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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): infectious bovine rhinotracheitis (IBR)

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Abstract

Infectious bovine rhinotracheitis (IBR) 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 IBR to be listed, Article 9 for the categorisation of IBR according to disease prevention and control rules as in Annex IV and Article 8 on the list of animal species related to IBR. 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, IBR 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 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 assessment here performed on compliance with the criteria as in Section 3 of Annex IV referred to in point (c) of Article 9(1) is inconclusive. The animal species to be listed for IBR according to Article 8(3) criteria belong to the order Artiodactyla.

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Table of contents

| | |
|---|----|
| Abstract..... | 1 |
| 1. Introduction..... | 4 |
| 1.1. Background and Terms of Reference as provided by the requestor..... | 4 |
| 1.2. Interpretation of the Terms of Reference..... | 4 |
| 2. Data and methodologies..... | 4 |
| 3. Assessments..... | 4 |
| 3.1. Assessment according to Article 7 criteria..... | 4 |
| 3.1.1. Article 7(a) Disease Profile..... | 4 |
| 3.1.1.1. Article 7(a)(i) Animal species concerned by the disease..... | 4 |
| 3.1.1.2. Article 7(a)(ii) The morbidity and mortality rates of the disease in animal populations..... | 5 |
| 3.1.1.3. Article 7(a)(iii) The zoonotic character of the disease..... | 6 |
| 3.1.1.4. Article 7(a)(iv) The resistance to treatments, including antimicrobial resistance..... | 6 |
| 3.1.1.5. Article 7(a)(v) The persistence of the disease in an animal population or the environment..... | 6 |
| 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..... | 7 |
| 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..... | 7 |
| 3.1.1.8. Article 7(a)(viii) The existence of diagnostic and disease control tools..... | 8 |
| 3.1.2. Article 7(b) The impact of diseases..... | 8 |
| 3.1.2.1. Article 7(b)(i) The impact of the disease on agricultural and aquaculture production and other parts of the economy..... | 8 |
| 3.1.2.2. Article 7(b)(ii) The impact of the disease on human health..... | 9 |
| 3.1.2.3. Article 7(b)(iii) The impact of the disease on animal welfare..... | 9 |
| 3.1.2.4. Article 7(b)(iv) The impact of the disease on biodiversity and the environment..... | 9 |
| 3.1.3. Article 7(c) Its potential to generate a crisis situation and its potential use in bioterrorism..... | 9 |
| 3.1.4. Article 7(d) The feasibility, availability and effectiveness of the following disease prevention and control measures..... | 10 |
| 3.1.4.1. Article 7(d)(i) Diagnostic tools and capacities..... | 10 |
| 3.1.4.2. Article 7(d)(ii) Vaccination..... | 12 |
| 3.1.4.3. Article 7(d)(iii) Medical treatments..... | 12 |
| 3.1.4.4. Article 7(d)(iv) Biosecurity measures..... | 12 |
| 3.1.4.5. Article 7(d)(v) Restrictions on the movement of animals and products..... | 13 |
| 3.1.4.6. Article 7(d)(vi) Killing of animals..... | 14 |
| 3.1.4.7. Article 7(d)(vii) Disposal of carcasses and other relevant animal by-products..... | 14 |
| 3.1.5. Article 7(e) The impact of disease prevention and control measures..... | 14 |
| 3.1.5.1. Article 7(e)(i) The direct and indirect costs for the affected sectors and the economy as a whole..... | 14 |
| 3.1.5.2. Article 7(e)(ii) The societal acceptance of disease prevention and control measures..... | 14 |
| 3.1.5.3. Article 7(e)(iii) The welfare of affected subpopulations of kept and wild animals..... | 15 |
| 3.1.5.4. Article 7(e)(iv) The environment and biodiversity..... | 15 |
| 3.2. Assessment according to Article 5 criteria..... | 15 |
| 3.2.1. Outcome of the assessment of infectious bovine rhinotracheitis according to criteria of Article 5(3) of the AHL on its eligibility to be listed..... | 16 |
| 3.3. Assessment according to Article 9 criteria..... | 16 |
| 3.3.1. Non-consensus questions..... | 19 |
| 3.3.2. Outcome of the assessment of criteria in Annex IV for infectious bovine rhinotracheitis for the purpose of categorisation as in Article 9 of the AHL..... | 20 |
| 3.4. Assessment of Article 8..... | 22 |
| 4. Conclusions..... | 22 |
| References..... | 23 |
| Abbreviations..... | 25 |

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 infectious bovine rhinotracheitis (IBR) according to the criteria of the AHL articles as follows:

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

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 IBR 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

IBR is caused by a virus of the order Herpesvirales, the family Herpesviridae and the species Bovine herpesvirus-1 (BoHV-1). IBR is a disease of domestic and wild cattle (OIE, 2017). Artiodactyla (e.g. cattle, goats, sheep, water buffaloes, camelids) may be infected with BoHV-1. Only those non-host (bovine) species from which BoHV-1 or DNA has been isolated from field material or following experimental challenge by a natural route are listed below.

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

Naturally susceptible wildlife species include: red deer (*Cervus elaphus*) (Frölich et al., 2006), roe deer (*Capreolus capreolus*) (Kálmán and Egyed, 2005), fallow deer (*Dama dama*) (Kálmán and Egyed, 2005), reindeer (*Rangifer tarandus*) (Lillehaug et al., 2003), and feral pig (Crandell et al., 1987).

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

Naturally susceptible domestic species include cattle (Raaperi et al., 2014; OIE, 2017), sheep (Whetstone and Evermann, 1988; Raaperi et al., 2014), goat (Whetstone and Evermann, 1988; Tolari et al., 1990; Raaperi et al., 2014), water buffalo (*Bubalus bubalis*) (Fusco et al., 2015), and pig (Derbyshire and Caplan, 1976; Varady et al., 1994).

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

Experimental infection in wildlife species have been produced in deer (Mollema et al., 2005), reindeer (*Rangifer tarandus*) (Thiry et al., 2006) and mule deer (*Odocoileus hemionus*) (Thiry et al., 2006).

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

Experimental infection in domestic species have been produced in rabbit (Rock and Reed, 1982).

Reservoir animal species

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

None recognised. The establishment of latency following infection with BoHV-1 is considered a prerequisite for a species to act as a reservoir. Latency is not established following infection of red deer or reindeer (Thiry et al., 2006).

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

BoHV-1 is able to establish a latent infection in the trigeminal ganglia of goats and sheep from which it can be reactivated. However, neither sheep, goats nor pigs are considered to play a role as an alternative reservoir for BoHV-1 (Wentink et al., 1993; Hage et al., 1997; Thiry et al., 2006; Muylkens et al., 2007). Latency, but not reactivation, has also been demonstrated in water buffaloes (*Bubalus bubalis*) leaving the role of this species as a reservoir to be proven (Scicluna et al., 2010).

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

Morbidity

Parameter 1 – Prevalence/incidence

In the absence of control, prevalence of infection is typically high both at animal and herd levels. Raaperi et al. (2014) reviewed several different prevalence surveys in Europe and found herd-level prevalences to range from 13.4% to 100% (mean 66.3%, median 70.4%) and animal-level prevalence to range from 12.0% to 77.5% (mean 37.7%, median 38.4%). Calves have a lower prevalence of infection than adult cattle, although the incidence of seroconversion is higher in animals aged < 24 months than in adult cattle.

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

Case morbidity is variable, depending on a number of factors including the virulence of the BoHV-1 strain, resistance factors/immune status of the host and potential concurrent bacterial infection (Muylkens et al., 2007). The outcome of infection in terms of case morbidity may range from very low in subclinical pictures to high (up to 90%), particularly in naïve populations, with morbidity and case mortality rate typically higher in neonatal and suckling calves than in adults (Wiseman et al., 1980; Patel, 2005a; EFSA, 2006; Muylkens et al., 2007; Nandi et al., 2009; Graham, 2013; Raaperi et al., 2014). Modelling studies from the Netherlands, however have considered that around 5% of infectious cows are clinically affected (Vonk Noordegraaf et al., 1998; Noordegraaf et al., 2000) as subclinical BoHV-1 infections are more common (Muylkens et al., 2007).

Mortality

Parameter 3 – Case-fatality rate

While infection with IBR can follow a subclinical course, it may also be occasionally associated with significant mortality, particularly associated with the introduction of BoHV-1.1 strains to Europe in the early 1970s (Edwards, 1988; Vonk Noordegraaf et al., 1998). Case-fatality rates of up to 8% were reported from the early outbreaks in Ireland in 1989/1990 (Gunn and Wilson, 1991) and in the United Kingdom (Wiseman et al., 1980). A case-mortality rate of 3% was reported for the initial description of IBR in California (Graham, 2013). Modelling studies from the Netherlands have considered a mortality rate around 2% among clinically affected animals (Vonk Noordegraaf et al., 1998; Noordegraaf et al., 2000).

A recent large study in Ireland (Sayers, 2017), examining the possible variables associated with the infection in herds (positive for BoHV-1 bulk milk antibody detection), showed no association between

infection and mortality across different age groups (calves, young stock, adults). Whole-herd mortality counts, however, showed a marginal increase by a factor of 1.001 in BoHV-1 ELISA positive herds ($p = 0.023$) (Sayers, 2017).

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

Presence

Parameter 1 – Report of zoonotic human cases (anywhere)

BoHV-1 is not considered zoonotic.

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 available, so resistance to treatment is not applicable.

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

During acute primary infection, BoHV-1 is excreted in nasal fluid over a period of 10–17 days with a peak at 4–6 days post-infection (Nandi et al., 2009). Cattle infected with BoHV-1.1 excrete higher titres of virus (10–100-fold greater) in nasal fluids than do cattle infected with BHV-1.2b. Following primary preputial infection, bulls may shed BoHV-1 for several days to several weeks. Infected bulls may also shed high concentrations of the virus in semen.

Parameter 2 – Presence and duration of latent infection period

Lifelong latent infection is considered to develop in most, if not all, cattle following acute infection. Latency may occur within the germinal centres of the pharyngeal tonsils (EFSA, 2006; Muylkens et al., 2007; Nandi et al., 2009).

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

The sensory ganglia of the trigeminal and sacral nerves are considered to be the main sites of latency following respiratory and venereal infection respectively (EFSA, 2006; Muylkens et al., 2007; Nandi et al., 2009). Latent BoHV-1 may be reactivated in, and shed from, carrier animals spontaneously or by a range of stressors including parturition, mating, transport, mixing, inclement weather, concomitant infection, poor husbandry or diet and overcrowding (EFSA, 2006; Muylkens et al., 2007; Raaperi et al., 2014). Because virus latency is a normal sequel to BoHV-1 infection, the identification of serologically positive animals provides a useful and reliable indicator of infection status. With the exception of animals with maternally derived antibodies or vaccinated with dead marker vaccine, seropositive animals are considered latently infected carriers and potential shedders of the virus. However, it is recognised that seronegative carriers may occur as a consequence of infection in the presence of maternally derived antibodies (EFSA, 2006; OIE, 2017).

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)

Inactivation of the virus in the environment depends on factors such as temperature, pH, light, humidity and the medium harbouring the virus, with survival enhanced by low temperature and high relative humidity (Nandi et al., 2009). At 4°C, the virus is stable for 1 month. It is inactivated at 56°C within 21 min, at 37°C within 10 days and at 22°C within 50 days. The virus may survive for more than 30 days in feeds. As the virus is enveloped, it is sensitive to organic solvents such as chloroform, ether and acetone. The virus is sensitive to many disinfectants and is readily inactivated by 0.5% NaOH, 0.01% HgCl₂, 1% chlorinated lime, 1% phenolic derivatives, 1% quaternary ammonium bases and 10% Lugol's iodine. Formalin (5%) inactivates BoHV-1 within 1 min.

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)

Transmission of BoHV-1 is usually by direct contact of a susceptible animal with an infected animal excreting virus in oronasal or genital secretions. Aerosol spread does occur but is considered to be limited in most cases to a few metres (EFSA, 2006). An additional transmission route is via infected semen and vertical transmission may occur in utero. BoHV-1 may also be shed in semen following a primary or reactivated infection, with the potential of transmission following either artificial or natural insemination. Embryo transfer may also result in transfer of BoHV-1 adsorbed to the zona pellucida. BoHV-1 has been isolated from milk and faeces but neither source is considered to be a significant transmission route in the field (EFSA, 2006).

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

Not relevant.

Speed of transmission

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

See below.

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

BoHV-1 transmits readily between cattle when introduced to a naïve population. An R_0 value of ≥ 9 has been reported in calves (Hage et al., 1997) while $R_0 \geq 7$ has been reported for adult cattle (Hage et al., 1996). In contrast, much lower R_0 values for transmission from sheep to calves or between red deer (0.1 and 0 [0–0.94; 95% one-sided CI] respectively) (Hage et al., 1997; Mollema et al., 2005). Based on published values for R_0 and the length of the infectious period (γ) (7 and 10 days respectively) (Hage et al., 1996), the transmission rate (β) is calculated as 0.7 where $R_0 = \beta \times \gamma$.

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

IBR is present in 23 EU Member States (MSs) and consequently in a significant part of the Union. That fact is underlined also in point 2.4 of the annual report on bovine and swine diseases for 2015 (European Commission, 2015).

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

A number of MSs, or regions thereof, are considered free of infection and have been awarded Article 10 status as laid down by Commission Decision 2004/558/EC¹. Annex II of Commission Implementing Decision (EU) 2015/250² lists the following countries/regions as free of BoHV-1: Denmark, Finland, Sweden, Austria, the Federal States of Bavaria, Thuringia, Saxony, Saxony-Anhalt, Brandenburg, Berlin and Mecklenburg-Western Pomerania in Germany and the Autonomous Province of Bolzano in Italy.

Annex I lists the following countries/regions as having been granted additional guarantees in respect of BoHV-1 in light of their having approved eradication programmes in place: Belgium, the

¹ 2004/558/EC: Commission Decision of 15 July 2004 implementing Council Directive 64/432/EEC as regards additional guarantees for intra-Community trade in bovine animals relating to infectious bovine rhinotracheitis and the approval of the eradication programmes presented by certain Member States. OJ L 249, 23.7.2004, p. 20–25.

² Commission Implementing Decision (EU) 2015/250 of 13 February 2015 amending Annexes I and II to Decision 2004/558/EC as regards the infectious bovine rhinotracheitis-free status of the Federal States of Saxony, Saxony-Anhalt, Brandenburg, Berlin and Mecklenburg-Western Pomerania in Germany. OJ L 41, 17.2.2015, p. 43–45.

Czech Republic, all regions of Germany except those listed above and the Regions of Friuli-Venezia Giulia and Valle d'Aosta and the Autonomous Province of Trento in Italy.

Infection is considered to be endemic in all other MSs and MS regions.

Risk of introduction

Infection is already present in most 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 range of reliable diagnostic tools for detection of virus, viral antigens and RNA and antibodies are available (see Section 3.1.4.1).

Control tools

Parameter 2 – Existence of control tools

Control tools have been applied successfully at both herd- and regional-/national-levels (EFSA, 2006; Muylkens et al., 2007; Raaperi et al., 2014).

Test and slaughter strategy. This has been used successfully in Finland, Sweden, Norway, Denmark, Austria and Switzerland.

Differentiating infected from vaccinating animals (DIVA) strategy. Marker (gE-deleted) vaccines, which are considered safe and efficacious based on both experimental and field data (European Commission, 2000; Dispas et al., 2004, 2009; EFSA, 2006; Makoschey et al., 2007; Ampe et al., 2012), are available and form the basis of a control strategy where initial prevalence is moderate to high. This approach, supplemented by biosecurity measures to address risks of introduction associated with breeding, trade and husbandry activities, can be used to reduce the initial prevalence, with remaining positive animals being culled when prevalence falls to 5%. The efficacy of this strategy, incorporating marker vaccination, has also been demonstrated in the field where it has been incorporated into successful national eradication programmes (Commission Implementing Decision (EU) 2015/250).

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

The disease is considered to be present in all non-free MS/regions, being endemic in the absence of appropriate controls. Some MSs and regions have Commission-approved programmes for the control and eradication of the disease and therefore may have a lower prevalence than that typically present in the absence of such programmes. MSs to which the additional guarantees for approved eradication programmes for IBR as defined in Commission Decision 2004/558/EC in accordance with Article 10 of Council Directive 64/432/EEC³ apply are Austria, Denmark, Finland, Germany and Sweden. In Italy, these guarantees apply in the Region Valle d'Aosta and Autonomous Province of Bolzano and in the United Kingdom in Jersey.

MSs to which the additional guarantees for IBR apply in accordance with Article 9 of Council Directive 64/432/EEC are Belgium, Czech Republic and Luxembourg. In Italy they apply in the Region Friuli-Venezia Giulia and in the Autonomous Province of Trento.

The loss of production due to the disease

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

BoHV-1 may cause production losses through its impact on health and welfare, manifest as respiratory (infectious bovine rhinotracheitis (IBR)) and venereal disease (infectious pustular

³ Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine. OJ L21, 29.7.1964, pp. 1977–2012.

vulvovaginitis/balanoposthitis (IPV)/(IPB); reduced fertility and abortion (Graham, 2013)) and a reduction in milk yield. Limited data are available to quantify the associated losses in the field.

Annual losses in the UK due to the disease and its treatment were estimated at up to £3.1 million in 2005, with the highest proportion of these accounted for by mortality/premature culling, followed by weight loss (Bennett and Ijpelaar, 2005). A more extensive study in Ireland estimated a reduced production of 250 L/year for multiparous cows in herds testing positive for antibodies in bulk milk tank samples (Sayers, 2017). Beside the reduced milk production, minor effects on herd fertility and mortality were identified, adding to the growing evidence that subclinical BoHV-1 can result in ongoing losses in dairy herds (Sayers, 2017).

Losses due to a drop in milk production associated with subclinical infection were estimated at approximately 9.5 L over an infectious period of 14 days during a subclinical bovine herpesvirus 1 infection on a dairy farm (Hage et al., 1998). Outbreaks in semen collection centres can be very costly, requiring destruction of all bulls in the centre (Raaperi et al., 2014).

Modelling of data from 133 herds in the Netherlands indicated an average loss of 0.92 kg of milk per cow per day over a 9-week period following infection (van Schaik et al., 1999). Modelling of data for a herd with a subclinical outbreak in the UK reported an estimated reduction of milk yield in seropositive compared with seronegative cows of 2.6 kg/day over a two-year period (Statham et al., 2015).

Parameters used in other modelling studies have included a reduction in milk yield of 263 kg and a 50% reduction in milk yield for a 3-week period in clinically affected cows (Vonk Noordegraaf et al., 1998; Noordegraaf et al., 2000). A 0.25% abortion rate in infectious cows and reductions in growth of 100% and 50% for 3 weeks and 0.5 weeks following clinical and subclinical infection respectively have also been used for modelling studies (Noordegraaf et al., 2000).

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

Not relevant as infection is not zoonotic.

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

Clinical signs may vary from inapparent to death, depending on a variety of factors including the strain of virus, with BoHV-1 subtype 1 generally being associated with more severe clinical outcomes, host factors and inter-current infections. Uncomplicated infections generally resolve in 7–14 days (Bosch et al., 1996; Patel, 2005a,b; Nandi et al., 2009).

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

None identified.

Parameter 2 – Mortality in wild species

No evidence of mortalities in wild species.

Environment

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

The pathogen can survive for short periods in the environment but has not been associated with mortalities in wildlife.

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

CFSPH (<http://www.cfsph.iastate.edu/DiseaseInfo/>): No

OIE (<http://www.oie.int/animal-health-in-the-world/oie-listed-diseases-2016/>): Yes

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

(http://www.australiagroup.net/en/human_animal_pathogens.html): No

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

None identified.

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

A range of direct (agent identification) and indirect (immune response) test methods for BoHV-1 are described in The OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (OIE, 2017) (Table 1). Within Europe, availability of laboratories offering tests for both agent identification and detection of the immune response is high, with these commonly accredited to ISO 17025. Kits are readily available commercially. In some countries, including Germany (<https://www.fli.de/en/services/licensing-authority/>) and Belgium (http://www.coda-cerva.be/index.php?option=com_content&view=article&id=376%3Acertifications-des-reactifs-de-diagnostiques&catid=194%3Acontrole-de-kits&Itemid=369&lang=en) protocols for approval of diagnostic kits for use in eradication programmes are in place. It is recommended that these are validated against EU strong positive (EU1), weak positive (EU2) and negative (EU3) sera (or derived national standards of equivalent potency).

Serological tests may be used for a variety of purposes, including to diagnose acute infection (using paired serum samples), to demonstrate freedom from infection for international trade, to determine prevalence of infection for seroepidemiological purposes and to support eradication programmes and subsequent surveillance. Annex III of Commission Decision 2004/558/EC lays down how these tests may be used to acquire and maintain a BoHV-1-free status for holdings in countries or regions with either an approved eradication programme or a recognised free status.

Table 1: Performance characteristics and comments thereon for diagnostic tests (EFSA, 2006; OIE, 2017)

| Method | Agent identification | | |
|---|--|--|---|
| | Commonly tested matrices | Analytical sensitivity | Comments |
| Virus isolation | Nasal, ocular and genital swabs, tissues, semen* | < 1–5 TCID ₅₀ /mL (EFSA, 2006) | Historically considered the reference standard but less commonly used now due to issues of time, cost and requirement for cell culture Toxicity to cell cultures can be an issue, especially with semen |
| Nucleic acid detection by (real time) PCR | Nasal, ocular and genital swabs, tissues, semen* | < 10 genome copies (EFSA, 2006) | Can also be used to detect DNA associated with latent infection Use of appropriate primers allows differentiation between wild type and gE-deleted vaccine strains Use of appropriate primers allows differentiation between BoHV-1 and other related alphaherpesviruses High analytical sensitivity, with sensitivity similar to, or exceeding virus isolation Appropriate controls necessary to avoid either false negative or false positive results |
| Antigen detection by ELISA | Nasal, ocular and genital swabs | 10 ⁴ –10 ⁵ TCID ₅₀ (EFSA, 2006) | More rapid than virus isolation but a lower analytical and diagnostic sensitivity |
| Immunofluorescent antibody testing | Nasal, ocular and genital swabs | Lower than virus isolation (OIE, 2017) | More rapid than virus isolation but a lower analytical and diagnostic sensitivity |
| Immunohistochemistry | Tissues | Lower than virus isolation (OIE, 2017) | More rapid than virus isolation but a lower analytical and diagnostic sensitivity |

| Method | Detection of immune response | | |
|-----------------------|------------------------------|--|---|
| | Commonly tested matrices | Diagnostic Se/Sp | Comments |
| Virus neutralisation* | Serum | 93%/96% (Kramps et al., 2004) | Historically considered the reference standard, but time-consuming and costly Does not discriminate between field and vaccine antibodies Antibody response detectable 9–11 days post-infection |
| gB ELISA* | Serum, milk, bulk tank milk | 96%/99% (serum) 81%/83% (milk) (Kramps et al., 2004) | Do not discriminate between field and vaccine antibodies Antibody response detectable 9–11 days post-infection Can be more sensitive than VN, presenting problems in confirmation |
| Indirect ELISA* | Serum, milk, bulk tank milk | 87%/99% (serum) 98%/93% (milk) (Kramps et al., 2004) | Do not discriminate between field and vaccine antibodies Antibody response detectable 9–11 days post-infection Can detect a single positive milk sample in a pool of 50 |
| gE ELISA* | Serum, milk, bulk tank milk | 72%/92% (serum) 58%/88% (milk) (Kramps et al., 2004) | Discriminates between field and vaccine (marker) antibodies Lower sensitivity than gB ELISA in serum and milk reflecting lower immunogenicity of gB Seroconversion may not be detected until 21–35 days post-infection Returns a negative bulk tank milk test result when seroprevalence falls below 10–15% Current lack of confirmatory test |

TCID: tissue culture infectious dose, 50%; PCR: polymerase chain reaction; ELISA: enzyme-linked immunosorbent assay.

*: Prescribed test for international trade.

Effectiveness

Parameter 2 – Se and Sp of diagnostic test

Virus isolation and polymerase chain reaction (PCR) are considered to have a high Se and Sp.

Virus neutralisation test (VNT) is considered a sensitive and specific assay for detection of antibodies to BoHV-1 in serum, being considered historically to be the reference standard. gB enzyme-linked immunosorbent assays (ELISAs) are also considered highly sensitive, which may be problematic because some weak positive gB ELISA results cannot be confirmed by alternative methods (VNT, indirect ELISA). Indirect ELISAs are considered to be somewhat less sensitive when applied to sera, based on the published results of an inter-laboratory ring trial (Kramps et al., 2004) which reported the Se/Sp values presented in Table 1. In contrast, indirect ELISAs were reported to be superior for testing of milk samples in this study. While these same conclusions remain accepted today, the reported performance characteristics should be interpreted with caution. First, the total number of samples tested was relative low, secondly the report included results for both commercial and in-house ELISA kits (with the former performing better) and finally the indirect kits used in the study have now largely been superseded by a new generation of highly sensitive kits (EFSA, 2006). In regard to gE ELISAs, much higher Se values (99–100%) have been reported (EFSA, 2006) while newer test methodologies, formats and antibody concentration techniques offer the possibility of increased Se values (Bertolotti et al., 2015; Casarin et al., 2016).

While the specificity of all ELISAs is considered to be high, non-specific reactions may occur for several reasons due to batch variation of kits, early testing after collection (freshness phenomenon), recent vaccination (vaccination phenomenon) and sub-optimal sample quality (OIE, 2017). Cross-reactivity with bovine herpesvirus 2 has been proposed as the cause of epidemiologically non-feasible singleton serological reactors (Böttcher et al., 2012). Close antigenic and genetic relationships exist between BoHV-1 and other ruminant alphaherpesviruses including BoHV-5, caprine herpesvirus 1 (CpHV-1), cervid herpesvirus 1 (CvHV-1; red deer), cervid herpesvirus 2 (CvHV-2; reindeer), bubaline

herpesvirus 1 (BuHV-1) and elk herpesvirus 1 (ElkHV-1), potentially resulting in serological cross-reactions (Thiry et al., 2006; Raaperi et al., 2014; OIE, 2017). Reports of serological evidence of infection (particularly in wildlife, including nyala (*Tragelaphus angasi*), bushbuck (*Tragelaphus scriptus*), kudu (*Tragelaphus strepsiceros*), eland (*Taurotragus oryx*), African buffalo (*Syncercus caffer*), sable (*Hippotragus niger*), impala (*Aepyceros melampus*), wildebeest (*Connochaetes taurinus*), tsessebe (*Damaliscus lunatus*) and giraffe (*Giraffa camelopardalis*) (Anderson and Rowe, 1998) in the absence of viral isolates must therefore be interpreted with caution.

Feasibility

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

See Table 1.

3.1.4.2. Article 7(d)(ii) Vaccination

Availability

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

A range of live and inactivated vaccines are available, including products with DIVA properties (based on deletion of the gene encoding glycoprotein E), the use of which plays an important role in the approved control and eradication programmes in place in a number of MSs (Patel, 2005a,b; EFSA, 2006; Muylkens et al., 2007; Raaperi et al., 2014).

Parameter 2 – Availability/production capacity (per year)

IBR vaccines are widely available in the EU and worldwide, but specific data on production capacities are lacking.

Effectiveness

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

All vaccines licensed in Member States must satisfy the requirements of the IBR Monograph of the European Pharmacopoeia (OIE, 2017). Vaccines with DIVA properties are considered safe and efficacious based on data from experimental and field studies (European Commission, 2000; Dispas et al., 2004, 2009; EFSA, 2006; Makoschey et al., 2007; Ampe et al., 2012). Ultimately their efficacy in the field has been demonstrated by their incorporation into successful national eradication programmes (Commission Implementing Decision (EU) 2015/250). Summaries of product characteristics generally contain claims in relation to a reduction in clinical signs and duration of virus shedding (for further details see <http://www.ema.europa.eu/ema> or <http://www.hpra.ie/homepage/veterinary>). Some products are also licensed for use to reduce the incidence of abortions associated with infection with BoHV-1.

Parameter 4 – Duration of protection

Duration of protection is dependent on the product used and the age and maternal antibody status of the vaccinated animal. Excluding calves, the duration of protection (and the booster interval) is commonly 6 months, although for some vaccination regimes this is extended to 12 months.

Feasibility

Parameter 5 – Way of administration

Depending on the product, these may be administered by the intramuscular, subcutaneous or intranasal routes.

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

No antiviral drugs are available for treating infection with BoHV-1.

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

The key risk factors for introduction of BoHV-1 are known (EFSA, 2006; Raaperi et al., 2014), falling broadly under the headings of trade in (and movement of) animals, fomites and personnel, semen, ova and embryos, and airborne spread.

Availability

Parameter 1 – Available biosecurity measures

Measures to address the routes of introduction are available. Quarantine, in conjunction with appropriate serological testing can reduce the risk associated with trade, particularly if supplemented with knowledge of the status of introduced animals and their source herds. These measures are further enhanced for countries with approved national or regional control and eradication programmes by additional guarantees with respect to trade (Council Directive 64/432/EEC). Contact of animals with those in other herds can be avoided or restricted by measures including a non-return policy and not participating in shows (or implementation of quarantine) and adequate boundary fencing. Aerosol spread may occur over very short distances. The R_0 is reported to fall below 1.0 at a distance of 4.4 m (Mars et al., 2000).

Risks associated with fomites and personnel can be addressed through appropriate disinfection procedures, limiting visitors and their degree of contact with cattle and applying appropriate disinfection procedures and/or provision of farm-specific boots and clothing.

Bulls entering semen-collection centres approved for intracommunity trade in MSs must meet quarantine and subsequent monitoring requirements, with semen and embryos imported from third countries subject to similar requirements (Mars et al., 2000).

Treatment of embryos prior to implantation can inactivate absorbed virus (EFSA, 2006).

Effectiveness

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

These measures are generally considered effective. However, the existence of seronegative latent carriers and the suboptimal sensitivity of diagnostic tests to detect antibodies to gE mean that quarantine and surveillance measures may not always be fully effective (EFSA, 2006; Raaperi et al., 2014).

Feasibility

Parameter 3 – Feasibility of biosecurity measure

These measures are considered feasible, forming the basis of the biosecurity measures that underpin approved control and eradication programmes and trade/importation of semen and embryos.

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

Availability

Parameter 1 – Available movement restriction measures

The key restriction measure relates to the movement of latently infected carrier animals. This is available through the application of serological screening. These measures are further enhanced for countries with approved national or regional control and eradication programmes by additional guarantees with respect to trade (Council Directive 64/432/EEC).

Effectiveness

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

The measures are considered effective, having formed the basis of the movement controls that underpin approved control and eradication programmes. However, the existence of seronegative latent carriers and the sub-optimal sensitivity of diagnostic tests to detect antibodies to gE mean that quarantine and surveillance measures may not always be fully effective (EFSA, 2006; Raaperi et al., 2014).

Feasibility

Parameter 3 – Feasibility of restriction of animal movement

The measures are considered feasible, having formed the basis of the movement controls that underpin approved control and eradication programmes.

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

Availability

Parameter 1 – Available methods for killing animals

Latently infected carrier animals are not excluded from the food chain subject to passing appropriate ante-mortem and post-mortem inspection. Therefore slaughter is normally carried out in abattoirs.

Effectiveness

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

Culling of seropositive animals to achieve eradication at farm level is effective when prevalence has fallen to low levels, but is not normally practiced in the face of an outbreak.

Feasibility

Parameter 3 – Feasibility of killing animals

Disposal of carrier animals through abattoirs is routinely practiced.

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

Carcasses and by-products of otherwise healthy carrier animals are disposed of through the abattoir system, entering the food chain. This procedure has been considered as effective.

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)

In general, there is a lack of reliable published disease data for economic analysis (Bennett and Ijpelaar, 2005). In one modelling study, a range of control strategies for Dutch dairy herds were evaluated (Vonk Noordegraaf et al., 1998). The optimal strategy achieved a national prevalence of gE-seropositive cattle of 5% after 241 weeks. Programme costs to this point were estimated at Dfl 219 million (equivalent to €99.5 million at 2.2 Dfl/euro). Of these costs, 62.5% was attributable to vaccination, with the remainder due to diagnosis (10.5%), monitoring (7.8%) and culling (19.2%). Additional costs of dealing with the remaining 5% seropositive animals were attributed to testing (€2.7 million) and culling (€25 million), with a payback period of 397 weeks.

Parameter 2 – Cost of eradication (culling, compensation)

See Parameter 1 above.

Parameter 3 – Cost of surveillance and monitoring

Countries or regions that achieved eradication and acquired Article 10 status have ongoing surveillance costs based on the requirements of Commission Decision 2004/558/EC.

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

Data are not available.

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

The current implementation/completion of control and eradication programmes by a number of Member States reflects the importance attached to the disease.

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

The control and eradication programmes that have either been completed or are currently underway in a number of MSs seem to have good societal acceptance.

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

Control measures which result in the control and eradication of infection are anticipated to have a beneficial impact on the welfare of domestic animals and a high degree of societal acceptance.

Parameter 2 – Wildlife depopulation as control measure

Depopulation of wildlife has not been implemented as a control measure for BoHV-1.

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)

Biocides and medicinal drugs are not used for control of BoHV-1.

Biodiversity

Parameter 2 – Mortality in wild species

Control measures are not anticipated to result in mortality in wild species.

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 IBR (Table 2). 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 11. 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 2: Outcome of the expert judgement on the Article 5 criteria for infectious bovine rhinotracheitis

| Criteria to be met by the disease: 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 | | Final outcome |
|--|--|----------------------|
| 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), red = not applicable (na), i.e. insufficient evidence or irrelevant to judge.

3.2.1. Outcome of the assessment of infectious bovine rhinotracheitis 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, 2017), a criterion is considered fulfilled when the outcome is 'Yes'. According to the results shown in Table 2, IBR 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 IBR (Tables 3, 4, 5, 6 and 7). 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 11. 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 3: Outcome of the expert judgement related to the criteria of Section 1 of Annex IV (category A of Article 9) for infectious bovine rhinotracheitis (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 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 | Y |
| 2.2 | There be possibilities of airborne or waterborne or vector-borne spread | N |
| 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 | 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 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 | NC |
| 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 | NC |

| | | |
|----------|---|----|
| 5(b)(PI) | The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals | NC |
| 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 4: Outcome of the expert judgement related to the criteria of Section 2 of Annex IV (category B of Article 9) for infectious bovine rhinotracheitis (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 | Y |
| 2.1 | The disease is moderately to highly transmissible | Y |
| 2.2 | There be possibilities of airborne or waterborne or vector-borne spread | N |
| 2.3 | The disease affects single or multiple species | Y |
| 2.4 | The disease may result in high morbidity with in general low mortality | NC |
| 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 | NC |
| 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 | NC |
| 5(b)(PI) | The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals | NC |
| 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 5: Outcome of the expert judgement related to the criteria of Section 3 of Annex IV (category C of Article 9) for infectious bovine rhinotracheitis (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 | Y |
| 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 | NC |
| 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 | NC |
| 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 | NC |
| 5(b)(PI) | The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals | NC |
| 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 6: Outcome of the expert judgement related to the criteria of Section 4 of Annex IV (category D of Article 9) for infectious bovine rhinotracheitis

| 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 7: Outcome of the expert judgement related to the criteria of Section 5 of Annex IV (category E of Article 9) for infectious bovine rhinotracheitis

| 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).

3.1.1. 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 the form of tables (Tables 8, 9, 10 and 11). The proportion of Y, N or 'na' answers are reported, followed by the list of different supporting views for each answer.

Table 8: Outcome of the expert judgement related to criterion 2.4 of Article 9

| Question | Final outcome | Response | | |
|--|---------------|----------|-------|--------|
| | | Y (%) | N (%) | na (%) |
| 2.4(cat.B) The disease may result in high morbidity with in general low mortality | NC | 64 | 0 | 0 |
| 2.4(cat.C) 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 | NC | 36 | | |

NC: non-consensus; number of judges: 11.

Reasoning supporting the judgement

Supporting Yes for 2.4 (cat.B):

- High morbidity (up to 90%) and case-fatality rate ranging from 2% to 8% in naive populations are reported.

Supporting Yes for 2.4 (cat.C):

- Production losses (e.g. milk losses) are often the sole signs of infection observed.

Table 9: Outcome of the expert judgement related to criterion 4(CI) of Article 9

| Question | Final outcome | Response | | |
|--|---------------|----------|-------|--------|
| | | Y (%) | N (%) | na (%) |
| 4(cat. A,B) 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 | NC | 36 | 9 | 0 |
| 4(cat.C) The disease has a significant impact on the economy of the Union, mainly related to its direct impact on certain types of animal production systems | NC | 55 | | |

NC: non-consensus; number of judges: 11.

Reasoning supporting the judgement

Supporting Yes for 4 (cat.A,B):

- The economic impact due to milk production losses can be considered significant at EU level.

Supporting Yes for 4 (cat.C):

- There may be losses for the dairy sector, but only during the clinical period which is relatively short.
- The economic impact cannot be considered significant for the Union as a whole, also considering that vaccination is available and some MSs managed to eradicate or control the disease.
- There is a significant impact on the sector relating to semen collection and artificial insemination.

Table 10: Outcome of the expert judgement related to criterion 5(b)(CI) of Article 9

| Question | Final outcome | Response | | |
|---|---------------|----------|-------|--------|
| | | Y (%) | N (%) | na (%) |
| 5(b) The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals | NC | 9 | 91 | 0 |

NC: no consensus; Number of judges: 11.

Reasoning supporting the judgement

Supporting Yes:

- Morbidity can be 100% and mortality 10%, and while uncomplicated cases of disease last 5–10 days only, about 10% of affected animals may also experience loss of body condition and pneumonia following the acute stage. Even in the acute stage, animal welfare appears to be compromised with fever, respiratory symptoms, fever, drop in milk yield, and ulcerations of the nasal mucosa (Nandi et al., 2009).

Supporting No:

- In endemic situation, which is the case in the largest part of the EU, the impact on animal welfare seems to be not significant.

Table 11: Outcome of the expert judgement related to criterion 5(b)(PI) of Article 9

| Question | Final outcome | Response | | |
|---|---------------|----------|-------|--------|
| | | Y (%) | N (%) | na (%) |
| 5(b) The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals | NC | 82 | 18 | 0 |

NC: non-consensus; number of judges: 11.

Reasoning supporting the judgement

Supporting Yes:

- Clinical signs may vary from inapparent to death, depending on a variety of factors including the strain of virus, with BoHV-1 subtype 1 generally being associated with more severe clinical outcomes.
- The impact on animal welfare could be significant in the case the disease is introduced in free areas.

Supporting No:

- The potential impact on animal welfare in absence of control measures would not be different from the current situation, given the situation of endemicity of the disease.

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

As from the legal text of the AHL, a disease is considered to fit 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 3–7. 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 the assessment is inconclusive if, in case of no 'Y', at least one outcome is 'NC'.

A description of the outcome of the assessment of criteria in Annex IV for IBR for the purpose of categorisation as in Article 9 of the AHL is presented in Table 12.

Table 12: Outcome of the assessment of criteria in Annex IV for IBR for the purpose of categorisation as in Article 9 of the AHL (CI = current impact; PI = potential impact)

| 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 | Y | N | Y | N | N | CI:NC PI:Y | N | NC | N | N |
| B | Y | Y | N | Y | NC | N | CI:NC PI:Y | N | NC | N | N |
| C | Y | Y | Y | Y | NC | N | CI:NC PI:N | N | NC | N | N |
| D | | | | | | Y | | | | | |
| E | | | | | | Y | | | | | |

According to the assessment here performed, IBR complies with the following criteria of the Sections 1 to 5 of Annex IV of the AHL for the application of the disease prevention and control rules referred to in points (a) to (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 IBR complies with criteria 2.1 and 2.3, but not with criteria 1, 2.2 and 2.4. 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 IBR complies with criterion 4, but not with criteria 3, 5a, 5c and 5d and the assessment is inconclusive on compliance with criterion 5b.
- 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 IBR complies with criteria 1, 2.1 and 2.3, but not with criterion 2.2 and the assessment is inconclusive on compliance with criterion 2.4. 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 IBR complies with criterion 4, but not with criteria 3, 5a, 5c and 5d and the assessment is inconclusive on compliance with criterion 5b.
- 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 IBR complies with criteria 1, 2.1, 2.2 and 2.3 and the assessment is inconclusive on compliance with criterion 2.4. 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 IBR does not comply with criteria 3, 4, 5a, 5c and 5d and the assessment is inconclusive on compliance with criterion 5b.
- 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 IBR 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 IBR 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 infectious bovine rhinotracheitis. 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 possible role of biological or mechanical vectors.⁴ According to the mapping, as presented in Table 5, Section 3.2 of the scientific opinion on the ad hoc methodology (EFSA AHAW Panel, 2017), the animal species to be listed for infectious bovine rhinotracheitis according to the criteria of Article 8(3) of the AHL are as displayed in Table 13.

Table 13: Main animal species to be listed for IBR according to criteria of Article 8 (*source*: data reported in Section 3.1.1.1)

| | Order | Family | Genus/species |
|-------------|--------------|-----------|---|
| Susceptible | Artiodactyla | Camelidae | <i>Camelus dromedarius</i> , <i>Camelus bactrianus</i> , <i>Lama glama</i> , <i>Vicugna pacos</i> , <i>Lama guanicoe</i> , <i>Vicugna vicugna</i> |
| | | Cervidae | <i>Cervus elaphus</i> , <i>Capriolus capriolus</i> , <i>Dama dama</i> , <i>Rangifer tarandus</i> , <i>Odocoileus hemionus</i> |
| | | Suidae | <i>Sus scrofa</i> |
| | | Bovidae | <i>Bos taurus</i> , <i>Bubalus bubalis</i> , <i>Capra hircus</i> , <i>Ovis aries</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, IBR 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, IBR meets 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. According to the assessment here performed, it is inconclusive whether IBR complies with the criteria as in Section 3 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in point (c) of

⁴ 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.

Article 9(1) of the AHL. Compliance of infectious bovine rhinotracheitis with the criteria as in Section 3 is dependent on a decision on criterion 2.4.

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 IBR according to Article 8(3) of the AHL are several species belonging to the families Bovidae, Cervidae, Camelidae and Suidae, as reported in Table 14 in Section 3.4 of the present document.

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Abbreviations

| | |
|--------|---|
| AHAW | EFSA Panel on Animal Health and Welfare |
| AHL | Animal Health Law |
| BoHV-1 | bovine herpesvirus-1 |
| BuHV | bubaline herpesvirus |
| CFSPH | Center for Food Security and Public Health |
| CITES | Convention on International Trade in Endangered Species of Wild Fauna and Flora |
| CpHV | caprine herpesvirus |
| CvHV | cervid herpesvirus |
| ELISA | enzyme-linked immunosorbent assay |
| ElkHV | elk herpesvirus |
| IBR | infectious bovine rhinotracheitis |
| ICBA | Individual and Collective Behavioural Aggregation |
| IPB | infectious pustular balanoposthitis |
| IPV | infectious pustular vulvovaginitis |
| IUCN | International Union for Conservation of Nature |
| OIE | World Organization for Animal Health |
| PCR | polymerase chain reaction |
| TCID | tissue culture infectious dose, 50% |
| ToR | Terms of Reference |
| VNT | virus neutralisation test |