	100	1–20
Stillborn piglets	100	7–35
Returns to service	69	10–50
Also: mummification, weak-born piglets, splay-legged, periorbital oedema, anoestrus		

Source: Meredith (1995)

Mortality

Parameter 3 – Case-fatality rate

In a study of a PRRS outbreak in a large swine farm in Poland (Pejsak and Markowska-Daniel, 1997), the following was observed: during the first month after onset of the outbreak, 25.6% of sows farrowed before 110 days of pregnancy, the percentage of mummifications was 21.7%, the percentage of piglets that died before weaning was 43.3%, losses among fatteners and weaners were 15%,. Prior to the occurrence of PRRS, the percentage of sows that farrowed before term was 1.4%, the piglets' mortality rate did not exceed 6%, and losses among fatteners and weaners were lower than 3.5%. The average production of weaned piglets per sow per year dropped from 21.1 prior the outbreak to 18.1 during the outbreak. The farrowing rate dropped from 80.5% to 47.7% and even 12 months after onset of the outbreak did not reach the level found before the outbreak.

In the USA, a study of 34 nursery units, where PRRS had been present for some time, reported mortalities of approximately 10% (Dee et al., 1997a) prior to application of various depopulation interventions.

A study in Thailand of aborted and mummified foetuses and stillborn piglets revealed that 67% (60/89) of the specimens contained PRRS virus. The virus was found in 66% (21/32) of aborted foetuses, 63% (19/30) of mummified foetuses and 74% (20/27) of stillborn piglets. Type 1, Type 2 and mixed Types of PRRS virus were detected in 19% (17/89), 26% (23/89) and 23% (20/89) of the specimens, respectively. The vaccination status of herds had no significant effect on the percentage of herd with active virus circulation (Olanratmanee et al., 2015). Stillbirth levels were reported to increase up to 30% and 10–15% of a litter may die in the last 3–4 weeks of pregnancy and be born mummified. Piglet mortality may peak as high as 70% in weeks 3 or 4 after the onset of clinical signs and only returns to normal levels after 8–12 weeks. The reproductive problems may persist for 4–8 months before returning to normal (Olanratmanee et al., 2015).

3.1.1.3. Article 7(a)(iii) The zoonotic character of the disease

Presence

Parameter 1 – Report of zoonotic human cases (anywhere)

There is no evidence of human infection with PRRSV.

3.1.1.4. Article 7(a)(iv) The resistance to treatments, including antimicrobial resistance

Parameter 1 – Resistant strain to any treatment even at laboratory level

No treatments for PRRSV infection have been described, beyond administration of antibiotics to combat secondary bacterial infections associated with the respiratory disease often associated with PRRSV infection.

3.1.1.5. Article 7(a)(v) The persistence of the disease in an animal population or the environment

Animal population

Parameter 1 – Duration of infectious period in animals

PRRSV has the ability to establish infections with extended periods of viraemia and excretion, beyond that normally seen with acute virus infections. Pigs are usually infectious between days 3 and 40 days post-infection, but can remain so for several months (OIE, online a). A longitudinal study in conventional piglets with a Type 1 strain of PRRSV, demonstrated lungs and alveolar macrophages to be PRRSV positive by immunohistochemistry method (IHC) and virus isolation until 35 days post-infection (Duan et al., 1997). A similar study, using PRRSV Type 2 in SPF piglets, demonstrated PRRSV to be detectable by polymerase chain reaction (PCR) in serum for 5 weeks and oral fluid for 4 weeks post-infection (Prickett et al., 2008). In breeding age gilts, the duration of shedding has been demonstrated to be relatively short, at around 14 days (Batista et al., 2002).

See also Parameter 3 below, concerning carrier status.

Parameter 2 – Presence and duration of latent infection period

For the purposes of international trade, the Draft OIE Code Chapter defines the incubation period for of PRRS as 14 days (OIE, online a). A true latent infection (beyond the normal incubation time), following infection of naïve animals has not been described for PRRS virus.

Parameter 3 – Presence and duration of the pathogen in healthy carriers

In a study of fattening pigs infected at three weeks of age, viable virus was demonstrated in 10 of 11 pigs, 105 days post-inoculation (dpi) (Horter et al., 2002). Oropharyngeal samples from intranasally infected 4-week-old pigs were virus isolation (VI) positive up to 84 dpi and, in one animal, up to 157 dpi, 134 days after the last isolation of virus from serum from this animal (Wills et al., 1997b).

Virus may persist for over 100 days in the semen of recovered boars (Albina, 1997) and has been demonstrated to be transmissible by this route (Prieto et al., 1997). The duration of excretion may vary: In boars infected with Type 2 PRRSV, viable virus was detected up to 43 days in semen (Swenson et al., 1994). In a more comprehensive study, the maximum number of days (+/- SD) for the duration of PRRSV shedding in semen was determined to be 51 +/- 26.9 days, in Landrace boars. Other breeds were infectious for a shorter period, but the differences were not significant (Christopher-Hennings et al., 2001). It is recognised as a significant pathway for introduction of disease via artificial insemination (Maes et al., 2008). A review of PRRSV in boars is also available (Prieto and Castro, 2005).

Environment

Parameter 4 – Length of survival (dpi) of the agent and/or detection of DNA in selected matrices (soil, water, air) from the environment (scenarios: high and low T)

A study of PRRSV survival in soil at ambient temperatures (10–16°C) showed virus to survive for only 1 or 2 h (Dee et al., 2003). The virus was isolated from water kept at 25–27°C for up to 11 days (Pirtle and Beran, 1996), and in swine lagoon effluent kept at 4°C for 8 days (Dee et al., 2005). Survival in air is very variable and a factor of UV254 dose, also with dependencies on temperature and relative humidity, with humidities of > 80% significantly increasing virus survival, regardless of temperature (Cutler et al., 2012). These authors calculated the dose of UV254 required to inactivate 99.9% of airborne PRRS virus as $(0.121 \text{ mJ/area}^2 \text{ per half-life}) \times (10 \text{ half-lives}) = 1.21 \text{ mJ/area}^2$.

An early study (Bloemraad et al., 1994) demonstrated that, in tissue culture medium, the virus is stable for prolonged periods of storage at –70°C and –20°C. At higher temperatures, the half-life of PRRSV is 140 h at 4°C, 20 h at 21°C, 3 h at 37°C and 6 min at 56°C. The half-life of PRRSV, both at 4°C and 37°C, varies considerably with pH; at 4°C and pH 6.25, it has a maximum half-life of 50 h and at 37°C and at pH 6.0, a maximum half-life of 6.5 h. However, increasing or decreasing the pH of the medium rapidly decreases the half-life of PRRSV at both temperatures.

3.1.1.6. Article 7(a)(vi) The routes and speed of transmission of the disease between animals, and, when relevant, between animals and humans

Routes of transmission

Parameter 1 – Types of routes of transmission from animal to animal (horizontal, vertical)

PRRSV has been recovered from a variety of porcine secretions and excretions including blood, semen, saliva, faeces, aerosols, milk, and colostrum (Albina, 1997; Wills et al., 1997a; Prieto and Castro, 2005). Faecal shedding remains a highly debated issue as studies report the presence of PRRSV in faeces from 28 to 35 dpi (Yoon et al., 1993), whereas others report no detection of virus in faecal samples (Wills et al., 1997a).

Horizontal transmission most commonly occurs by close contact between pigs or by exposure to contaminated body fluids (semen, virus-contaminated blood, secretions, contaminated needles, coveralls, and boots). Social behaviour and pig-to-pig interactions are important in direct transmission, particularly the aggressive behaviours (scraping and biting) associated with establishing social order, where blood and saliva may be exchanged. Other behaviours that result in exchange of blood and saliva, eg; tail-biting and ear-biting, may also play a role in transmission. Airborne transmission has also been demonstrated, both experimentally and in the field (Brockmeier and Lager, 2002; Kristensen et al., 2004; Dee et al., 2009; Otake et al., 2010). Transmission by insects has been proposed, but the importance of its role in field transmission of PRRS is unknown (Pitkin et al., 2009).

Vertical transmission from pregnant sows to their piglets can occur in utero, with infection and consequent fetal and neonatal death particularly likely following infection in late gestation (Prieto et al., 1996, 1997; Mengeling et al., 1998a,b; Rowland, 2010).

A review of PRRSV transmission (Desrosiers, 2011) concluded that, in cases of introduction of PRRS to PRRS-negative farms, between 81% and 100% were via an indirect route, which reflects both the efficacy of biosecurity procedures associated with breeding and pig movements and the challenges that still need to be overcome in preventing PRRSV infections by other routes.

Parameter 2 – Types of routes of transmission between animals and humans (direct, indirect, including food-borne)

Not applicable. PRRSV has never been known to infect humans.

Speed of transmission

Parameter 3 – Incidence between animals and, when relevant, between animals and humans

The virus may spread rapidly among naïve pigs in close proximity, with younger animals being both more susceptible, with higher rates of excretion and seroconversion (Nodelijk et al., 2003). In the case of piglets, the key consequence of PRRSV infection is a respiratory disease which main associated lesion is interstitial pneumonia. The severity of the respiratory signs is determined mostly by the participation of other complicating agents, particularly bacteria although interactions with other viruses (e.g. Porcine Circovirus 2) have been demonstrated (Thacker et al., 1999; Thanawongnuwech et al., 2000; Szeredi and Szentirmai, 2008) and can result in very rapid spread among littermates and housemates (Palzer et al., 2008; Tousignant et al., 2015). Also, differences among isolates with regard to the severity of the respiratory disease exist (Mengeling et al., 1996).

Parameter 4 – Transmission rate (beta) (from R_0 and infectious period) between animals and, when relevant, between animals and humans

Due to the nature of infection with this virus, it is difficult to assign a transmission rate for PRRSV. This is because the course of infection, the quantity and the profile of virus excretion all vary over time. Excretion and therefore the transmission is dependent on a number of factors, including the strain/virulence of the virus involved, the infection dose, and route, as well as the age, immune response and presence of other pathogens in the pig. In particular, highly virulent viruses seem to be much more transmissible by the airborne route (Cho et al., 2007).

In an experimental study in SPF piglets, excretion increased from 7 to 14 dpi and then decreased slowly until 42 dpi, allowing the authors to model the time-dependent infectiousness by a log normal-like function with a latency period of 1 day, indicating an estimated basic reproduction ratio, R_0 of 2.6, with a range of between 1.8 and 3.3 during the infectious period (Charpin et al., 2012).

In an analysis of a PRRS outbreak in a breeding herd in the Netherlands, the basic reproduction ratio¹ (R_0) was calculated to be 3.0 (95% confidence interval 1.5–6.0), based on the assumptions that the infectious period lasts 56 days and that no lifelong immunity exists after infection (Nodelijk et al., 2000).

In an experimental study, demonstrating airborne transmission, a seroconversion in 94–100% of the pigs were demonstrated in each of three individual groups of previously PRRSV-seronegative pigs within 3 weeks after introduction of infection (Kristensen et al., 2004).

3.1.1.7. Article 7(a)(vii) The absence or presence and distribution of the disease in the Union, and, where the disease is not present in the Union, the risk of its introduction into the Union

Presence and distribution

Parameter 1 – Map where the disease is present in EU

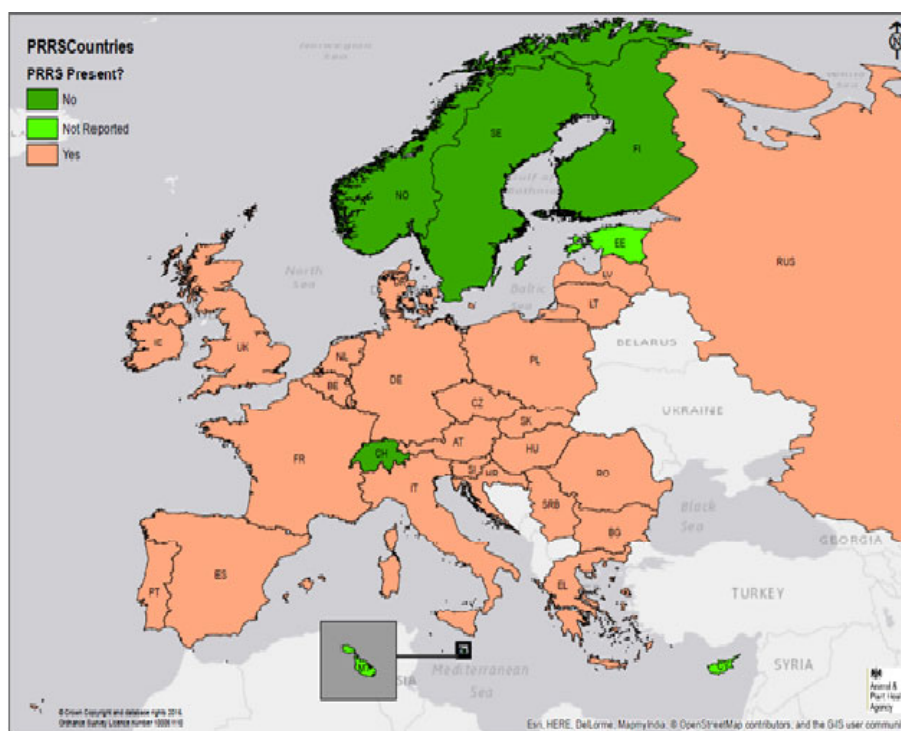


Figure 1: Map of PRRS presence in EU

Parameter 2 – Type of epidemiological occurrence (sporadic, epidemic, endemic) at MS level

PRRS is widespread and endemic in most Member States of the European Union (EU) and is considered absent in only four countries (Table 2): Norway, Sweden, Finland and Switzerland (Baekbo and Kristensen, 2015). Based on a short questionnaire by these researchers, mailed to 20 EU countries (response rate 50%), Type 1 (EU strain) is the most prevalent, and is the only serotype in most countries, whereas Type 2 (US strain) is known to be present in, e.g. Austria, Denmark, Germany, Hungary, Lithuania, the Netherlands and Poland.

Table 2: PRRS status in EU Member States and adjoining countries

Country	Present?	Genotypes reported	Reference
Austria	Yes	Type 1 and Type 2	Indik et al. (2005), Stadejek et al. (2013)
Belgium	Yes	Type 1 (and Type 2?)	Houben et al. (1995b)
Bulgaria	Yes	Type 1?	Mortrovski et al. (2009)
Croatia	Yes	Type 1?	Prpic et al. (2014)

¹ The basic reproductive ratio R_0 is defined as the expected number of secondary infections arising from a single individual during his or her entire infectious period, in a population of susceptibles.

Country	Present?	Genotypes reported	Reference
Cyprus	Not reported		
Czech Republic	Yes	Type 1	Indik et al. (2000)
Denmark	Yes	Type 1 and Type 2	Kvisgaard et al. (2013a,b)
Estonia	Not reported		
Finland	No		Rautiainen et al. (2001), Niederwerder and Rowland (2016), EVIRA (online)
France	Yes	Type 1	Baron et al. (1992)
Germany	Yes	Type 1 and Type 2	Greiser-Wilke et al. (2010)
Greece	Yes	Type 1?	Alexopoulos et al. 2005)
Hungary	Yes	Type 1 and Type 2	Stadejek et al. (2013), Balint et al. (2015)
Ireland	Yes		Anonymous (online a)
Italy	Yes	Type 1	Pesente et al. (2006), Franzo et al. (2015)
Latvia	Yes	Type 1	Stadejek et al. (2013)
Lithuania	Yes	Type 1 and Type 2	Stadejek et al. (2002, 2013)
Luxembourg	Yes	Type 1	Schroder and Bemerich (2003)
Malta	Not reported		
Netherlands	Yes	Type 1 and Type 2	Wellenberg et al. (2004)
Poland	Yes	Type 1 and Type 2	Stadejek et al. (2013)
Portugal	Yes	Type 1 only?	
Romania	Yes	Type 1	Zaulet et al. (2012)
Slovakia	Yes	Type 1 and Type 2	Jackova et al. (2013)
Slovenia	Yes	Type 1	Toplak et al. (2012)
Spain	Yes	Type 1	Mateu et al. (2003), Lopez-Soria et al. (2010)
Sweden	No		Rautiainen et al. (2001), Niederwerder and Rowland (2016)
United Kingdom	Yes	Type 1	Frossard et al. (2012)
Norway	No		Rautiainen et al. (2001), Grøntvedt et al. (2014), Niederwerder and Rowland, (2016)
Russia	Yes	Type 1	Bulgakov et al. (2014)
Serbia	Yes	Type 1	Balka et al. (2010), Petrovic et al. (2011)
Switzerland	No		Baekbo and Kristensen (2015), Niederwerder and Rowland (2016)

Note: Where virus type is marked '?', type is assumed, based on neighbouring countries or because vaccine of that type is licensed in that country.

Due to a general lack of systematic surveillance in most countries, the true prevalence of infected herds is unknown, but based on estimations, is expected to be 25–50%, in e.g. Denmark and Romania, 50–75% in, e.g. Germany, Greece and Austria and 80–95% in, e.g. Italy and Spain.

A HP strain of PRRSV Type 2 (HP-PRRS) has been described in Asia, but this has never been detected in the EU. A new strain of PRRSV is present in some non-EU eastern European countries, putatively named PRRSV Type 1, subtype 3, which is claimed to have higher virulence than conventional European strains (Morgan et al., 2013; Weesendorp et al., 2014). Its precise distribution is unknown.

Risk of introduction

Infection is already present in MSs.

3.1.1.8. Article 7(a)(viii) The existence of diagnostic and disease control tools

Diagnostic tools

Parameter 1 – Existence of diagnostic tools

A number of commercial diagnostic kits are available to detect antibody to PRRSV. Additionally, specialist laboratories can provide indirect fluorescent antibody (IFA) tests for immunoglobulin M (IgM), which can be useful for detecting evidence of active infection in a herd.

The serological tests used for PRRS in diagnosis (Collins et al., 1996) are provided in Table 3.

Table 3: Serological tests used for diagnosis of PRRS

Serological tests for porcine reproductive and respiratory syndrome (PRRS) virus							
Serological test	Antibody first detected	Peak antibody titre	Decline in antibody titre	Antibody undetectable at	Positive titre	Sensitivity	Specificity
Indirect fluorescent antibody (IFA) (detects IgG)	7–11 days PI ^(a)	30–50 days PI	Rapid	4–6 months PI	$\geq 1:16$ or $\geq 1:20$ ^(b)	?	High
Indirect fluorescent antibody (IFA) (detects IgM)	5 days PI in 3-week-old pigs; 7 days PI in sows	14 days PI	Very rapid	28 days PI in 3-week-old pigs; 21 days PI in sows	$\geq 1:16$ or $\geq 1:20$ ^(b)	?	?
ELISA	9–13 days PI	30–50 days PI	Rapid	4 to ≥ 10 months PI	S:P ratio ≥ 0.4	High ^(c)	High
Serum neutralisation	9–28 days PI	60–90 days PI	Gradual	≥ 1 year PI	$\geq 1:4$	Low	High

ELISA: enzyme-linked immunosorbent assay; IgM: immunoglobulin M; IgG: immunoglobulin G.

(a): PI = post-infection.

(b): Depends on the initial dilution used in the IFA test.

(c): Sensitivity (100%, 35/35 samples) and specificity (99.5%, 413/415 samples); personal communication, Michael L. Synder, IDEXX Laboratories Inc. Source: Collins et al. (1996).

A few serological tests (enzyme-linked immunosorbent assay (ELISA) and immunoperoxidase monolayer assay (IPMA)) have been developed to differentiate between infection with PRRS Type 1 and 2 (Sorensen et al., 1998; Botner et al., 2000). For virus detection, a small number of commercial PCR kits are now available (e.g. QiaGen, Life Technologies, Bioingentech, etc.), some of which can differentiate between PRRS Type 1 and 2.

Virus isolation of PRRS Type 1 virus is particularly challenging, since isolates generally do not grow in permanent cell lines, so primary cultures are used, derived from alveolar macrophages harvested from piglets from negative herds. This makes the test very expensive and only used in research.

A number of specialist laboratories throughout the EU can provide diagnostic service and virus characterisation.

Control tools

Parameter 2 – Existence of control tools

PRRS outbreaks are generally controlled by a combination of husbandry and vaccination (Dee and Joo, 1997).

- a) A herd management programme involving:
 - 1) Cross fostering before 24 h.
 - 2) No movement of pigs between sections (all in/all out and disinfection).
 - 3) Euthanasia of unthrifty piglets.
 - 4) No contact between weaned pigs and sows.
- b) A vaccination programme, involving
 - 1) Moving the oldest gilts to the breeding unit.
 - 2) Immediately vaccinating these gilts with a PRRS modified live vaccine appropriate to the prevailing genotype.
 - 3) Vaccinating the rest of the gilts the same day.
 - 4) Initiating a quarantine period for 12 weeks thereafter.

- c) Herds are generally protected thereafter by:
- 1) Vaccination and quarantine of all new pigs.
 - 2) Maintenance of the rules in a) above.
 - 3) Vaccination of all piglets with Modified Live Vaccine (MLV) at 4–6 weeks.
 - 4) Sows may be vaccinated with a killed vaccine, if considered necessary.

In some circumstances, where disease has been present for some time, a total depopulation of the nursery units has been prescribed (Dee et al., 1997b).

For boars, a fairly recent review of the subject (Althouse and Rossow, 2011) concluded that representative screening of boar-semen donors should be carried out daily for PRRSV via PCR prior to extended semen distribution and use. They also recommended serial pre-screening of boars prior to introduction into the resident herd, filtration of air entering the stud and biosecurity were best methods of control.

There has been much controversy concerning live modified vaccines. PRRS virus is highly mutable and there have been several recorded cases spread from vaccinated to unvaccinated animals and of reversion to virulence (Botner et al., 1997; Nielsen et al., 2001). Additionally, boars are known to excrete vaccine virus in semen, representing an additional risk of spread (Nielsen et al., 1997). Manufacturers stress the importance of vaccinating all animals in a herd simultaneously and maintaining biosecurity and also of the potential hazards of vaccinating boars.

3.1.2. Article 7(b) The impact of diseases

3.1.2.1. Article 7(b)(i) The impact of the disease on agricultural and aquaculture production and other parts of the economy

The level of presence of the disease in the Union

Parameter 1 – Number of MSs where the disease is present

PRRS is widespread and endemic in most Member States of the EU and is absent only in four European countries: Norway, Sweden, Finland and Switzerland (Baekbo and Kristensen, 2015). Based on a short questionnaire by these researchers, mailed to 20 EU countries (response rate 50%), Type 1 (EU strain) is the most prevalent and only serotype in most countries.

The loss of production due to the disease

Parameter 2 – Proportion of production losses (%) by epidemic/endemic situation

The cost of the PRRSV infection in Europe seems not to be very well estimated in most countries. The economic impact of this disease, under field conditions, is often overlooked and the few studies available were often carried out in the USA (Fraile, 2012). In the US, the total annual economic impact of PRRS on US swine producers has been estimated at USD 66.75 million in breeding herds and USD 493.57 million in growing-pig populations (Neumann et al., 2005).

In naïve herds in Poland, production losses have been observed as high as 10–20% in weaners and 1–3% of adults. Depending on the stage of gestation, pregnant sows may farrow early, with resultant heavy piglet losses, with mortalities of as high as 75% recorded in animals up to five weeks of age. In addition expenses dealing with preventing and treating secondary infections, during the 12 months after the outbreak were on average 60% higher than, those found, during the previous year (Pejsak et al., 1997).

In a Dutch study (Nieuwenhuis et al., 2012), an outbreak of PRRSV reduced the number of sold pigs per sow by 1.7. The economic loss varied between €59 and €379 per sow per 18-week period outbreak. The mean loss per sow per outbreak was €126. The costs after the outbreak varied significantly from €3 to 160 per sow, due to the different methods used by farmers to tackle PRRSV outbreaks.

In an endemic situation, however, the scale of losses will depend on the timing of any re-introduction of virus and the similarity to viruses causing past infection (Molitor et al., 1997; Murtaugh et al., 2002; Mateu and Diaz, 2008). Immunity is often poor and transient, both to field infection and to vaccines (Lyo, 2015). When comparing a large number of chronically infected herds to non-infected herds, Danish studies showed only a marginally reduction in productivity. The piglet mortality was 0.8–0.9%-point higher and the nursery mortality was 0.4%-point higher in infected herds. No difference was seen in mortality among finishers (Baekbo and Kristensen, 2015).

3.1.2.2. Article 7(b)(ii) The impact of the disease on human health

Not applicable – humans are not susceptible to infection with PRRS virus.

3.1.2.3. Article 7(b)(iii) The impact of the disease on animal welfare

Parameter 1 – Severity of clinical signs at case level and related level and duration of impairment

Infection of pregnant sows can lead to abortion, through replication of virus in endometrial/placental tissues (Karniychuk and Nauwynck, 2013). *In utero* infection may also lead to subsequent death of fetuses, which are born mummified or partially autolysed, along with high rates of weak born and neonatal deaths among piglets born live (Rossow, 1998). In nursery pigs, breathing difficulties, fever and inappetence are common and respiratory disease can be severe, complicated by secondary infections, which may continue for several weeks and will result in further high rates of mortality. This may continue into the finisher stage (Young et al., 2010). Uncomplicated infections with HP strains of PRRSV will cause fever, anorexia, dyspnoea and tachypnoea in piglets, with associated high mortality (Liu et al., 2015).

Adult pigs may show some or few clinical signs, apart from inappetence and a mild, transient fever. HP strains of PRRS may, however, cause high fever and pneumonia in adults which may continue for some weeks (Li et al., 2007).

3.1.2.4. Article 7(b)(iv) The impact of the disease on biodiversity and the environment

Biodiversity

Parameter 1 – Endangered wild species affected: listed species as in CITES and/or IUCN list

In northern India, there is considerable concern about the fate of the pygmy hog (*Porcula salvania/Sus salvanius*), consequent with the appearance of PRRS in the region. It is a critically endangered suid, now only found in Assam, with a current population of about 150 individuals (Prof Nagendra Barman, Assam Agricultural University (Pers. Comm.)).

The susceptibility of other IUCN Red Listed Asian suids (bearded and warty hogs *Sus* spp., *Babyrusa babyrussa* spp.), African suids (warthogs, *Phacochoerus* spp.; giant forest hog – *Hylochoerus meinertzhageni*, red river hog – *Potamochoerus larvatus*; bushpig – *Potamochoerus porcus*) and South/Central American suids (peccaries – *Tayassu* spp.) is unknown.

Parameter 2 – Mortality in wild species

Unknown. It is assumed that, at individual animal level, the mortality in wild boar (*Sus scrofa*) is the same as for domestic pigs (*Sus scrofa domesticus*), though the roaming nature, animal density and herd sizes of wild boar 'sounders' is much smaller than may be found in pig rearing units, so overall mortalities are likely to be much less.

Environment

Parameter 3 – Capacity of the pathogen to persist in the environment and cause mortality in wildlife

PRRSV is regularly detected in wild boar populations. A comparative genotyping study of isolates from wild boar and domestic pigs in the same region concluded there was only a weak relationship between viruses found in the two populations (Reiner et al., 2009). This suggests that PRRS in wild boar is a self-sustaining infection, with likely mortalities in individual animals as for domestic pigs.

3.1.3. Article 7(c) Its potential to generate a crisis situation and its potential use in bioterrorism

Parameter 1 – Listed in OIE/CFSPH classification of pathogens

PRRS is an OIE-listed disease. It is also listed in the OIE Manual Diagnostic Tests and Vaccines for Diseases of Terrestrial Animals, but not in the OIE Code – a Chapter is in preparation. It is listed on the CFSPH website, but no classification is given, nor is there a Disease Factsheet for this disease.

Parameter 2 – Listed in the Encyclopaedia of Bioterrorism Defence of Australia Group

PRRSV is not listed in the Australia Group List of Human and Animal Pathogens and Toxins for Export Control. (Anonymous, online b).

Parameter 3 – Included in any other list of potential bio- agro-terrorism agents

No specific lists identified, but PRRSV has been considered, in the context more insidious forms of agroterrorism, by virtue of its relatively prolonged infection and slower spread, compared to listed pathogens (Keeling and Rohani, 2011).

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

No diagnostic kits for PRRS are listed on the Register of diagnostic kits certified by the OIE as validated as fit for purpose.

The OIE Manual lists the following tests for the purposes detailed in Table 4:

Table 4: Diagnostic tests for PRRS and their application (OIE, online b)

Method	Purpose					
	Population freedom from infection	Individual animal freedom from infection prior to movement	Contribution to eradication policies	Confirmation of clinical cases	Prevalence of infection – surveillance	Immune status in individual animals or populations post-vaccination
Agent identification^(a)						
Virus isolation	–	++	–	+++	–	–
RT-PCR	+++	+++	+++	+++	++	–
IHC	–	–	–	++	–	–
ISH	–	–	–	++	–	–
Detection of immune response^(b)						
ELISA	+++	++	+++	++	+++	++
IPMA	++	++	++	+	++	+++
IFA	++	++	++	+	++	+++

+++ : recommended method; ++ : suitable method; + : may be used in some situations, but cost, reliability, or other factors severely limits its application; – : not appropriate for this purpose.

Although not all of the tests listed as category +++ or ++ have undergone formal validation, their routine nature and the fact that they have been used widely without dubious results, makes them acceptable.

RT-PCR: reverse-transcription polymerase chain reaction; IHC: immunohistochemistry method; ISH: *in-situ* hybridisation; ELISA: enzyme-linked immunosorbent assay; IPMA: immunoperoxidase monolayer assay, IFA: immunofluorescence assay.

(a): A combination of agent identification methods applied on the same clinical sample is recommended.

(b): One of the listed serological tests is sufficient.

Effectiveness

Parameter 2 – Se and Sp of diagnostic test

Antibody ELISA for serum have very high sensitivity, generally considered to be 100%. Specificity can vary, depending on the manufacturer, with reported ranges of between 90% and 100%. In one study, differences were also seen between ELISAs, in terms of how early seroconversion could be detected (Gerber et al., 2014).

In monitoring boar studs, antibody ELISA using oral fluid are reported to have approximately 97% sensitivity and specificity (Kittawornrat et al., 2012; Sattler et al., 2015).

The IPMA was the first serological test to be used for detection of antibody to PRRS. Comparisons with commercial ELISAs showed them to be superior to the IPMA, in terms of sensitivity and specificity (Drew, 1995; Houben et al., 1995a) and IPMA is now only rarely used.

Molecular detection tests can be exquisitely sensitive, being able to detect viraemia as early as day 1 of infection (Drigo et al., 2014) and with a large number of multiplex PCRs (Wernike et al., 2013; Hu et al., 2015) and alternative assays isothermal amplification also being described (Park et al., 2016). All PCRs in general use have sensitivity and specificity values at, or close to 100%.

Feasibility

Parameter 3 – Type of sample matrix to be tested (blood, tissue, etc.)

The nature of PRRS infection provides a number of diagnostic challenges and the purpose and timing of the testing will dictate the samples taken and tests applied.

Figure 2 provides a schematic, illustrating the diagnostic tools which may be applied and the appropriate samples.

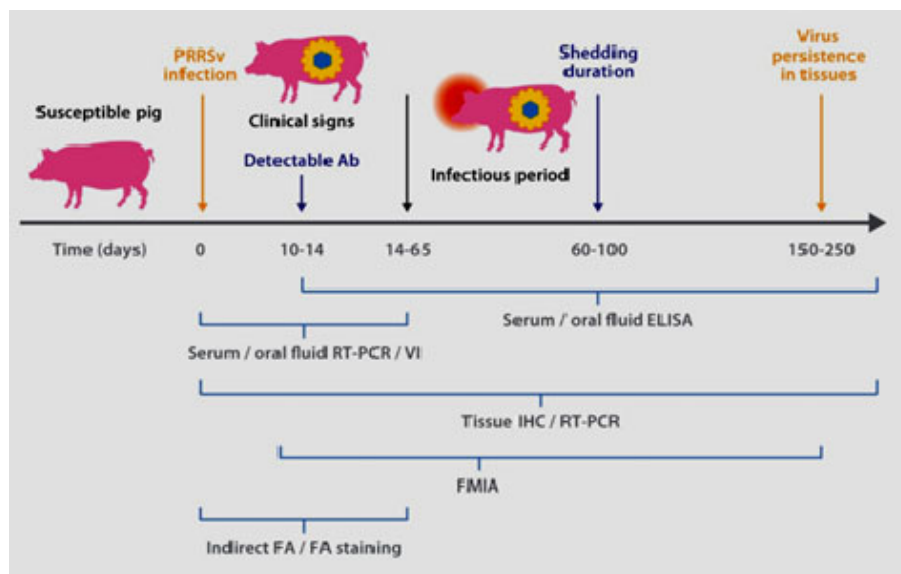


Figure 2: Sampling strategies for diagnosing PRRS and determining the infectious status of herds. From 'Global PRRS Solutions' website: <https://www.prrs.com/en/prrs/diagnostics/> (Global PRRS Solutions, online)

3.1.4.2. Article 7(d)(ii) Vaccination

Availability

Parameter 1 – Types of vaccines available on the market (live, inactivated, DIVA, etc.)

No PRRS vaccines are authorised at EU level – they are licensed at national level.

PRRS vaccines available in the EU and globally have been recently reviewed (Charentantanakul, 2012). An updated table of modified live vaccines are given in Table 5 and killed/subunit vaccines in Table 6.

Table 5: Modified live vaccines available in EU Member States (Note: national licensing applies – Type 2 vaccines may not be licensed in all MSs)

Vaccine	Manufacturer	Genotype (strain)	For use in	Route	Dose	Program
PRRSFlex EU	Boehringer Ingelheim	Type 1 (94881)	Piglet/nursery/ growing	i/m	1 mL	From 17 days of age until the end of fattening
Ingelvac PRRS* MLV	Boehringer Ingelheim	Type 2 (VR-2332)	Gilt/sow	i/m	2 mL	At any stage of production
			Piglet/nursery/ growing	i/m	2 mL	At any stage of production
Ingelvac PRRS ATP*	Boehringer Ingelheim	Type 2 (JA-142)	Nursery/ growing	i/m	2 mL	At 3–18 week of age

Vaccine	Manufacturer	Genotype (strain)	For use in	Route	Dose	Program
Porcilis PRRS	MSD Animal Health	Type 1 (DV)	Gilt/sow	i/m or i/d	2/0.2	Primary: 2–4 week prior to breeding
						Booster: 2–4 week prior to subsequent breeding/ or every 4 months
			Piglet/nursery/ growing	i/m or i/d	2/0.2 mL	At 2 week of age or older
Amervac-PRRS	Hipra	Type 1 (VP046)	Nursery/ growing	i/m	2 mL	At 4 week of age or older
Pyrsvac-183	Syva	Type 1 (All-183)	Gilt/sow	i/m	2 mL	Primary: 2–4 week prior to breeding
						Booster: 3–4 week prior to subsequent breeding
			Piglet/nursery/ growing	i/m	2 mL	At 2–3 week of age or older

*: The Type 2 vaccines highlighted in red were formerly used in some EU MSs, but have been found to spread to non-vaccinated animals and have either never been, or are no longer licensed in many countries.

Table 6: PRRS vaccines available in EU Member States (vaccines are licensed at national level, so not all vaccines may be available in all countries)

Vaccine	Manufacturer	Genotype/ strain	For use in	Route	Dose	Program
Ingelvac PRRS KV	Boehringer Ingelheim	Type 1 (P120)	Gilt	i/m	2 mL	Primary: twice, 3–4 week interval, at any stage of production
						Booster: 60–70 days of each gestation
ReproCyc PRRS	Boehringer Ingelheim	Type 1 (94481)	Gilt/sow	i/m	2 mL	Primary: 2–5 week prior to breeding. PRRSV naïve gilts should not be vaccinated during pregnancy
						Booster: 3 - monthly. Can be used during pregnancy and lactation
Progressis	Merial	Type 1 (P120)	Sow	i/m	2 mL	Primary: twice, 3–4 week interval, at least 3 week prior to breeding
						Booster: 60–70 days of each gestation
Suipravac-PRRS	Hipra	Type 1 (VP-046 BIS or 5710?)	Gilt	i/m	2 mL	Primary: twice, 3–4 week interval, when entering the farm
						Booster: Follow sows' vaccination program
			Sow	i/m	2 mL	Primary: twice, 3–4 week interval, during pregnancy or lactation
						Booster: every 4 months
Suivac PRRS-INe and Suivac PRRS-IN	Dyntec	Type (VD-E1 and VD-E2) or (VD-E1, VD-E2 and VD-A1)	Gilt/sow	i/m	2 mL	Primary: three times; 1st at 5–6 months of age, 2nd at 3–4 week after 1st, and 3rd at 6–4 week prior to expected farrowing
						Booster: twice; 1st at 3–4 week after the farrowing, and 2nd at 6–4 week prior to the further expected farrowing
			Boar	i/m	2 mL	Primary: twice, 4 week interval, starting at 6 months of age
						Booster: every 4–6 months
			Nursery/ growing	i/m	2 mL	Three times: 3–4 week interval, starting at 6–10 week of age

Vaccine	Manufacturer	Genotype/strain	For use in	Route	Dose	Program
Suvaxyn PRRS	Zoetis	Type 1 (218)	Gilt/Sow	i/m	2 mL	Primary: Can be used in any stage of pregnancy, but recommended to avoid vaccination during the 8–10 days before and after the cover. Repeat every 3–4 months

The CFSPH List of vaccines for PRRS licensed for use in European countries is provided in Appendix 3. It does not include some of the more recent vaccines, listed in the tables above.

Parameter 2 – Availability/production capacity (per year)

Unknown, but given the large number of vaccines and manufacturers, supply is not considered an issue.

Effectiveness

Parameter 3 – Field protection as reduced morbidity (as reduced susceptibility to infection and/or to disease)

Modified live vaccines are generally effective, short-term, in reducing morbidity and mortalities in young pigs, although they must be matched to the prevailing genotype (Meng, 2000; Thanawongnuwech and Suradhat, 2010). Prior vaccination of gilts is also important in preventing *in utero* infections. Boar vaccination is also important, but vaccine virus may be excreted in semen so should be done at least four months before semen collection. The risks of live vaccine virus spread to unvaccinated animals is a constant risk and should be mitigated by simultaneous vaccination of all pigs on a farm and strict biosecurity.

Cross-protection between genotypes is generally poor, i.e. Type 1 vaccines are generally only effective against Type 1 viruses and similarly for Type 2 viruses and vaccines. For Type 2 viruses, a number of studies of HP strains, which recently emerged in China, have claimed lesser efficacy afforded by conventional Type 2 vaccines, compared to vaccines derived from the HP genotypes (Tian et al., 2009; Leng et al., 2012; Do et al., 2015a; Yu et al., 2015). One study claims that a vaccine derived from HP-PRRS does, however, also protect against conventional Type 2 virus challenge (Gallagher-Beckley et al., 2015). Killed vaccines are much less effective and are generally only used to maintain some level of immunity in breeding animals.

Parameter 4 – Duration of protection

Duration of protection against homologous strains of virus is usually only around 6 months, even with animals vaccinated multiple times. For heterologous challenge, protection is very poor.

Feasibility

Parameter 5 – Way of administration

All vaccines should be administered intra-muscularly, often with a diluent also supplied. Porcine PRRS may also be given intradermally.

3.1.4.3. Article 7(d)(iii) Medical treatments

Availability

Parameter 1 – Types of drugs available on the market

No drugs specific to PRRS are produced. For the respiratory disease complex, secondary bacterial infections may compound the disease initiated by PRRS infection and, in such cases, antibiotics may be prescribed.

Vitamin E and selenium supplements added to piglet feed, are advocated by many practitioners, but their value is questionable (Toepfer-Berg et al., 2004).

3.1.4.4. Article 7(d)(iv) Biosecurity measures

Availability

Parameter 1 – Available biosecurity measures

At farm level, standard biosecurity practice is an essential tool in controlling PRRS. Additionally, all-in/all-out for batches of piglets with disinfection and empty periods is also practiced. There is an increasing appreciation of the value of regional coordination in reducing between-farm transmission (Corzo et al., 2010) and, for pig-dense areas, air filtration is also practiced (Dee et al., 2006; Spronk et al., 2010). Internationally, restrictions and conditions of importation of pigs and pig products from outside the EU are detailed in Commission Regulation (EU) No 206/2010² and subsequent amendments; however, there are no specific conditions for PRRS specified in that Regulation.

Effectiveness

Parameter 2 – Effectiveness of biosecurity measures in preventing the pathogen introduction

Where biosecurity practice is rigidly adhered to, it can be very effective in reducing losses due to PRRS. In some instances, practices which employ strict biosecurity within separate different stages of production have even succeeded in eliminating PRRS from herds (Yang et al., 2008; Corzo et al., 2010).

Feasibility

Parameter 3 – Feasibility of biosecurity measures

At farm level, in general, PRRS is controlled by the combination of measures adopted, which include increased levels of biosecurity, so not considered feasible.

At the international level, all MS have competent Veterinary Authorities which ensure compliance with the relevant EU legislation. International trade continues, so biosecurity measures are generally considered feasible.

3.1.4.5. Article 7(d)(v) Restrictions on the movement of animals and products

Availability

Parameter 1 – Available movement restriction measures

PRRS is not controlled at EU level, so there are no formal restriction movement measures applied. In those EU Member/Affiliated States free of PRRS (Norway, Sweden, Finland and Switzerland), controls apply at national level.

Effectiveness

Parameter 2 – Effectiveness of restriction of animal movement in preventing the between farm spread

Pig movements are a major means of PRRSV spread. Movement restrictions and associated measures contribute significantly in reducing spread. However, the virus is also spread by fomites and by aerosol, so effectiveness is not absolute.

Feasibility

Parameter 3 – Feasibility of restriction of animal movement

Restrictions on animal movements in the form of quarantine and movement subject to testing are commonly used, so clearly feasible. More stringent application of movement restrictions, consequent with outbreaks, can lead to overcrowding and may lead to welfare issues.

² Commission Regulation (EU) No 206/2010 of 12 March 2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements. OJ L 73, 20.3.2010, p. 1–121.

3.1.4.6. Article 7(d)(vi) Killing of animals

Availability

Parameter 1 – Available methods for killing animals

EU MSs are required to have animal killing capability as part of measures for control of foot-and-mouth disease (FMD), classical swine fever (CSF), etc. Available measures and associated procedures to assure animal protection are detailed in Council Regulation (EC) No 1099/2009³.

Effectiveness

Parameter 2 – Effectiveness of killing animals (at farm level or within the farm) for reducing /stopping spread of the disease

Removal of underweight piglets and partial herd slaughter i.e. test and removal (Dee and Molitor, 1998; Dee et al., 2001) are regularly used in control and, in combination with husbandry measures and biosecurity, are effective in reducing or even eliminating PRRSV from herds.

Feasibility

Parameter 3 – Feasibility of killing animals

In outbreaks in countries free of PRRS, the usual logistical challenges and degree of risk of spread will depend on speed of slaughter and avoidance of aerosol generation. To reduce risk for fast spreading of an outbreak, infected herds must be culled within 48 h of diagnosis. Some operational settings, such as free-ranging pig production systems, may present additional logistical challenges.

3.1.4.7. Article 7(d)(vii) Disposal of carcasses and other relevant animal by-products

Availability

Parameter 1 – Available disposal option

Disposal options for pig carcasses and associated wastes are: commercial fixed plant incineration; rendering (category 1 and 2 of Regulation (EC) No 1069/2009⁴ approved); permitted commercial landfill sites.

Effectiveness

Parameter 2 – Effectiveness of disposal option

Incineration and rendering are closed systems that produce an effective inactivation of PRRSV. Burial and landfill may also be used – PRRSV is relatively labile and would be inactivated relatively quickly.

Feasibility

Parameter 3 – Feasibility of disposal option

Pigs are regularly disposed of by the methods described. Strict biosecurity during carcass transport is also required (Hayama et al., 2015).

3.1.5. Article 7(e) The impact of disease prevention and control measures

3.1.5.1. Article 7(e)(i) The direct and indirect costs for the affected sectors and the economy as a whole

Parameter 1 – Cost of control (e.g. treatment/vaccine, biosecurity)

Very difficult to quantify, since this will depend greatly on the size of the premise, the type of production and the control method selected. See answers elsewhere in this section for costs of individual elements.

³ Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing. OJ L 303, 18.11.2009, p. 1–30.

⁴ Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation). OJ L 300, 14.11.2009, p. 1–33.

Parameter 2 – Cost of eradication (culling, compensation)

In Denmark, the most likely national cost of PRRSV has been calculated to be around €15 million per year, whereas cost of a national eradication program running over a 5-year period, has been estimated to €120 million. It was estimated that this would give a payback-time for eradication of around 15 years (Baekbo and Kristensen, 2015). The breakdown of these costs is mainly in testing, culling of piglets which fail to gain weight, vaccines and culling. No formal programme has been implemented in Denmark, due to this high cost and the high risk of reinfection - current schemes are voluntary and no compensation is paid.

Parameter 3 – Cost of surveillance and monitoring

No specific studies identified, and difficult to quantify.

Parameter 4 – Trade loss (bans, embargoes, sanctions) by animal product

Data not available. PRRS is not generally reported to OIE and no official controls apply at EU level.

Parameter 5 – Importance of the disease for the affected sector (% loss or € lost compared to business amount of the sector)

The cost of the PRRSV infection in Europe seems not to be very well estimated in most countries – economic impact of this disease, under field conditions, is often overlooked and the few studies available were often carried out in the USA (Fraile, 2012). Studies in sow herds that experience acute PRRSV problems have shown a loss of €59 to €379/sow during outbreak in the Netherlands (median €75) and of €4 to €95/sow in Denmark (median €44).

However, when comparing a large number of chronically infected herds to non-infected herds, Danish studies show only a marginally reduction in productivity. The piglet mortality was 0.8–0.9%-point higher and the nursery mortality was 0.4%-point higher in infected herds. No difference was seen in mortality among finishers (Baekbo and Kristensen, 2015).

At farm level, an analysis of outbreaks in the Netherlands (Nieuwenhuis et al., 2012) estimated the economic loss to be between €59 and €379 for one sow per 18-week period outbreak. The mean loss per sow per outbreak was €126. The costs after the outbreak varied significantly from €3 to 160 per sow, due to the different methods used by farmers to tackle PRRSV outbreaks. The calculated costs in this study correlated with the costs of the initial outbreak in The Netherlands of €98 per sow.

As well as the direct costs due to the immediate effects an outbreak, the longer-term impacts of the disease can also be of significant cost. In an outbreak in a large farm in Poland, the expenses dealing with preventing and treating secondary infections, during the 12 months after the outbreak were on average 60% higher than during the previous year (Pejsak and Markowska-Daniel, 1997).

3.1.5.2. Article 7(e)(ii) The societal acceptance of disease prevention and control measures

No social science case studies specific to PRRS have been identified. For EU MS with free status, the programmes were largely industry-driven, on the premise of improved welfare, health animals and improved productivity – so anticipated to be socially very acceptable.

3.1.5.3. Article 7(e)(iii) The welfare of affected subpopulations of kept and wild animals

Parameter 1 – Welfare impact of control measures on domestic animals

From control of other diseases, e.g. FMD, CSF, movement restrictions may be detrimental to animal welfare and culling of healthy animals for welfare reasons is seen as a last resort. For PRRS, the lack of effective vaccines and no DIVA capability may be a significant constraint.

Parameter 2 – Wildlife depopulation as control measure

Unlikely to be carried out, given endemicity. Welfare unlikely an issue, given these are a hunted species in most parts of the EU anyway.

3.1.5.4. Article 7(e)(iv) The environment and biodiversity

Environment

Parameter 1 – Use and potential residuals of biocides or medical drugs in environmental compartments (soil, water, feed, manure)

Manufacture and use of disinfectants in the EU must comply with Regulation (EU) No 528/2012⁵.

Biodiversity

Parameter 2 – Mortality in wild species

For wild boar, assumed to be the same as for domestic pigs.

3.2. Assessment according to Article 5 criteria

This section presents the results of the expert judgement on the criteria of Article 5 of the AHL about PRRS (Table 7). The expert judgement was based on Individual and Collective Behavioural Aggregation (ICBA) approach described in detail in the opinion on the methodology (EFSA AHAW Panel, 2017). Experts have been provided with information of the disease fact-sheet mapped into Article 5 criteria (see supporting information, Annex A), based on that the experts indicate their Y/N or 'na' judgement on each criterion of Article 5, and the reasoning supporting their judgement.

The minimum number of judges in the judgement was 12. The expert judgement was conducted as described in the methodological opinion (EFSA AHAW Panel, 2017). For details on the interpretation of the questions, see Appendix B of the methodological opinion (EFSA AHAW Panel, 2017).

Table 7: Outcome of the expert judgement on the Article 5 criteria for PRRS

Criteria to be met by the disease:		Final outcome
According to AHL, a disease shall be included in the list referred to in point (b) of paragraph 1 of Article 5 if it has been assessed in accordance with Article 7 and meets all of the following criteria		
A(i)	The disease is transmissible	Y
A(ii)	Animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union	Y
A(iii)	The disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character	Y
A(iv)	Diagnostic tools are available for the disease	Y
A(v)	Risk-mitigating measures and, where relevant, surveillance of the disease are effective and proportionate to the risks posed by the disease in the Union	Y
At least one criterion to be met by the disease:		
In addition to the criteria set out above at points A(i)–A(v), the disease needs to fulfil at least one of the following criteria		
B(i)	The disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic character	Y
B(ii)	The disease agent has developed resistance to treatments and poses a significant danger to public and/or animal health in the Union	na
B(iii)	The disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union	Y
B(iv)	The disease has the potential to generate a crisis or the disease agent could be used for the purpose of bioterrorism	N
B(v)	The disease has or could have a significant negative impact on the environment, including biodiversity, of the Union	N

Colour code: green = consensus (Yes/No), yellow = no consensus (NC), red = not applicable (na), i.e. insufficient evidence or irrelevant to judge.

⁵ Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products. OJ L 167, 27.6.2012, p. 1–123.

3.2.1. Outcome of the assessment of PRRS according to criteria of Article 5(3) of the AHL on its eligibility to be listed

As from the legal text of the AHL, a disease is considered eligible to be listed as laid down in Article 5 if it fulfils all criteria of the first set from A(i) to A(v) and at least one of the second set of criteria from B(i) to B(v). According to the assessment methodology (EFSA AHAW Panel et al., 2017), a criterion is considered fulfilled when the outcome is 'Yes'. According to the results shown in Table 7, PRRS complies with all criteria of the first set and with two criteria of the second set, therefore it is considered eligible to be listed as laid down in Article 5 of the AHL.

3.3. Assessment according to Article 9 criteria

This section presents the results of the expert judgement on the criteria of Annex IV referring to categories as in Article 9 of the AHL about PRRS (Tables 8, 9, 10, 11 and 12). The expert judgement was based on ICBA approach described in detail in the opinion on the methodology. Experts have been provided with information of the disease fact-sheet mapped into Article 9 criteria (see supporting information, Annex A), based on that the experts indicate their Y/N or 'na' judgement on each criterion of Article 9, and the reasoning supporting their judgement. The minimum number of judges in the judgement was 12. The expert judgement was conducted as described in the methodological opinion (EFSA AHAW Panel, 2017). For details on the interpretation of the questions see Appendix B of the methodological opinion (EFSA AHAW Panel, 2017).

Table 8: Outcome of the expert judgement related to the criteria of Section 1 of Annex IV (category A of Article 9) for PRRS (CI=current impact; PI=potential impact)

Criteria to be met by the disease:		Final outcome
The disease needs to fulfil all of the following criteria		
1	The disease is not present in the territory of the Union OR present only in exceptional cases (irregular introductions) OR present in only in a very limited part of the territory of the Union	N
2.1	The disease is highly transmissible	NC
2.2	There be possibilities of airborne or waterborne or vector-borne spread	Y
2.3	The disease affects multiple species of kept and wild animals OR single species of kept animals of economic importance	Y
2.4	The disease may result in high morbidity and significant mortality rates	Y
At least one criterion to be met by the disease:		
In addition to the criteria set out above at points 1–2.4, the disease needs to fulfil at least one of the following criteria		
3	The disease has a zoonotic potential with significant consequences on public health, including epidemic or pandemic potential OR possible significant threats to food safety	N
4(CI)	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	Y
4(PI)	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	Y
5(a)(CI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(a)(PI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(b)(CI)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	Y
5(b)(PI)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	Y
5(c)(CI)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(c)(PI)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N

5(d)(CI)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N
5(d)(PI)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N

Colour code: green = consensus (Yes/No), yellow = no consensus (NC).

Table 9: Outcome of the expert judgement related to the criteria of Section 2 of Annex IV (category B of Article 9) for PRRS (CI=current impact; PI=potential impact)

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		Final outcome
1	The disease is present in the whole OR part of the Union territory with an endemic character AND (at the same time) several Member States or zones of the Union are free of the disease	NC
2.1	The disease is moderately to highly transmissible	NC
2.2	There be possibilities of airborne or waterborne or vector-borne spread	Y
2.3	The disease affects single or multiple species	Y
2.4	The disease may result in high morbidity with in general low mortality	N
At least one criterion to be met by the disease: In addition to the criteria set out above at points 1–2.4, the disease needs to fulfil at least one of the following criteria		
3	The disease has a zoonotic potential with significant consequences on public health, including epidemic potential OR possible significant threats to food safety	N
4(CI)	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	Y
4(PI)	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	Y
5(a)(CI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(a)(PI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(b)(CI)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	Y
5(b)(PI)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	Y
5(c)(CI)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(c)(PI)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(d)(CI)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N
5(d)(PI)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N

Colour code: green = consensus (Yes/No), yellow = no consensus (NC).

Table 10: Outcome of the expert judgement related to the criteria of Section 3 of Annex IV (category C of Article 9) for PRRS (CI = current impact; PI = potential impact)

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		Final outcome
1	The disease is present in the whole OR part of the Union territory with an endemic character	Y
2.1	The disease is moderately to highly transmissible	NC
2.2	The disease is transmitted mainly by direct or indirect transmission	Y
2.3	The disease affects single or multiple species	Y
2.4	The disease usually does not result in high morbidity and has negligible or no mortality AND often the most observed effect of the disease is production loss	N
At least one criterion to be met by the disease: In addition to the criteria set out above at points 1–2.4, the disease needs to fulfil at least one of the following criteria		
3	The disease has a zoonotic potential with significant consequences on public health, or possible significant threats to food safety	N
4(CI)	The disease has a significant impact on the economy of parts of the Union, mainly related to its direct impact on certain types of animal production systems	N
4(PI)	The disease has a significant impact on the economy of parts of the Union, mainly related to its direct impact on certain types of animal production systems	N
5(a)(CI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(a)(PI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(b)(CI)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	Y
5(b)(PI)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	Y
5(c)(CI)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(c)(PI)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(d)(CI)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N
5(d)(PI)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N

Colour code: green = consensus (Yes/No), yellow = no consensus (NC).

Table 11: Outcome of the expert judgement related to the criteria of Section 4 of Annex IV (category D of Article 9) for PRRS

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		Final outcome
D	The risk posed by the disease in question can be effectively and proportionately mitigated by measures concerning movements of animals and products in order to prevent or limit its occurrence and spread	Y
The disease fulfils criteria of Sections 1, 2, 3 or 5 of Annex IV of AHL		Y

Colour code: green = consensus (Yes/No).

Table 12: Outcome of the expert judgement related to the criteria of Section 5 of Annex IV (category E of Article 9) for PRRS

Diseases in category E need to fulfil criteria of Sections 1, 2 or 3 of Annex IV of AHL and/or the following:		Final outcome
E	Surveillance of the disease is necessary for reasons relating to animal health, animal welfare, human health, the economy, society or the environment (If a disease fulfils the criteria as in Article 5, thus being eligible to be listed, consequently category E would apply.)	Y

Colour code: green = consensus (Yes/No).

3.3.1. Non-consensus questions

This section displays the assessment related to each criterion of Annex IV referring to the categories of Article 9 of the AHL where no consensus was achieved in form of tables (Tables 13 and 14). The proportion of Y, N or 'na' answers are reported, followed by the list of different supporting views for each answer.

Table 13: Outcome of the expert judgement related to criterion 1 of Article 9

Question	Final outcome	Response		
		Y (%)	N (%)	na (%)
1(cat.B) The disease is present in the whole OR part of the Union territory with an endemic character AND (at the same time) several Member States or zones of the Union are free of the disease	NC	83	17	0

NC: non-consensus; number of judges: 12.

Reasoning supporting the judgement

Supporting Yes for 1 (cat.B):

- Four European countries including two MSs (Sweden, Finland, Norway and Switzerland) are free from the disease, thus indicating that it is possible to demonstrate freedom of disease.

Supporting No for 1 (cat.B):

- Only two MSs, thus not several, are free from the disease.

Table 14: Outcome of the expert judgement related to criterion 2.1 of Article 9

Question	Final outcome	Response		
		Y (%)	N (%)	na (%)
2.1(cat.A) The disease is highly transmissible	NC	58	42	0
2.1(cat.B,C) The disease is moderately to highly transmissible	NC	42	58	0

NC: non-consensus; number of judges: 12.

Reasoning supporting the judgement

Supporting Yes for 2.1 (cat.A):

- The disease generally spreads to all animals in a herd unit and easily spreads between herds by various routes including direct, indirect (e.g. semen) and airborne routes.

Supporting Yes for 2.1 (cat.B,C):

- The transmissibility varies considerably depending on a number of factors, including the strain/virulence of the virus involved, the infection dose, and route, as well as the age, immune response and presence of other pathogens in the pig.

3.3.2. Outcome of the assessment of criteria in Annex IV for PRRS for the purpose of categorisation as in Article 9 of the AHL

As from the legal text of the AHL, a disease is considered fitting in a certain category (A, B, C, D or E corresponding to point (a) to point (e) of Article 9(1) of the AHL) if it is eligible to be listed for Union intervention as laid down in Article 5(3) and fulfils all criteria of the first set from 1 to 2.4 and at least one of the second set of criteria from 3 to 5(d) as shown in Tables 8–12. According to the assessment methodology (EFSA AHAW Panel, 2017), a criterion is considered fulfilled when the outcome is 'Yes'. With respect to different type of impact where the assessment is divided into current and potential impact, a criterion will be considered fulfilled if at least one of the two outcomes is 'Y' and, in case of no 'Y', the assessment is inconclusive if at least one outcome is 'NC'.

A description of the outcome of the assessment of criteria in Annex IV for PRRS for the purpose of categorisation as in Article 9 of the AHL is presented in Table 15.

Table 15: Outcome of the assessment of criteria in Annex IV for PRRS for the purpose of categorisation as in Article 9 of the AHL

Category	Article 9 criteria										
	1° set of criteria					2° set of criteria					
	1	2.1	2.2	2.3	2.4	3	4	5a	5b	5c	5d
	Geographical distribution	Transmissibility	Routes of transmission	Multiple species	Morbidity and mortality	Zoonotic potential	Impact on economy	Impact on society	Impact on animal welfare	Impact on environment	Impact on biodiversity
A	N	NC	Y	Y	Y	N	Y	N	Y	N	N
B	NC	NC	Y	Y	N	N	Y	N	Y	N	N
C	Y	NC	Y	Y	N	N	N	N	Y	N	N
D						Y					
E						Y					

According to the assessment here performed, PRRS complies with the following criteria of the sections 1–5 of Annex IV of the AHL for the application of the disease prevention and control rules referred to in points (a)–(e) of Article 9(1):

- 1) To be assigned to category A, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and according to the assessment PRRS complies with criteria 2.2, 2.3 and 2.4 but not with criterion 1 and the assessment is inconclusive on compliance with criterion 2.1. To be eligible for category A, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5a–d) and PRRS complies with criteria 4 and 5b but not with criteria 3, 5a, 5c and 5d.
- 2) To be assigned to category B, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and according to the assessment PRRS complies with criteria 2.2 and 2.3, but not with criterion 2.4 and the assessment is inconclusive on compliance with criteria 1 and 2.1. To be eligible for category B, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5a–d) and PRRS complies with criteria 4 and 5b but not with criteria 3, 5a, 5c and 5d.
- 3) To be assigned to category C, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and according to the assessment PRRS complies with criteria 1, 2.2 and 2.3 but not with criterion 2.4 and the assessment is inconclusive on compliance with criterion 2.1. To be eligible for category C, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5a–d) and PRRS complies with criterion 5b but not with criteria 3, 4, 5a, 5c and 5d.
- 4) To be assigned to category D, a disease needs to comply with criteria of sections 1, 2, 3 or 5 of Annex IV of the AHL and with the specific criterion D of section 4, with which PRRS complies.

- 5) To be assigned to category E, a disease needs to comply with criteria of sections 1, 2 or 3 of Annex IV of the AHL and/or the surveillance of the disease is necessary for reasons relating to animal health, animal welfare, human health, the economy, society or the environment. The latter is applicable if a disease fulfils the criteria as in Article 5, with which PRRS complies.

3.4. Assessment of Article 8

This section presents the results of the assessment on the criteria of Article 8(3) of the AHL about PRRS. The Article 8(3) criteria are about animal species to be listed, as it reads below:

'3. Animal species or groups of animal species shall be added to this list if they are affected or if they pose a risk for the spread of a specific listed disease because:

- a) they are susceptible for a specific listed disease or scientific evidence indicates that such susceptibility is likely; or
- b) they are vector species or reservoirs for that disease, or scientific evidence indicates that such role is likely'.

For this reason the assessment on Article 8 criteria is based on the evidence as extrapolated from the relevant criteria of Article 7, i.e. the ones related to susceptible and reservoir species or routes of transmission, which cover also the possible role of biological or mechanical vectors.⁶ According to the mapping, as presented in Table 5, section 3.2 of the scientific opinion on the *ad hoc* methodology (EFSA AHAW Panel et al., 2017), the main animal species to be listed for PRRS according to the criteria of Article 8(3) of the AHL are as displayed in Table 16.

Table 16: Main animal species to be listed for PRRS according to criteria of Article 8 (*source:* data reported in Section 3.1.1.1)

	Class	Order	Family	Genus/species
Susceptible	Mammalia	Artiodactyla	Suidae	<i>Sus scrofa</i>
Reservoir			None	
Vectors			None	

4. Conclusions

TOR 1: for each of those diseases an assessment, following the criteria laid down in Article 7 of the AHL, on its eligibility of being listed for Union intervention as laid down in Article 5(3) of the AHL;

- According to the assessment here performed, PRRS complies with all criteria of the first set and with two criteria of the second set and therefore can be considered eligible to be listed for Union intervention as laid down in Article 5(3) of the AHL.

TOR 2a: for each of the diseases which was found eligible to be listed for Union intervention, an assessment of its compliance with each of the criteria in Annex IV to the AHL for the purpose of categorisation of diseases in accordance with Article 9 of the AHL;

- According to the assessment here performed, PRRS complies with the criteria as in Sections 4 and 5 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in points (d) and (e) of Article 9(1) of the AHL.

TOR 2b: for each of the diseases which was found eligible to be listed for Union intervention, a list of animal species that should be considered candidates for listing in accordance with Article 8 of the AHL.

- According to the assessment here performed, the animal species that can be considered to be listed for PRRS according to Article 8(3) of the AHL are domestic pigs and wild boar, as reported in Table 16 in Section 3.4 of the present document.

⁶ A vector is a living organism that transmits an infectious agent from an infected animal to a human or another animal. Vectors are frequently arthropods. Biological vectors may carry pathogens that can multiply within their bodies and be delivered to new hosts, usually by biting. In mechanical vectors the pathogens do not multiply within the vector, which usually remains infected for shorter time than in biological vectors.

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Abbreviations

AHAW	EFSA Panel on Animal Health and Welfare
AHL	Animal Health Law
CFSPH	Center for Food Security and Public Health
CSF	classical swine fever
dpi	days post-inoculation
ELISA	enzyme-linked immunosorbent assay
FMD	foot-and-mouth disease
HP	highly pathogenic
ICBA	Individual and Collective Behavioural Aggregation
IFA	indirect fluorescent/immunofluorescence antibody
IgG	immunoglobulin G
IgM	immunoglobulin M
IHC	immunohistochemistry method
IPMA	immunoperoxidase monolayer assay
ISH	<i>in-situ</i> hybridisation
IUCN	International Union for Conservation of Nature
MLV	modified live vaccine
OIE	World Organisation for Animal Health
PCR	polymerase chain reaction
PRRS	porcine reproductive and respiratory syndrome
PRRSV	Porcine reproductive and respiratory syndrome virus
RT-PCR	reverse-transcription polymerase chain reaction
ToR	Terms of Reference