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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): antimicrobial-resistant *Brachyspira hyodysenteriae* in swine

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Abstract

Brachyspira hyodysenteriae (*B. hyodysenteriae*) was identified among the most relevant antimicrobial-resistant (AMR) bacteria in the EU for swine in a previous scientific opinion. Thus, it 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 its eligibility to be listed, Annex IV for its categorisation according to disease prevention and control rules as in Article 9, and Article 8 for listing animal species related to the bacterium. The assessment has been performed following a methodology previously published. The outcome is the median of the probability ranges provided by the experts, which indicates whether each criterion is fulfilled (lower bound $\geq 66\%$) or not (upper bound $\leq 33\%$), or whether there is uncertainty about fulfilment. Reasoning points are reported for criteria with uncertain outcome. According to the assessment here performed, it is uncertain whether AMR *B. hyodysenteriae* can be considered eligible to be listed for Union intervention according to Article 5 of the AHL (33–66% probability). According to the criteria in Annex IV, for the purpose of categorisation related to the level of prevention and control as in Article 9 of the AHL, the AHAW Panel concluded that the bacterium does not meet the criteria in Sections 1, 2 and 3 (Categories A, B and C; 1–10%, 10–33% and 10–33% probability of meeting the criteria, respectively) and the AHAW Panel was uncertain whether it meets the criteria in Sections 4 and 5 (Categories D and E, 50–90% and 33–66% probability of meeting the criteria, respectively). The main animal species to be listed for AMR *B. hyodysenteriae* according to Article 8 criteria are pigs and some species of birds, such as chickens and ducks.

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1. Introduction

The European Food Safety Authority (EFSA) received a mandate from the European Commission to investigate the global state of play as regards antimicrobial-resistant (AMR) animal pathogens that cause transmissible animal diseases (Term of Reference (ToR) 1), to identify the most relevant AMR bacteria in the European Union (EU) (first part of ToR 2), to summarise the existing or potential animal health impact of those identified bacteria in the EU (second part of ToR 2) and to perform the assessment of those bacteria to be listed and categorised according to the criteria in Article 5, Annex IV according to Article 9 and Article 8 within the Regulation (EU) No 2016/429¹ on transmissible animal diseases ('Animal Health Law') (ToR 3).

The global state of play for AMR animal pathogens that cause transmissible animal diseases (ToR 1) and the results of the assessment of the most relevant AMR bacteria in the EU (first part of ToR 2) for swine were published in a separate EFSA scientific opinion (EFSA AHAW Panel, 2021a).

According to the results of the assessment already conducted, *Brachyspira hyodysenteriae* (*B. hyodysenteriae*) was identified among the most relevant AMR bacteria in the EU for swine due to the perceived importance of use of antimicrobials to control *B. hyodysenteriae* infections (no vaccines currently available in spite of its importance), coupled with the limited number of antimicrobials licensed for use to control *Brachyspira* infections in pigs (EFSA AHAW Panel, 2021a).

This scientific opinion presents the results of the assessment on AMR *B. hyodysenteriae* in swine on its eligibility to be listed and categorised within the AHL framework. Special focus is placed on the animal health impact of AMR *B. hyodysenteriae* in swine in the EU, which is also summarised here as part of the assessment conducted according to the profile of the infection and its impact on animal welfare (Article 7).

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

The background and ToRs as provided by the European Commission for the present document are reported in Sections 1.1 and 1.2 of the scientific opinion on the ad hoc method to be followed for the assessment of animal diseases caused by bacteria resistant to antimicrobials within the AHL framework (EFSA AHAW Panel, 2021b).

1.2. Interpretation of the Terms of Reference

The interpretation of the ToRs is as in Sections 1.2.3 and 1.3.3 of the scientific opinion on the ad hoc method to be followed for the assessment of animal diseases caused by bacteria resistant to antimicrobials within the AHL framework (EFSA AHAW Panel, 2021b).

The present document reports the results of the assessment on AMR *B. hyodysenteriae* in swine according to the criteria of the AHL articles as follows:

- Article 7: AMR *B. hyodysenteriae* infection profile and impacts;
- Article 5: eligibility of AMR *B. hyodysenteriae* infection to be listed;
- Article 9: categorisation of AMR *B. hyodysenteriae* infection according to disease prevention and control rules as in Annex IV;
- Article 8: list of animal species (also apart from swine) related to AMR *B. hyodysenteriae* infection.

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 listing and categorisation of animal diseases within the AHL framework (EFSA AHAW Panel, 2017).

In order to take into account the specifics related to animal diseases caused by bacteria resistant to antimicrobials, the term 'disease' as in the AHL was interpreted in a broader sense, referring also to colonisation by commensal and potentially opportunistic bacteria, and the general presence of the identified AMR bacteria in the EU, depending on each criterion.

The following assessment was performed by the EFSA Panel on Animal Health and Welfare (AHAW) based on the information collected and compiled in form of a fact sheet as in Section 3.1 of the

¹ Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law'). OJ L 84, 31.3.2016, p. 1–208.

present document. The outcome is the median of the probability ranges provided by the experts, which are accompanied by verbal interpretations as spelled out in Table 1.

Table 1: Approximate probability scale recommended for harmonised use in EFSA (EFSA Scientific Committee, 2018)

Probability term	Subjective probability range
Almost certain	99–100%
Extremely likely	95–99%
Very likely	90–95%
Likely	66–90%
About as likely as not	33–66%
Unlikely	10–33%
Very unlikely	5–10%
Extremely unlikely	1–5%
Almost impossible	0–1%

3. Assessment

3.1. Assessment of AMR *Brachyspira hyodysenteriae* according to Article 7 criteria of the AHL

3.1.1. Article 7(a) Disease profile

This fact sheet concerns *Brachyspira hyodysenteriae*, the main cause of swine dysentery (SD), and when available and relevant, the data presented include also information on resistance to macrolides, pleuromutilins (such as tiamulin and valnemulin) and tetracyclines in this species. The reason for choosing these drugs is that they are the main recommended antimicrobial classes for treatment of swine dysentery caused by this bacterium, which can only be treated with a limited number of antimicrobials. Apart from the antimicrobial resistance data in this fact sheet, systematically collected antimicrobial resistance data on clinical *B. hyodysenteriae* isolates can be retrieved from a recent EFSA scientific opinion (EFSA AHAW Panel, 2021a).

SD is most commonly caused by the Gram-negative anaerobic spirochete *B. hyodysenteriae*, previously known as *Treponema hyodysenteriae* and *Serpulina hyodysenteriae*. Alternatively, SD may be caused by the related bacteria *Brachyspira hamptonii* and *Brachyspira suanatina*, but these species have not been described further in this fact sheet. SD is a disease of the large intestine in pigs, most commonly occurring during the growth and finishing periods, hence between 8 and 26 weeks of age (Burrough, 2017). *B. hyodysenteriae* is transmitted to pigs by ingestion. Clinical signs can develop 5–21 days after infection (Burrough, 2017). The disease is characterised by various degrees of mucoid and haemorrhagic diarrhoea, fever, dehydration, loss of body condition, depression and apathy, and sometimes disease is followed by death (Bellgard et al., 2009). Once a pig herd is infected with *B. hyodysenteriae*, elimination of the pathogen is extremely difficult therefore often resulting in long-term losses and continued use of antimicrobials (Neiryck et al., 2020). As described in the following sections, several other animal species have been reported to be subclinical carriers of *B. hyodysenteriae*.

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/order)

Compared to pigs, relatively scarce information is available on occurrence, prevalence and quantity of *B. hyodysenteriae* in wildlife species. Most studies have been concerned with wildlife species as a reservoir for *B. hyodysenteriae* in relation to transmission to domesticated pigs (Desrosiers, 2011; Alvarez-Ordóñez et al., 2013; Zeeh et al., 2018). From these studies, it is not always evident whether the wildlife species are susceptible to disease caused by the organism or are merely to be considered as non-affected carriers of potential risk to pig production. Feral pig (*Sus scrofa*), rat (*Rattus rattus* and *Rattus norvegicus*), mouse (*Mus musculus*), common/European sterling (*Sturnus vulgaris*), crow

(*Corvus corone*) and mallard (*Anas platyrhynchos*) have all been identified as potential carriers of *B. hyodysenteriae* (Hampson et al., 1991; Jansson et al., 2001, 2004, 2011; Phillips et al., 2009; Backhans et al., 2010; Pearson et al., 2016; Zeeh et al., 2018). *B. hyodysenteriae* has also been isolated from cockroaches (*Blattodea*) and flies (*Musca domestica*) (Blunt and McOrist, 2009; Gallie et al., 2009).

Clinical manifestations, likely associated with the presence of *B. hyodysenteriae* in intestinal content, have been reported in common rheas (*Rhea americana*) (Buckles et al., 1997; McFadzean et al., 2021).

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

Swine is by far the domestic species most commonly clinically affected by *B. hyodysenteriae*. Despite the fact that *B. hyodysenteriae* is frequently isolated from domestic birds, the clinical significance of the bacterium in birds and other non-porcine domestic animals remains somewhat unclear (Alvarez-Ordóñez et al., 2013). Nevertheless, clinical manifestations likely associated with the presence of *B. hyodysenteriae* in intestinal content have been reported in commercial laying hens (Feberwee et al., 2008).

Dogs (*Canis lupus familiaris*) might also become clinically affected, since one report associated the clinical manifestation of *B. hyodysenteriae* diarrhoea with the dog's consumption of faeces from pigs with dysentery (Songer et al., 1978b).

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

Experimental challenge of mallards (*Anas platyrhynchos*) with *B. hyodysenteriae* has been attempted (Jansson et al., 2009). Results showed a colonisation rather than infection of birds, and colonisation only occurred with a strain of mallard origin, not with a strain of porcine origin. Joens (1980) inoculated mice intragastrically with *B. hyodysenteriae*. Mice became colonised with the bacterium but failed to develop disease. Healthy pigs exposed to faeces of these mice became colonised with *B. hyodysenteriae* within 5–17 days and developed SD within 11–13 days, thus suggesting that rodents in the field may be a reservoir host and may also be involved in spreading swine dysentery.

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

Pigs are the primary susceptible domestic species, and experimental infections with *B. hyodysenteriae* have been induced on multiple occasions in different age groups including only 2-week-old piglets (e.g. Eriksen and Andersen, 1970; Kinyon et al., 1977; Leser et al., 2000). However, chicks have also been used as models of disease for this bacterium. Trott and Hampson (1998) in fact induced histological lesions in the intestine and reduced growth rate following oral inoculation of 1-day-old specific pathogen-free chicks.

Reservoir animal species

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

Apart from pigs, farmed mallards appear to constitute the most important domestic reservoir (with no clinical affection) (Jansson et al., 2004).

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

This information is included under Parameter 1 of this section.

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

Morbidity

Parameter 1 – Prevalence/incidence

Although SD occurs globally, relatively few studies have investigated prevalence and epidemiology of the disease (Alvarez-Ordóñez et al., 2013). The lack of data may also be influenced by the difficulty of the laboratory diagnosis of the bacterium. The reported prevalence of *B. hyodysenteriae* has ranged from 0% to near 40% (Fellström et al., 1996; Møller et al., 1998; Stege et al., 2000; Suh and Song, 2005; Carvajal et al., 2006), but it should be noted that reported prevalence in the different studies is not always comparable. For example, Stege et al. (2000) found 2.8% of 79 randomly selected farms

(with no information on occurrence of diarrhoea) positive for *B. hyodysenteriae* when culturing 20 faecal samples per farm. Carvajal et al. (2006) found 32.1% of 421 pig farms positive for the agent, but samples were taken from pigs (5–20 per farm) with clinical signs such as diarrhoea or from pigs with decreased growth rate. A US study by Duff et al. (2014) estimated in one endemically SD-infected farm the prevalence of carriage in sows and suckling pigs at different time points. The proportion of sows positive for *B. hyodysenteriae* ranged from 0% to 5% with an overall prevalence of 1.04%. In suckling piglets, the proportion ranged from 0% to 5% with an overall prevalence of 1.88%. The same study found 0–1.33% of sows from five endemically infected breeding farms to be positive for *B. hyodysenteriae*. An earlier study by Høgh and Knox (1976) reported that *B. hyodysenteriae* could be isolated from 12 of 543 sows (2.2%) and 136 of 680 weaned pigs (20.0%) from non-clinical faecal samples in 26 Danish herds.

Apart from variations in study design, prevalence can be influenced by the use of different diagnostic methods, feeding regimes, housing, management, etc. (Johnston et al., 2001; Jacobson et al., 2005). The incidence of SD within farms likely varies a lot, but has not been systematically assessed.

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

It has been reported that the morbidity can approach 90% (Gelberg, 2017). However, case-morbidity rates for *B. hyodysenteriae* may vary considerably between farms, as clinical disease manifestations in infected individuals depend on several other factors, including stress (Moreng et al., 1980), the animals' age (Olson, 1974), acid secretion in the stomach (Savage, 1980), differences in the dose of the infectious agent, diet and *B. hyodysenteriae* virulence properties (Kinyon et al., 1980; Hampson et al., 1992). Likely, immunity following previous exposure to the bacterium also influences case morbidity.

Mortality

Parameter 3 – Case-fatality rate

Severity of disease can vary substantially between farms. Case-fatality rates of up to 50–90% can be seen among pigs with severe haemorrhagic diarrhoea (Alvarez-Ordóñez et al., 2013). The highest mortality is observed in naïve flocks following exposure to infective animals. It is unknown if antimicrobial resistance contributes to increase case-fatality rate or not.

In infected rheas, mortality rates during disease outbreaks have been reported to range from 25% to 80% (Sagartz et al., 1992).

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

Parameter 1 – Report of zoonotic human cases (anywhere)

Whereas zoonotic transfer of *Brachyspira pilosicoli* isolates has been reported to be likely to occur after exposure to infected animals, their faeces or contaminated water (Hampson et al., 2006), reports on zoonotic human cases of *B. hyodysenteriae* appear not to exist (Norris, 2019).

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

Antimicrobial treatment constitutes an important tool to control outbreaks of SD. Pleuromutilins like tiamulin and valnemulin are the most widely used antibiotics for treatment of SD, due to efficacy towards *B. hyodysenteriae* and relatively short withdrawal periods (van Duijkeren et al., 2014). Treatment with antimicrobials other than pleuromutilins is generally limited to the macrolides tylosin and tylvalosin, and lincomycin (a lincosamide), although off-label use of other antibiotics (e.g. doxycycline) may take place under the cascade system, which allows veterinarians to treat with an alternative product when there is no other appropriate authorised veterinary medicine available (Card et al., 2018).

Resistance to pleuromutilins in *B. hyodysenteriae* can be due to different point mutations in the 23S rRNA gene and on the ribosomal protein L3 coding sequence (Hillen et al., 2014). More recently, a tiamulin-valnemulin resistance gene named *tva(A)* has been identified (Card et al., 2018). Cross-resistance to the lincosamide lincomycin and the macrolides tylosin and tylvalosin can be attributed to mutations in the V domain of the 23S rRNA gene (Karlsson et al., 1999). In addition, a specific transposon-associated lincosamide resistance gene, *Inu(C)* has been detected recently

(De Luca et al., 2018). Resistance to doxycycline can be linked to a mutation in the 16S rRNA gene (Pringle et al., 2007).

It is generally agreed that levels of antimicrobial resistance are on the rise in *B. hyodysenteriae*. A thorough evaluation of antimicrobial resistance in *B. hyodysenteriae* at a global scale was published recently by Hampson et al. (2019). In the following, a subset of European studies with antimicrobial resistance data are described – when possible with the focus of highlighting temporal trends of antimicrobial resistance. It should be noted that proportions of resistance reported here are not necessarily comparable between studies, as different breakpoints for data interpretation may have been used. This is due to the lack of internationally recognised clinical breakpoints for *B. hyodysenteriae*.

In a recent German study, the proportion of resistance to pleuromutilins in 116 porcine clinical *B. hyodysenteriae* isolates obtained between 1990 and 2016 was 40.9%, but ranged from 0% to 85.7% depending on the sequence type assessed (Joerling et al., 2018). The study confirmed trends of increasing resistance to pleuromutilins reported in previous German studies on *B. hyodysenteriae* (Rohde et al., 2004; Herbst et al., 2014).

In a Belgian study, proportions of resistance in 30 clinical isolates collected between 2010 and 2015 to tiamulin, valnemulin, tylosin, tylvalosin, lincomycin and doxycycline were 53%, 57%, 80%, 70%, 83% and 87%, respectively (Mahu et al., 2017). Tiamulin resistance was observed in 54.3% of 108 Italian isolates obtained from SD between 2002 and 2012, and the authors reported a significant trend in the reduction of susceptibility over time (Rugna et al., 2015). In Sweden, Pringle et al. (2012) reported that minimum inhibitory concentration (MIC) values for tiamulin had gradually increased from 1990 to 2003, whereas levels had ceased afterwards. The authors explained that this cease was likely due to a reduction in tiamulin use following the launch of a national control programme in the year 2000, during which nucleus and multiplying herds were certified as free of SD by going through a sampling and observation period of 6 months. A targeted eradication programme would then be launched if SD were detected. More recent data from the Swedish national surveillance programme on antimicrobial resistance indicates that, for the first time, isolates with tiamulin MICs above the clinical breakpoint (> 2 µg/mL) were detected during 2016, and that therapeutic failure also was observed in that year (SVARM-Swedres, 2019). However, it was not clearly stated whether treatment failure was linked to those resistant isolates. A Polish study with 21 clinical *B. hyodysenteriae* isolates collected between 2006 and 2010 did not find resistance to pleuromutilins, whereas all isolates were resistant to tylosin, and 91% of isolates displayed reduced susceptibility to doxycycline (Zmudzki et al., 2012). In the Czech Republic, 202 *B. hyodysenteriae* isolates from the period 1997 to 2006 were tested for susceptibility to tylosin, lincomycin, tylvalosin, chlortetracycline, tiamulin and valnemulin. The authors reported increasing MICs to all tested antibiotics, and for tiamulin, the proportion of resistance increased from 22.2% in 2000 to 42.8% in 2005–2006 (Prášek et al., 2014). Hidalgo et al. (2011) reported substantially increasing levels of resistance to pleuromutilins, as MIC₅₀ values for tiamulin and valnemulin had increased at least fourfold when comparing isolates from 2008 to 2009 to isolates from 2000 to 2007. In the same period, levels of resistance to lincomycin and tylosin had remained stable.

Importantly, two studies provided typing-based evidence that *B. hyodysenteriae* clones, including tiamulin-resistant variants, appear to have spread within and between countries in Europe, possibly due to subclinically infected pigs being transported from breeding to production herds (Hidalgo et al., 2010; Rugna et al., 2015).

As mentioned above, further details on antimicrobial resistance in porcine *B. hyodysenteriae* isolates can be found in Hampson et al. (2019), and antimicrobial resistance data are also available in the recent EFSA scientific opinion (EFSA AHAW Panel, 2021a).

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

Asymptomatic carriers can be considered as persistent sources for transfer of the bacteria and potentially SD to other animals. Duration of the infectious period in animals affected by SD may exceed the duration of disease. For example, in a study of pigs convalescent from experimentally induced SD, *B. hyodysenteriae* was shed for up to 82 days after the last clinical evidence of disease (Fisher and Olander, 1981).

Parameter 2 – Presence and duration of latent infection period

Jacobson et al. (2004) inoculated weaners experimentally with *B. hyodysenteriae*. All pigs started shedding the bacterium 2 days post-inoculation and clinical signs developed 5–10 days post-inoculation. In other words, pigs may start shedding *B. hyodysenteriae* already before they develop clinical signs of SD, at least in experimental settings. As this study represents limited data under experimental conditions, it is likely that the latent infection period would be different from this study under different field conditions.

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

It is unknown exactly how long pigs may be healthy carriers of *B. hyodysenteriae*, but asymptomatic carriage appears to be common. For example, a recent study showed that six out of 18 pig herds in Australia with no clinical signs of SD were culture-positive for the bacterium (Hampson et al., 2016). A similar proportion of asymptomatic carriage (35 of 102 farms) was suspected in an earlier Australian study (Mhoma et al., 1992), but that study was based on serology, hence it could not be excluded that farms had been previously exposed to *B. hyodysenteriae* and therefore not subclinically infected at the time of sampling. Another study used a *B. hyodysenteriae* isolate obtained from healthy pigs in an experimental pig model resulting in development of SD (Hampson et al., 1992). This result suggests that not only strain virulence but also factors related to pigs or farms may be determining factors for when clinical signs of SD develop. In that regard, it has been shown that feed composition seems an important determining factor for development of SD (Burroughs, 2017), likely due to an influence on gut bacteria, which may act synergistically or antagonistically with *B. hyodysenteriae*.

Environment

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

Boye et al. (2001) tested survival of *B. hyodysenteriae* at 10°C in soil and faeces. The bacterium survived in soil for 10 days, whereas survival increased to 112 days in pure faeces. Another study showed that the bacterium may survive for up to 48 days in dysenteric faeces kept between 0°C and 10°C, but survival was much shorter when the same experiment was carried out at 25°C (7 days) and 37°C (< 24 h) (Chia and Taylor, 1978). Olson (1995) showed that after removal of *B. hyodysenteriae*-infected pigs from a contaminated sewage lagoon, the lagoon effluent remained for 5–6 days a source of *B. hyodysenteriae* infection in healthy pigs when the lagoon was used as the sole source of drinking water.

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)

Carrier animals without clinical signs are epidemiologically important, as shown by Songer (1978a) who demonstrated that a small number of asymptomatic carrier pigs (sows or piglets) can transmit *B. hyodysenteriae* to susceptible animals, thereby maintaining the infection within herds or recipient herds. This risk is particularly important when introducing new animals into previously uninfected herds (Desrosiers, 2011), and even more so if carrier animals shed pleuromutilin-resistant clones (Hidalgo et al., 2010; Hampson et al., 2015; Rugna et al., 2015).

B. hyodysenteriae is transmitted horizontally by uptake of contaminated faeces. Furthermore, transmission via vectors appears to be possible, since typing studies using pulsed-field gel electrophoresis have linked strains detected in infected pigs with those isolated from mice and rats from the same farm (Trott et al., 1996; Backhans et al., 2011). Other wild animal species (e.g. cockroach, feral pigs, mallards) can also be carriers of *B. hyodysenteriae* and may thus potentially act as vectors for introducing the bacterium into pig farms.

Once a pig herd is infected with *B. hyodysenteriae*, elimination of the pathogen is extremely difficult therefore often resulting in long-term losses and continued use of antimicrobials (Neiryck et al., 2020). Transmission from carrier sows to their offspring appears to be possible, most likely by faecal shedding followed by piglets ingesting faeces of the sow or fomites contaminated with faeces.

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

Not applicable, since zoonotic transmission has not been demonstrated.

Speed of transmission

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

There is no evidence of transmission of *B. hyodysenteriae* between animals and humans. The incidence between animals is unknown.

Parameter 4 – Transmission rate (β) (from R0 and infectious period) between animals and, when relevant, between animals and humans

No information is available on the transmission rate.

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

SD is considered endemic in most parts of the world (Burrough, 2017); hence, it can be assumed that the disease is endemic in all Member States.

Risk of introduction

B. hyodysenteriae has a ubiquitous occurrence. Nevertheless, it should be noted that new clones may be introduced into countries following trade and transport of pigs. As stated above (Section 3.1.1.4), Rugna et al. (2015) showed that this was likely the case for certain clones, e.g. ST52, which is present in both Italy, Belgium, Germany and Spain. Both this and other internationally disseminated clones are known to sometimes display reduced susceptibility to pleuromutilins (Hidalgo et al., 2010; Rugna et al., 2015). Also, it cannot be excluded that certain clones (including clones resistant to antibiotics) are transported across borders with migratory birds or other wild animals.

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

Diagnostic tools

Parameter 1 – Existence of diagnostic tools

Diagnosis of SD relies on a combination of approaches, including evaluation of clinical signs, evaluation of gross lesions in the gut (haemorrhagic typhlocolitis with thickened intestinal wall is characteristic of SD) and detection of the infectious agent (Burrough, 2017). Detection of *B. hyodysenteriae* can be done in various ways, e.g. by culture of faecal or colonic tissue. The bacterium is slow-growing; hence, 6–9 days of anaerobic culture is typically required before characteristic haemolytic colonies appear. These can be identified using either biochemical testing, polymerase chain reaction (PCR) or matrix-assisted laser desorption ionisation–time-of-flight mass spectrometry (MALDI-TOF MS). PCR may also be applied directly on faecal material instead of colonies appearing from culture. The bacterium can also be detected by other means, e.g. by fluorescent in situ hybridisation (FISH) of colonic tissue using probes specific for *B. hyodysenteriae* (Wilberts et al., 2015), or by the less specific silver staining of tissue, thereby visualising the characteristic spiral-shaped bacterium in intestinal tissue.

Serology, e.g. using enzyme-linked immunosorbent assays (ELISAs) can be used to identify if pigs have been exposed to the bacterium (Hampson et al., 2016). Although this is not useful during SD outbreaks, it may be implemented in abattoirs for monitoring of prior infection or asymptomatic carriage. Especially asymptomatic carriage may otherwise go undetected due to (i) reluctance to screen healthy animals in farms or (ii) false-negative results using methods less likely than serology to capture low-level shedding of the bacterium (e.g. PCR on faeces or colonic tissue).

Susceptibility to antibiotics can be tested by determination of the MIC using broth or agar dilution. In the lack of internationally recognised breakpoints for interpretation of results, it seems that most recent studies have adapted the epidemiological cut-offs (ECOFFs) proposed by Pringle et al. (2012).

Parameter 2 – Existence of control tools

There are several tools available to control SD. Yet none of them are fully effective and eradicating an SD infection from a pig farm requires a long and expensive effort, often with disappointing results (Neiryneck et al., 2020). Antimicrobial treatment using pleuromutilins or alternative antimicrobial agents may be used once the infection is diagnosed, and treated animals should be moved to a segregated clean environment when possible. In addition, there are several ways to prevent the infection from entering farms or from spreading within farms. These include biosecurity and husbandry measures such as rodent control and isolation from waterfowl, thorough cleaning and disinfection procedures, restricting access of vehicles and persons, hygiene measures for farm personnel and visitors (e.g. proper changing facilities), use of quarantine for newly purchased animals, avoiding mixing of age groups, reduction of stress in the environment (e.g. by ensuring adequate temperature and ventilation, reducing stocking density and minimising movement and handling of pigs), screening to detect subclinically infected breeding stock, use of all-in–all-out procedures and potentially the use of autogenous vaccines. A partial or total depopulation strategy is also possible as described later under Parameter 1 in Section 3.1.4.4.

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 actual extent or level of SD in individual Member States is unknown, since no systematic surveillance takes place in Member States. Also, levels of antimicrobial resistance are to a large extent unknown on a country-wide level. Instead, sporadic reports with antimicrobial resistance data are available as elaborated in Section 3.1.1.4.

The loss of production due to the disease

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

It is difficult to give precise estimates for production and economic losses associated with SD, since (i) data are scarce with most studies only referring to ‘major losses’, (ii) the few studies available are not necessarily representative across countries, e.g. due to different production costs and different ways of producing pigs and (iii) studies calculate production losses in different ways.

According to Dufresne (2006), a previous study determined that SD resulted in up to 17% decrease in average daily gain (ADG), and dramatically decreased (3–10%) feed efficiency. A study from Hungary estimated that effective metaphylactic antibiotic treatment of farms with SD would result in 3.1% increase in ADG, 28.5% decrease in mortality rate and 0.33% reduction in feed conversion rate in the finishing phase. These estimates are averages compared to herds without SD control (Ózsvári, 2017).

Other studies do not refer specifically to production losses or refer only to the economy of production losses. These studies are referred to and elaborated under Parameter 1 in Section 3.1.5.1.

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

B. hyodysenteriae is not reported to colonise or cause disease in humans (Norris, 2019).

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

Mostly, pigs in the growing and finishing period (8–26 weeks old) are affected by the disease. The severity of disease may vary from mild diarrhoea to more severe clinical signs. Initially, pigs typically exhibit anorexia and passage of soft faeces. If the disease progresses, diarrhoea becomes more pronounced with watery stools containing blood and mucufibrinous exudate. Depending on the severity of the infection, SD can be accompanied by dehydration, weight loss, depression, fever and sometimes death. The disease progresses through groups of pigs, sometimes with high morbidity rates (see Parameter 2 in Section 3.1.1.2) and may occur in a cyclic manner within farms (3- to 4-week intervals) if left untreated (Alvarez-Ordóñez et al., 2013). Clinical signs can develop 5–21 days after infection (Burrough, 2017).

In theory, antimicrobial resistance may contribute to treatment failure, but to the authors' knowledge, no studies have proven a link between microbiological antimicrobial resistance in *B. hyodysenteriae* and reduced efficacy of SD treatment.

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

The greater (also referred to as 'common') rhea (*Rhea americana*) is listed as a near threatened species on the IUCN list.

Parameter 2 – Mortality in wild species

In infected rheas, mortality rates during disease outbreaks have been reported to range from 25% to 80% (Sagartz et al., 1992). Mortality for other wild species has not been reported.

Environment

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

As stated above (Section 3.1.1.5), *B. hyodysenteriae* is able to survive in farm environments for considerable periods of time, depending on the presence of organic matter and the environmental temperature. For example, the bacterium can survive in soil held at 10°C for 10 days, and in faeces for 112 days at the same temperature.

It is possible that the length of survival in the environment impacts transmission to wildlife, but as stated earlier (Parameter 3 in Section 3.1.1.2), it does not appear as if wildlife is particularly susceptible to severe disease, with the exception of the common rhea.

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

Not listed.

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

Not listed.

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

Not listed.

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 tools, OIE-certified

Despite the importance of SD, a gold standard diagnostic test is not available (Hartnack et al., 2014). Diagnostic approaches for SD should be sufficiently broad to detect all potentially pathogenic spirochaete species causing the disease, even at low counts.

Effectiveness

Parameter 2 – Sensitivity and specificity of diagnostic tests

A large study comprising 239 samples from 103 pig herds, and using Bayesian latent class modelling (a statistical method applicable for situations of test evaluation where no gold standard test is readily available), estimated diagnostic sensitivity and specificity of a *B. hyodysenteriae* PCR on faecal material (95% CI) to be 73.2% (62.3; 82.9) and 96.2% (90.9; 99.8), respectively. In that study, bacterial culture was superior in terms of sensitivity (96.2% (90.9; 99.8)), whereas specificity of culture was assumed to be 100% (Hartnack et al., 2014). An earlier study compared sensitivity of six different agar media to recover *B. hyodysenteriae* from pigs experimentally inoculated with the

bacterium. The best medium had 89.9% sensitivity, meaning *B. hyodysenteriae* grew on this medium nine out of 10 times the bacterium was detected in any of the six media tested (Achacha and Messier, 1992). Positive predictive value and negative predictive value were not assessed in any of these studies.

It has been stated that selective anaerobic culture remains important, as it allows growth of not only *B. hyodysenteriae* but also other spirochaete species that may cause SD, and it has higher sensitivity than most molecular tests (Hampson and Burrough, 2019). Indeed, culture has on multiple occasions proven superior in terms of ability to detect low concentrations of *B. hyodysenteriae* when compared to qPCR (Burrough et al., 2012; Patterson et al., 2013; Wilberts et al., 2015) and FISH (Wilberts et al., 2015). This property is particularly important when it comes to surveillance of subclinically infected animals, which tend to shed low concentrations of the bacterium intermittently (Duff et al., 2014). Importantly, the time from sampling to culture should be limited as much as possible to prevent bacteria from dying. As stated earlier (Parameter 1 in Section 3.1.1.8), serological testing by ELISA may also be useful for surveillance purposes, e.g. for screening *B. hyodysenteriae* carriers at abattoirs.

Feasibility

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

Faecal samples or colonic mucosa are the most appropriate samples for detection of *B. hyodysenteriae*, although oral fluids may also be considered for penwise screening of active disease (Hampson and Burrough, 2019). Serum or meat juice (at abattoirs) may be used for serological tests.

3.1.4.2. Article 7(d)(ii) Vaccination

No commercial vaccines exist for control of SD.

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

Availability

Parameter 1 – Types of drugs available on the market

Antimicrobial treatment constitutes an important tool to control outbreaks of SD. Pleuromutilins like tiamulin and valnemulin are the most widely used antibiotics for treatment of SD, due to efficacy towards *B. hyodysenteriae* and relatively short withdrawal periods (van Duijkeren et al., 2014). Treatment with antimicrobials other than pleuromutilins is generally limited to the macrolides tylosin and tylvalosin, and lincomycin (a lincosamide), although off-label use of other antibiotics (e.g. doxycycline) may take place under the cascade system, which allows veterinarians to treat with an alternative product when there is no other appropriate authorised veterinary medicine available (Card et al., 2018).

Parameter 2 – Availability/production capacity (per year)

Antimicrobial drugs for treatment of pig infections are widely available on the market.

Effectiveness

Parameter 3 – Therapeutic effects in the field (effectiveness)

Based on susceptibility data and pharmacokinetic properties, pleuromutilins (tiamulin, valnemulin) are the most suitable antibiotics for treatment of SD, and they are also the most widely recommended and used antibiotics for this disease (Hampson and Burrough, 2019). In an experimental study where pigs were infected with susceptible isolates of *B. hyodysenteriae* or *B. hamptonii*, water medication with tiamulin resolved clinical signs of SD within 24 h, and the inoculated strain was eradicated from faecal samples within 72 h (Wilberts et al., 2014). Macrolides (e.g. tylosin) and lincosamides (e.g. lincomycin) are suitable alternatives for treatment, whereas other potential drugs generally have pharmacokinetic properties resulting in low concentrations in the porcine gut.

Based on the emergence of pleuromutilin resistance in some countries and the indication that tiamulin-resistant *B. hyodysenteriae* clones may easily spread within and across countries, future treatment recommendations may have to be adjusted. This, and the fact that there are not many suitable antimicrobial alternatives for SD are reasons why prevention of infection is key to control the disease.

Feasibility

Parameter 4 – Way of administration

The preferred route of administration of tiamulin is intramuscular or as feed or water additive for flock treatment (Walczak et al., 2017). The intramuscular route is preferred for severely sick animals. Water medication may be preferable to feed medication, since pigs affected by SD may suffer from anorexia, whereas water consumption typically remains at normal levels.

When eradication of SD through medication is aimed for in a pig farm, large numbers of animals (due to the frequent subclinical carrier stage) are to be treated for a long duration (multiple weeks) resulting in excessively high antimicrobial usage with often disappointing results, as the infection may reappear after cessation of the treatments.

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

Availability

Parameter 1 – Available biosecurity measures

It is generally recommended to practice all-in–all-out systems to disrupt infection transmission among production stages and from consecutive reared batches. When stables of all-in–all-out systems are emptied, they should be properly cleaned before inserting new batches. Cleaning should be done with hot water using high pressure, followed by disinfection and proper drying of premises.

Newly acquired pigs, e.g. breeding gilts, should always originate from the same farm, and the health status of that farm should be high, at least at the level of the destination farm and without indications or evidence of SD. Upon arrival, new pigs should undergo quarantine for at least 28 days in facilities isolated from other pigs. Whenever newly introduced pigs are diagnosed positive for SD in the quarantine stable, they should not be introduced in the farm. Vehicles entering farms should be cleaned and disinfected to minimise the risk of acting as fomites for transmission of SD agents (Giacomini et al., 2018). Farm personnel and visitors should be instructed to respect good hygiene practices, e.g. to avoid bringing boots or clothes from other premises and to wash their hands before entering. Also, hygiene precautions should be taken when moving between batches within a farm.

Biosecurity measures also include proper rodent control, as mice and rats may be carriers of *B. hyodysenteriae*. At the same time, wild birds should be prevented from entering buildings, and any water supplies should be protected from faeces of birds and rodents. Dogs and cats should not be allowed to enter stables, and fly and cockroach control is also a potential biosecurity measure.

Apart from the above-mentioned preventative biosecurity measures, more active eradication strategies may be implemented in farms with SD. A recent study by Neiryck et al. (2020) evaluated different, farm-specific eradication strategies in 10 pig farms. Eradication of SD was possible in only four of these farms indicating the difficulty of this process. Two of the successful farms had applied a total depopulation strategy followed by a 3-week stand-empty period. A third farm applied partial depopulation with rooms being empty for 28 days, and the farmer switched to another supplier of breeding gilts. The last successful farm also applied partial depopulation, kept stables empty for 3 weeks and subjected remaining pigs to antimicrobial treatment. All of these successful strategies required long-term efforts and huge investments by the farmer in terms of time and financial resources. In the remaining six farms, programmes based on antimicrobial treatment with depopulation or partial depopulation, but without strictly adhering to all suggested biosecurity measures, were not successful.

Effectiveness

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

The effectiveness of single biosecurity measures can be difficult to evaluate, as most measures represent 'common sense' recommendations. It was, however, clear from the study by Neiryck et al. (2020) that eradication of SD from infected farms is only possible using a multifaceted strategy involving complete or partial depopulation, whereas failure to stick to biosecurity measures (cleaning and disinfection procedures, rodent control, stand-empty period, etc.) is likely to result in failure to eradicate SD.

Feasibility

Parameter 3 – Feasibility of biosecurity measures

All biosecurity measures mentioned above are feasible, although some may be easier and cheaper to implement than others. For example, handwashing and change of boots and clothes are easy measures, whereas switching to an all-in–all-out system requires a new management procedure and sufficient space to be able to keep stables empty for some days between batches of pigs.

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

Availability

Parameter 1 – Available movement restriction measures

In general, avoiding the purchase of breeding animals is the safest option to avoid buying in diseases. Whenever animals are bought, avoiding mixing of animals in farms is a good way to reduce stress and to limit transfer of any infectious agent including *B. hyodysenteriae*. This can be practiced in different ways, e.g. by using an all-in–all-out production system with appropriate cleaning, disinfection and drying of stables between batches. Keeping newly acquired animals in quarantine, as described under Parameter 1 in Section 3.1.4.5 is another way to restrict movement. Finally, pigs with clinical signs of SD should be moved to separate clean pens where the risk of onwards transmission is minimal. Ideally an SD-‘free’ certification should become available to assure that animals acquired from other farms are free of SD.

Effectiveness

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

Controlling SD is very difficult, even when following the above-mentioned restriction movement measures. This is illustrated by Neiryneck et al. (2020) describing that even using a multifaceted strategy involving partial or complete depopulation, a temporary stop for animal purchase as well as all-in–all-out production often fails, especially if biosecurity measures are not followed properly.

Feasibility

Parameter 3 – Feasibility of restriction of animal movement

A recent questionnaire-based survey described that only 10% of 68 surveyed pig herds in Belgium used optimal introduction procedures for newly acquired gilts when considering purchase, quarantine and acclimation (Bernaerdt et al., 2021). Accordingly, such measures may not always be feasible, or at least they would require proper training of staff. All-in–all-out procedures are used already by most farms in Member States, but for remaining farms implementing all-in–all-out may be costly, as it requires additional space and new managerial procedures. The depopulation procedures are extremely costly and therefore not always feasible, especially as they cannot stand alone in attempts to control SD.

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

Availability

Parameter 1 – Available methods for killing animals

Since *B. hyodysenteriae* is not regarded a zoonotic and highly contagious agent, infected pigs can be killed in slaughterhouses and killed animals can enter human consumption if they do not show clinical signs or lesions.

Treatment of severely affected animals is pointless, as there is little or no chance of recovery. Hence, such animals should be euthanised on farm (stunning and bleeding, or lethal injection).

Effectiveness

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

Killing individual animals with clinical signs may be justified for animal welfare reasons, but it would not prevent the infection from spreading from subclinically infected animals. Instead, complete or partial depopulation (together with biosecurity measures) is the only option for reducing/stopping

spread of disease (with variable success as described above), but in most cases animals would not need to be killed within farms or at farm level, since the infective agent is not regarded a zoonotic and highly contagious agent. Instead, pigs would be sent for slaughter, and then – over time – stables would be emptied.

Feasibility

Parameter 3 – Feasibility of killing animals

Killing animals within farms or at farm level is feasible.

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

No special precautions should be taken concerning disposal of carcasses and animal by-products, as *B. hyodysenteriae* is not regarded a zoonotic and highly contagious agent.

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

It is difficult to give precise estimates for production and economic losses associated with SD, since (i) data are scarce with most studies only referring to 'major losses', (ii) the few studies available are not necessarily representative across countries, e.g. due to different production costs and different ways of producing pigs and (iii) studies calculate production losses in different ways.

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

In the USA, it was estimated in 2013 that the total annual financial cost of SD approximates USD168–236 millions. For each pig produced, the cost of medication was estimated at USD11.70–15.50, and in addition to that are losses due to slower growth, decreased feed efficiency and increased mortality (McKean et al., 2013). In the UK, SD has been estimated in 2012 to cost farmers £4–10 per infected pig due to decreased growth rate (Alderton, 2012). Dufresne (2006) quoted three earlier studies (from 1983 to 1990) reporting economic costs from USD2.6–15 per pig produced, but it was not specified exactly what these costs covered. In Sweden, assuming an average of 22 pigs produced per sow per year, SD has been estimated to lead to annual losses of about €133 per sow for fattening pigs affected by clinical SD (Sjölund et al., 2014). That amount comprised of 5-day prolonged rearing time (€55) and 3% mortality (78€). In an early study, Windsor and Simmons (1981) estimated that, 'the hidden costs of swine dysentery in terms of an increased food conversion ratio may be more than four times the cost of medication'.

Costs related to biosecurity are already budgeted in many farms; hence, additional costs to minimise the impact of *B. hyodysenteriae* on animals may not be needed depending on the farm. The actual costs for implementing specific parts of biosecurity (e.g. rodent control) may vary substantially depending on the type and size of a farm and country.

In general, costs for antimicrobial treatment vary depending on the drug used and the length of treatment. Yet, as mentioned before, antimicrobial treatments often have to be maintained for a long period (several weeks) in large groups of animals, which results in an increase of the costs.

Parameter 2 – Cost of eradication (culling, compensation)

As stated under Parameter 1 in Section 3.1.4.4, Neiryneck et al. (2020) evaluated the effect of partial and total depopulation in farms infected with SD. The authors drew the conclusion that total or partial depopulation combined with implementing strict biosecurity measures allowed eradication of *B. hyodysenteriae*. The actual costs of these eradication strategies were not provided, but would necessarily correspond to the cost of depopulation, medical treatment and (if not already present at the farm) continuous implementation of a high-level biosecurity management system. A questionnaire-based survey from Switzerland concluded, based on responses from 68 pig farmers having experience with SD eradication, that costs of eradication varied considerably within the different production types (Cadetg et al., 2019). Likely, this variation was largely due to great differences in duration of partial depopulation (0–519 days) and total depopulation (97–768 days). Even without exact figures for costs, it is clear that full or partial depopulation and repopulation requires substantial efforts from the farmer in terms of time and finances.

Parameter 3 – Cost of surveillance and monitoring

The bacterium/infection is not subject to regular surveillance or monitoring, with the exception of occasional reporting of antimicrobial resistance in national surveillance reports, e.g. SVARM-Swedres (2019). The costs for such surveillance are unknown, but likely very low, as data represent passive surveillance of samples submitted to a diagnostic laboratory.

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

Bans, embargoes or sanctions have not been enforced for this bacterium/disease.

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

Available information on economic losses to individual farms and the pig sector has been provided above under Parameter 1 of this section.

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

The control measures for *B. hyodysenteriae* are all likely to have a societal acceptance. This appears also to be the perception of farmers, since almost half (43%) of 68 surveyed pig farmers having experience with an SD eradication programme, claimed that external pressure (from marketers and the national pig health service association assigning health status of farms) was a driving force to try and eradicate SD (Cadetg et al., 2019). Nevertheless, farmers may be reluctant to devote the resources required for implementation of management practices. Failure to follow biosecurity recommendations concerning acquisition of breeding gilts was recently found to be frequent (Bernaerd et al., 2021), and another study showed that failure to follow recommendations concerning biosecurity likely attributed to failure to eradicate SD in pig farms (Neiryck et al., 2020).

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

Available control measures, if properly implemented, are likely to have positive impact on the welfare of domestic pigs if SD is reduced or eradicated. Antimicrobial resistance in *B. hyodysenteriae* may potentially cause treatment failure in pigs undergoing antimicrobial treatment, but research is needed to confirm this theory.

Parameter 2 – Wildlife depopulation as control measure

With the exception of rodent control, wildlife depopulation has not so far been considered as a control measure for SD.

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)

The extent of antimicrobial treatment for SD in pigs (and consequently spill-over to the environment) is unknown.

Jensen et al. (2003) assessed the toxicity of different antibacterial agents (including tiamulin) to the invertebrate species *Folsomia fimetaria* (Collembola) and *Enchytraeus crypticus* (Enchytraeidae). There was no toxic effect of the antibacterial agents to adults, and effects on their reproduction occurred above the concentrations normally detected in soil or dung. These results suggest a minor impact on tiamulin residuals on the fauna.

Biodiversity

Parameter 1 – Mortality in wild species

Control measures like antimicrobial treatment and keeping biosecurity appropriate are not expected to result in mortality in wild species.

3.2. Assessment of AMR *Brachyspira hyodysenteriae* according to Article 5 criteria of the AHL on its eligibility to be listed

3.2.1. Detailed outcome on Article 5 criteria

In Table 2 and Figure 1, the results of the expert judgement on the Article 5 criteria of the AHL for AMR *B. hyodysenteriae* in swine are presented.

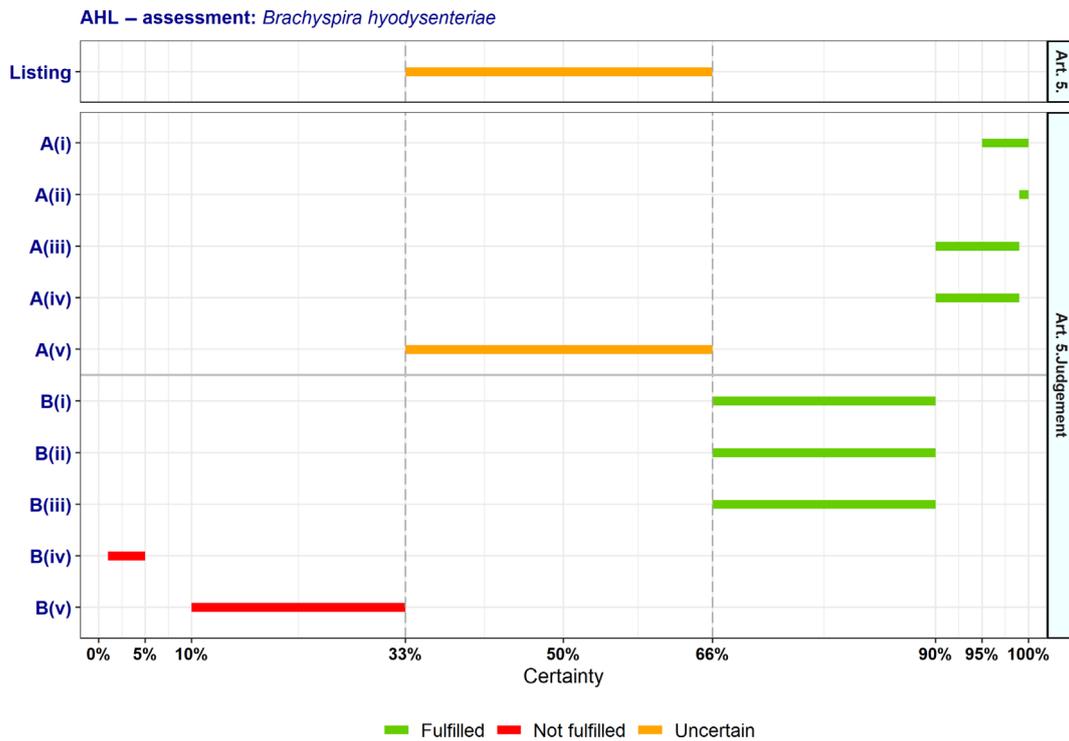
The distribution of the individual answers (probability ranges) provided by each expert for each criterion is reported in Sections A.1 and A.2 of Appendix A.

Table 2: Outcome of the expert judgement on Article 5 criteria

Criteria to be met by the disease: According to the 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		Outcome			
		Median range (%)	Criterion fulfilment	Number of na	Number of experts
A(i)	The disease is transmissible	95–100	Fulfilled	0	14
A(ii)	Animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union	99–100	Fulfilled	0	14
A(iii)	The disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character	90–99	Fulfilled	0	12
A(iv)	Diagnostic tools are available for the disease	90–99	Fulfilled	0	13
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	33–66	Uncertain	0	13
At least one criterion to be met by the disease:					
In addition to the criteria set out above at point 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	66–90	Fulfilled	0	13
B(ii)	The disease agent has developed resistance to treatments which poses a significant danger to public and/or animal health in the Union	66–90	Fulfilled	0	13
B(iii)	The disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union	66–90	Fulfilled	0	13
B(iv)	The disease has the potential to generate a crisis or the disease agent could be used for the purpose of bioterrorism	1–5	Not fulfilled	0	13
B(v)	The disease has or could have a significant negative impact on the environment, including biodiversity, of the Union	10–33	Not fulfilled	0	13

na: not applicable.

In Figure 1, the outcome of the expert judgement is graphically shown together with the estimated overall probability of the AMR bacterium meeting the criteria of Article 5 on its eligibility to be listed.



Listing: The probability of the disease to be listed according to Article 5 criteria of the AHL (overall outcome).

Figure 1: Outcome of the expert judgement on Article 5 criteria and overall probability of AMR *B. hyodysenteriae* on its eligibility to be listed

3.2.1.1. Reasoning for uncertain outcome on Article 5 criteria

Criterion 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)

- Several risk-mitigating measures (e.g. antimicrobial treatment, biosecurity, all-in–all-out, control of entries, depopulation) are available and relatively effective at farm level.
- Risk-mitigating measures may be difficult to implement in certain farms (depending on the farming system – easier in industrialised pig farming) and hence not fully effective.
- In some farms in the EU, *B. hyodysenteriae* may have been eradicated and nowadays only occurs occasionally, but the situation might be different for others. In cases of disease, it can be effectively controlled via depopulation followed by cleaning and disinfection of the affected premises (Neiryck et al., 2020).
- Eradication from pig farms requires long and expensive effort, as persistence of *B. hyodysenteriae* is described as common in infected farms.
- Detection of latent carriers can be a challenge.
- Antimicrobial resistance is widespread in most EU countries and increasing. Without effective antimicrobials, risk mitigation is difficult.
- No surveillance is in place.

3.2.2. Overall outcome on Article 5 criteria

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, a criterion is considered fulfilled when the lower bound of the median range lays above 66%.

According to the results shown in Table 2, AMR *B. hyodysenteriae* complies with four criteria of the first set (A(i)–A(iv)), but there is uncertainty (33–66% probability) on the assessment on compliance

with Criterion A(v). Therefore, it is uncertain whether AMR *B. hyodysenteriae* can be considered eligible to be listed for Union intervention as laid down in Article 5 of the AHL. The estimated overall probability range for the AMR bacterium being eligible to be listed is 33–66% (Figure 1).

3.3. Assessment of AMR *Brachyspira hyodysenteriae* according to criteria in Annex IV for the purpose of categorisation as in Article 9 of the AHL

In Tables 3–7 and related graphs (Figures 2–4), the results of the expert judgement on AMR *B. hyodysenteriae* in swine according to the criteria in Annex IV of the AHL, for the purpose of categorisation as in Article 9, are presented.

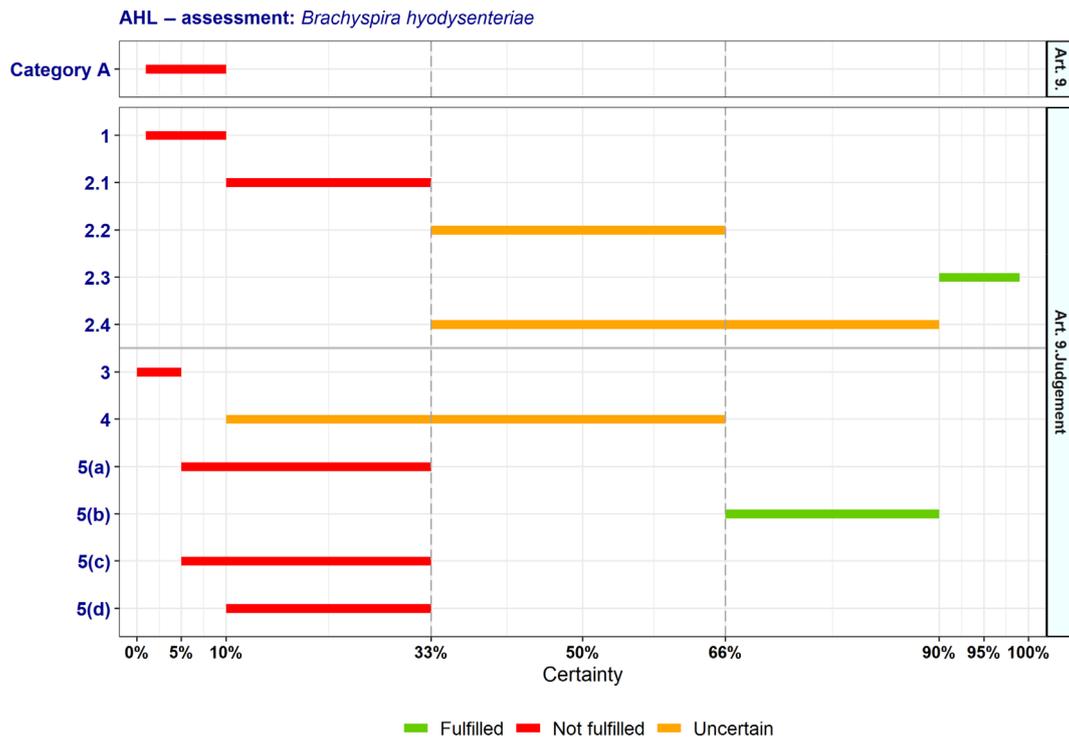
The distribution of the individual answers (probability ranges) provided by each expert for each criterion is reported in Sections B.1 and B.2 of Appendix B.

3.3.1. Detailed outcome on Category A criteria

Table 3: Outcome of the expert judgement related to the criteria of Section 1 of Annex IV (Category A of Article 9)

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		Outcome			
		Median range (%)	Criterion fulfilment	Number of na	Number of experts
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	1–10	Not fulfilled	0	13
2.1	The disease is highly transmissible	10–33	Not fulfilled	0	13
2.2	There are possibilities of airborne or waterborne or vector-borne spread	33–66	Uncertain	0	13
2.3	The disease affects multiple species of kept and wild animals or single species of kept animals of economic importance	90–99	Fulfilled	0	13
2.4	The disease may result in high morbidity and significant mortality rates	33–90	Uncertain	0	13
At least one criterion to be met by the disease:					
In addition to the criteria set out above at point 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 for public health, including epidemic or pandemic potential or possible significant threats to food safety	0–5	Not fulfilled	0	14
4	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	10–66	Uncertain	0	13
5(a)	The disease has a significant impact on society, with in particular an impact on labour markets	5–33	Not fulfilled	0	13
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	66–90	Fulfilled	0	13
5(c)	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	5–33	Not fulfilled	0	13
5(d)	The disease has a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	10–33	Not fulfilled	0	13

na: not applicable.



Category A: the probability of the disease to be categorised according to Section 1 of Annex IV of the AHL (overall outcome).

Figure 2: Outcome of the expert judgement on criteria of Section 1 of Annex IV and overall probability of the AMR bacterium to be fitting in Category A of Article 9

3.3.1.1. Reasoning for uncertain outcome on Category A criteria

Criterion 2.2 (there are possibilities of airborne or waterborne or vector-borne spread)

- There is no evidence of airborne or waterborne spread.
- There is a possible role of vectors (e.g. mice, rats, cockroaches, mallards, feral pigs), but more information is required to differentiate those from reservoirs and to establish their epidemiological importance.
- Transmission of *B. hyodysenteriae* occurs mainly horizontally via fomites.
- The bacterium survives in water and can be transmitted oro-faecally, but it is not truly waterborne because between-farm spread via water is unlikely.

Criterion 2.4 (the disease may result in high morbidity and significant mortality rates)

- Under certain circumstances, but not generally, high morbidity and significant mortality have been reported in individual farms.
- Morbidity can approach 90%.
- Case fatality may reach 50–90% with severe haemorrhagic diarrhoea in naive herds.
- There is no information about the specific role of antimicrobial resistance in increasing mortality compared with non-resistant *B. hyodysenteriae*, but this is likely.
- Prevalence, morbidity and mortality are variable, as presence, transmission and disease occurrence are multifactorial.

Criterion 4 (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):

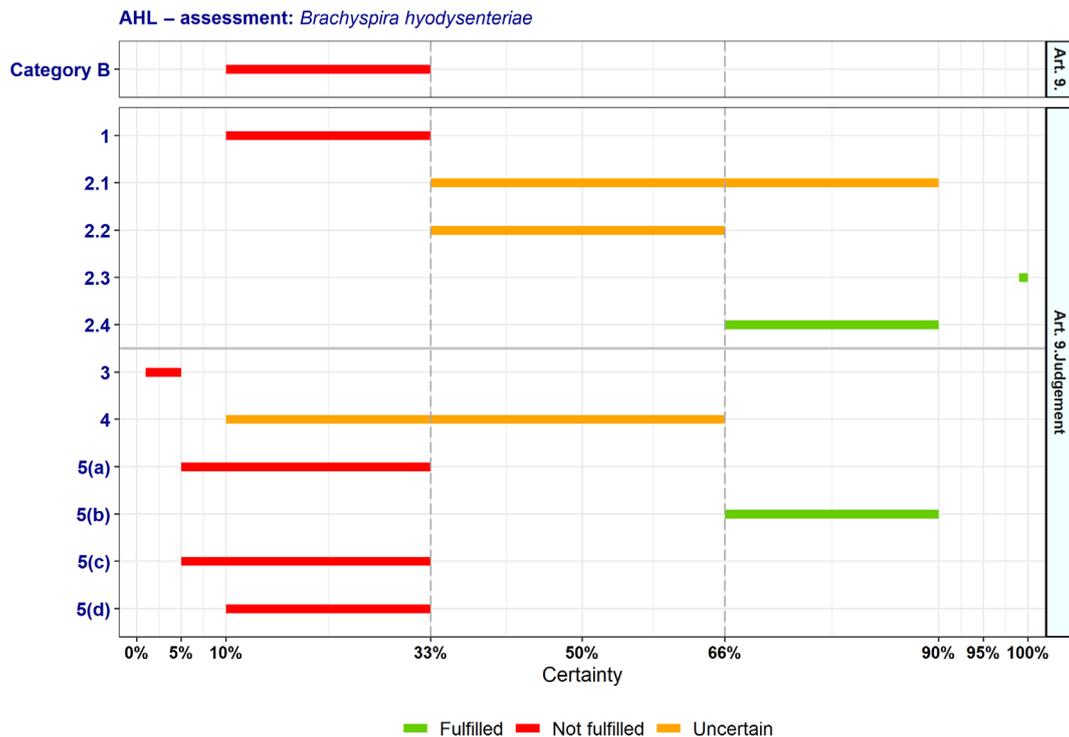
- Data are scarce for EU countries.
- *B. hyodysenteriae* has been described to cause major economic impact in the USA.
- The disease may have significant impact at farm level, but its role at Union level is unclear.
- The bacterium can be managed and even eradicated.

- Currently there is no significant impact, as the description of challenges regarding the treatment of certain strains is relatively new.
- If antimicrobial resistance is increasing, there will potentially be higher costs due to treatment failure. The impact may also be more significant due to increasing morbidity and mortality rates.

Table 4: Outcome of the expert judgement related to the criteria of Section 2 of Annex IV (Category B of Article 9)

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		Outcome			
		Median range (%)	Criterion fulfilment	Number of na	Number of experts
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	10–33	Not fulfilled	0	13
2.1	The disease is moderately to highly transmissible	33–90	Uncertain	0	13
2.2	There are possibilities of airborne or waterborne or vector-borne spread	33–66	Uncertain	0	13
2.3	The disease affects single or multiple species	–	Fulfilled	0	13
2.4	The disease may result in high morbidity with in general low mortality	66–90	Fulfilled	0	12
At least one criterion to be met by the disease: In addition to the criteria set out above at point 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 for public health, including epidemic potential or possible significant threats to food safety	1–5	Not fulfilled	0	14
4	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	10–66	Uncertain	0	13
5(a)	The disease has a significant impact on society, with in particular an impact on labour markets	5–33	Not fulfilled	0	13
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	66–90	Fulfilled	0	13
5(c)	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	5–33	Not fulfilled	0	13
5(d)	The disease has a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	10–33	Not fulfilled	0	13

na: not applicable.



Category B: the probability of the disease to be categorised according to Section 2 of Annex IV of the AHL (overall outcome).

Figure 3: Outcome of the expert judgement on criteria of Section 2 of Annex IV and overall probability of the AMR bacterium to be fitting in Category B of Article 9

3.3.2. Detailed outcome on Category B criteria

3.3.2.1. Reasoning for uncertain outcome on Category B criteria

Criterion 2.1 (the disease is moderately to highly transmissible)

- *B. hyodysenteriae* can be present with high prevalence in some farms, but it does not always result in high prevalence despite a potential ubiquitous presence.
- Carriers may be involved in transmission, and their existence can contribute to within-farm spread.
- There are possibilities of vector-borne transmission (e.g. mice, rats, cockroaches, mallards, feral pigs), but more information is required to differentiate those from reservoirs and to establish their epidemiological importance.
- There are not enough data to assess between-herd transmission.
- The bacterium is highly transmissible, but the disease caused by it is multifactorial.

Criterion 2.2 (the disease may result in high morbidity and significant mortality rates): See above in Section 3.3.1.1.

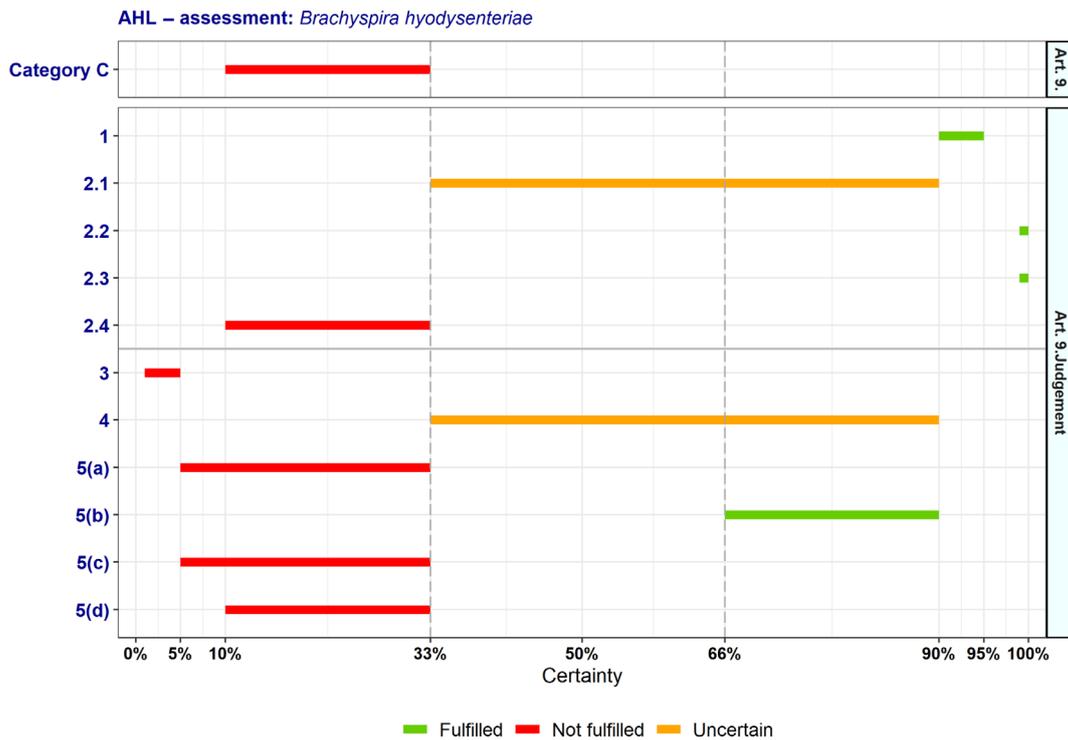
Criterion 4 (the disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals): See above in Section 3.3.1.1.

3.3.3. Detailed outcome on Category C criteria

Table 5: Outcome of the expert judgement related to the criteria of Section 3 of Annex IV (Category C of Article 9)

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		Outcome			
		Median range (%)	Criterion fulfilment	Number of na	Number of experts
1	The disease is present in the whole or part of the Union territory with an endemic character	90–95	Fulfilled	0	14
2.1	The disease is moderately to highly transmissible	33–90	Uncertain	0	13
2.2	The disease is transmitted mainly by direct or indirect transmission	–	Fulfilled	0	13
2.3	The disease affects single or multiple species	–	Fulfilled	0	13
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	10–33	Not fulfilled	0	12
At least one criterion to be met by the disease:					
In addition to the criteria set out above at point 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 for public health or possible significant threats to food safety	1–5	Not fulfilled	0	14
4	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	33–90	Uncertain	0	13
5(a)	The disease has a significant impact on society, with in particular an impact on labour markets	5–33	Not fulfilled	0	13
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	66–90	Fulfilled	0	13
5(c)	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	5–33	Not fulfilled	0	13
5(d)	The disease has a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	10–33	Not fulfilled	0	13

na: not applicable.



Category C: the probability of the disease to be categorised according to Section 3 of Annex IV of the AHL (overall outcome).

Figure 4: Outcome of the expert judgement on criteria of Section 3 of Annex IV and overall probability of the AMR bacterium to be fitting in Category C of Article 9

3.3.3.1. Reasoning for uncertain outcome on Category C criteria

Criterion 2.1 (the disease is moderately to highly transmissible): See above in Section 3.3.2.1.

3.3.4. Detailed outcome on Category D criteria

Table 6: Outcome of the expert judgement related to the criteria of Section 4 of Annex IV (Category D of Article 9)

Diseases in Category D need to fulfil criteria of Section 1, 2, 3 or 5 of Annex IV of the AHL and the following:		Outcome			
		Median range (%)	Criterion fulfilment	Number of na	Number of experts
D	The risk posed by the disease can be effectively and proportionately mitigated by measures concerning movements of animals and products in order to prevent or limit its occurrence and spread	50–90	Uncertain	0	13

na: not applicable.

3.3.5. Detailed outcome on Category E criteria

Table 7: Outcome of the expert judgement related to the criteria of Section 5 of Annex IV (Category E of Article 9)

Diseases in Category E need to fulfil criteria of Section 1, 2 or 3 of Annex IV of the AHL and/or the following:		Outcome	
		Median range (%)	Fulfilment
E	Surveillance of the disease is necessary for reasons related 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.)	33–66	Uncertain

3.3.6. Overall outcome on criteria in Annex IV for the purpose of categorisation as in Article 9

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 points (a) to (e) of Article 9(1) of the AHL) if it 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, a criterion is considered fulfilled when the lower bound of the median range lays above 66%.

The overall outcome of the assessment on criteria in Annex IV of the AHL, for the purpose of categorisation of AMR *B. hyodysenteriae* as in Article 9, is presented in Table 8 and Figure 5.

Table 8: Outcome of the assessment on criteria in Annex IV of the AHL for the purpose of categorisation as in Article 9

Category	Article 9 criteria										
	1° set of criteria					2° set of criteria					
	1	2.1	2.2	2.3	2.4	3	4	5(a)	5(b)	5(c)	5(d)
	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	1–10	10–33	33–66	90–99	33–90	0–5	10–66	5–33	66–90	5–33	10–33
B	10–33	33–90	33–66	–	66–90	1–5	10–66	5–33	66–90	5–33	10–33
C	90–95	33–90	–	–	10–33	1–5	33–90	5–33	66–90	5–33	10–33
D	50–90										
E	33–66										

Probability ranges (% certainty; –: criterion is fulfilled by default) and fulfilment of criteria (green: fulfilled; red: not fulfilled; orange: uncertain) (EFSA AHAW Panel, 2017).

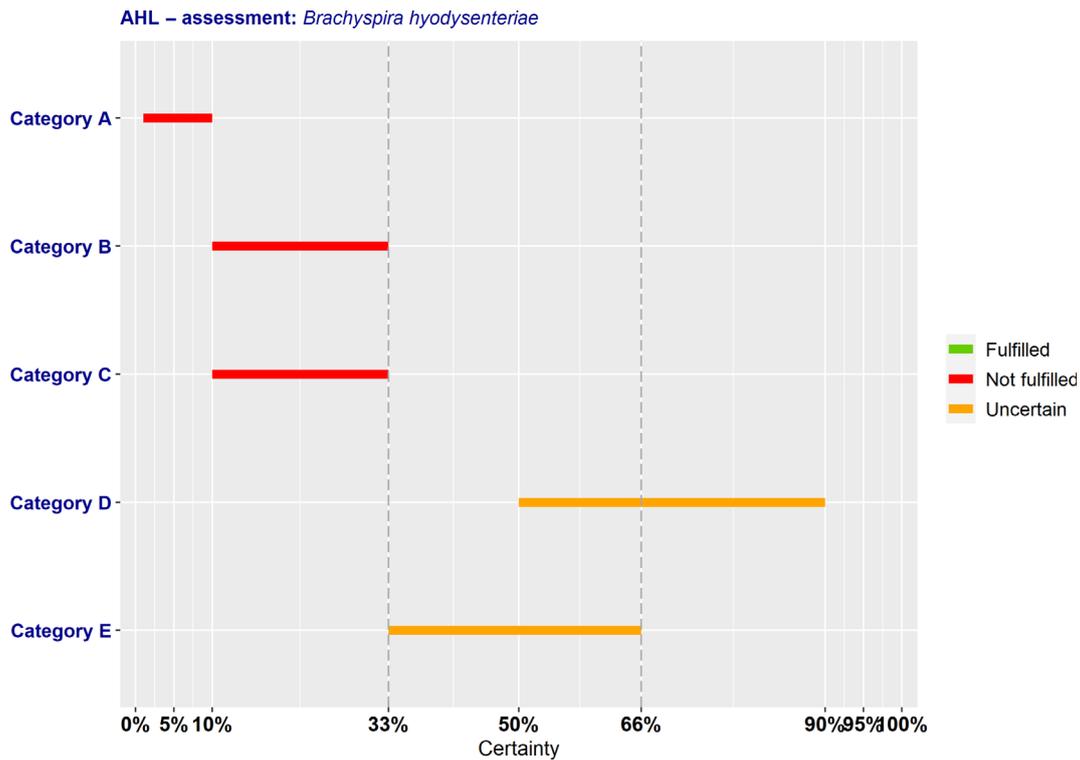


Figure 5: Outcome of the expert judgement on criteria in Annex IV and overall probabilities for categorisation of the AMR bacterium in accordance with Article 9

According to the assessment here performed, AMR *B. hyodysenteriae* complies with the following criteria of Sections 1–5 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, AMR *B. hyodysenteriae* complies only with Criterion 2.3 (90–99% probability). The assessment was inconclusive on compliance with Criteria 2.2 (33–66% probability) and 2.4 (33–90% probability). To be eligible for Category A, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5 (a)–(d)) and AMR *B. hyodysenteriae* complies with Criterion 5(b) (66–90% probability). The assessment was inconclusive on compliance with Criterion 4 (10–66% probability). Overall, it was assessed with 1–10% probability that AMR *B. hyodysenteriae* may be assigned to Category A according to criteria in Section 1 of Annex IV for the purpose of categorisation as in Article 9 of the AHL.
- 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, AMR *B. hyodysenteriae* complies only with Criteria 2.3 (fulfilled by default) and 2.4 (66–90% probability). The assessment was inconclusive on compliance with Criteria 2.1 (33–90% probability) and 2.2 (33–66% probability). To be eligible for Category B, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5(a)–(d)) and AMR *B. hyodysenteriae* complies with Criterion 5(b) (66–90% probability). The assessment was inconclusive on compliance with Criterion 4 (10–66% probability). Overall, it was assessed with 10–33% probability that AMR *B. hyodysenteriae* may be assigned to Category B according to criteria in Section 2 of Annex IV for the purpose of categorisation as in Article 9 of the AHL.
- 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, AMR *B. hyodysenteriae* complies with Criteria 1 (90–95% probability), 2.2 and 2.3, which are fulfilled by default. The assessment was inconclusive on compliance with Criterion 2.1 (33–90% probability). To be eligible for Category C, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5(a)–(d)) and AMR *B. hyodysenteriae* complies with Criterion 5(b) (66–90% probability). The assessment was inconclusive on compliance with Criterion 4 (33–90%

probability). Overall, it was assessed with 10–33% probability that AMR *B. hyodysenteriae* may be assigned to Category C according to criteria in Section 3 of Annex IV for the purpose of categorisation as in Article 9 of the AHL.

- 4) To be assigned to Category D, a disease needs to comply with criteria of Section 1, 2 or 5 of Annex IV of the AHL and with the specific Criterion D of Section 4, for which the assessment for AMR *B. hyodysenteriae* is inconclusive (50–90% probability).
- 5) To be assigned to Category E, a disease needs to comply with criteria of Section 1, 2 or 3 of Annex IV of the AHL, and/or the surveillance of the disease is necessary for reasons related 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, for which the assessment is inconclusive (33–66% probability of fulfilling the criteria).

3.4. Assessment of AMR *Brachyspira hyodysenteriae* according to Article 8 criteria of the AHL

In this section, the results of the assessment on the criteria of Article 8(3) of the AHL for AMR *B. hyodysenteriae* are presented. 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 the list if they are affected or if they pose a risk for the spread of a specific listed disease because:

- a) they are susceptible to 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.²

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 AMR *B. hyodysenteriae* according to the criteria of Article 8(3) of the AHL are as displayed in Table 9 (elaborated from information reported in Section 3.1.1.1 of the present document).

The table contains all animal species in which AMR *B. hyodysenteriae* has been described, but also those animal species from which only the bacterium itself has been isolated. The latter makes susceptibility to AMR clones likely.

Table 9: Animal species to be listed for AMR *B. hyodysenteriae* according to the criteria of Article 8

	Class	Order	Family	Genus/Species
Susceptible	Mammalia	Artiodactyla	Suidae	Pig (<i>Sus scrofa</i>)
		Carnivora	Canidae	Dog (<i>Canis lupus familiaris</i>)
		Rodentia	Muridae	Mouse (<i>Mus musculus</i>) Rat (<i>Rattus rattus</i> and <i>Rattus norvegicus</i>)
	Aves	Anseriformes	Anatidae	Mallard (<i>Anas platyrhynchos</i>)
		Galliformes	Phasianidae	Chicken (<i>Gallus gallus domesticus</i>)
		Passeriformes	Corvidae	Carrion crow (<i>Corvus corone</i>)
			Sturnidae	Common starling (<i>Sturnus vulgaris</i>)
Struthioniformes	Rheidae	Greater rhea (<i>Rhea americana</i>)		
Reservoir	Mammalia	Artiodactyla	Suidae	Pig (<i>Sus scrofa</i>)
	Aves	Anseriformes	Anatidae	Mallard (<i>Anas platyrhynchos</i>)
Vector	None			

B. hyodysenteriae has also been isolated from cockroaches (*Blattodea*) and flies (*Musca domestica*) (Blunt and McOrist, 2009; Gallie et al., 2009), but their role as susceptible animal species, reservoirs or vectors has not been demonstrated.

² 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.

4. Conclusions

The AHAW Panel emphasises that the assessment of impacts, as well as prevention and control measures, related to AMR bacteria using the criteria as laid down in Articles 5 and 9 of the AHL is particularly challenging for opportunistic pathogens that can also be found as commensal bacteria in healthy animals. Furthermore, for AMR *B. hyodysenteriae*, assessment of the clinical significance of antimicrobial resistance is difficult due to the lack of specific clinical breakpoints.

TOR 1: for each of those identified AMR bacteria considered most relevant in the EU, following the criteria laid down in Article 7 of the AHL, an assessment on its eligibility to be listed for Union intervention as laid down in Article 5(3) of the AHL;

- It is uncertain (33–66% probability, ‘as likely as not’) whether AMR *B. hyodysenteriae* can be considered eligible to be listed for Union intervention as laid down in Article 5 of the AHL.

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

- The AHAW Panel considered with 1–10% probability (from ‘extremely unlikely’ to ‘very unlikely’) that AMR *B. hyodysenteriae* meets the criteria as in Section 1 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in point (a) of Article 9(1) of the AHL.
- The AHAW Panel considered with 10–33% probability (‘unlikely’) that AMR *B. hyodysenteriae* meets the criteria as in Section 2 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in point (b) of Article 9(1) of the AHL.
- The AHAW Panel considered with 10–33% probability (‘unlikely’) that AMR *B. hyodysenteriae* meets 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 Article 9(1) of the AHL.
- The AHAW Panel was uncertain (50–90% probability, from ‘as likely as not’ to ‘likely’) whether AMR *B. hyodysenteriae* meets the criteria as in Section 4 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in point (d) of Article 9(1) of the AHL.
- The AHAW Panel was uncertain (33–66% probability, ‘as likely as not’) whether AMR *B. hyodysenteriae* meets the criteria as in Section 5 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in point (e) of Article 9(1) of the AHL.

TOR 3: for each of the AMR bacteria 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;

- The main animal species that can be considered to be listed for AMR *B. hyodysenteriae* according to Article 8(3) of the AHL are pigs and birds (chickens and ducks), as reported in Table 9 in Section 3.4 of the present document.

The AHAW Panel highlights that monitoring of antimicrobial resistance in opportunistic pathogens could help to assess their impacts. Therefore, even though the assessment on AMR *B. hyodysenteriae* is inconclusive on its eligibility to be listed for Union intervention, specific initiatives (e.g. monitoring or applied research) into various aspects of AMR *B. hyodysenteriae* can be useful to better understand its distribution and to assess its impact on animal health and welfare in the EU.

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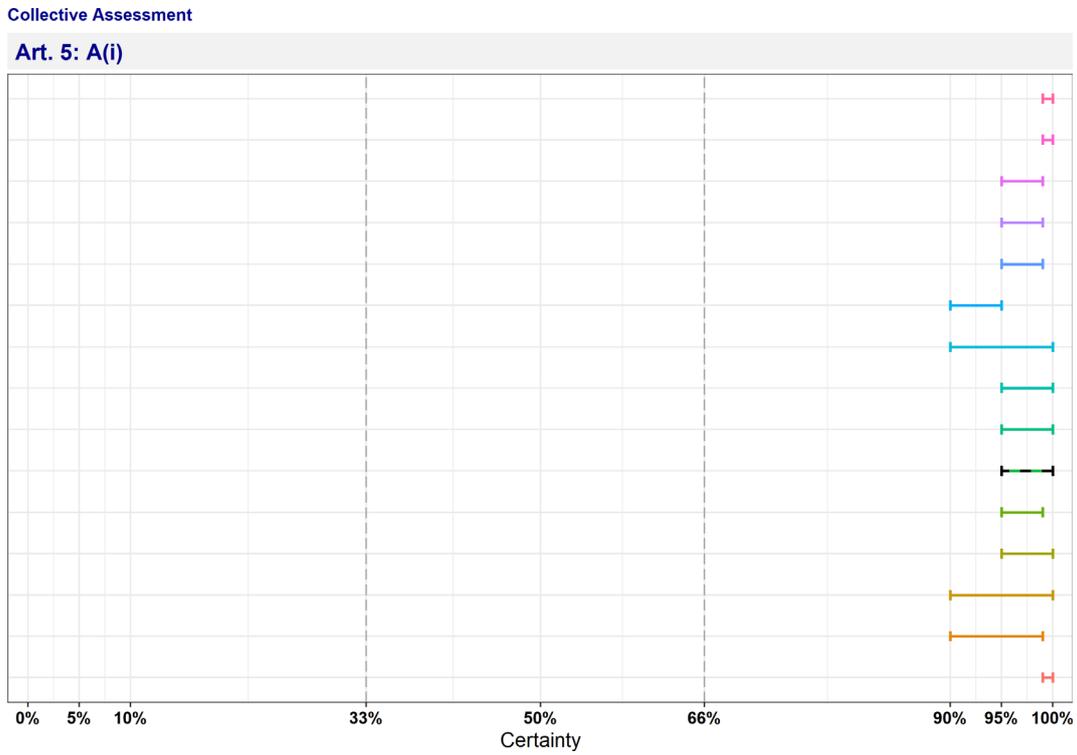
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Abbreviations

ADG	Average daily gain
AHAW	Animal Health and Welfare
AHL	Animal Health Law
AMR	Antimicrobial-resistant
CFSPH	Center for Food Security and Public Health
CI	Current impact
CITES	Convention on International Trade in Endangered Species
DALY	Disability-adjusted life year
DIVA	Differentiation of infected from vaccinated animals
ECOFF	Epidemiological cut-off
FISH	Fluorescent in situ hybridisation
ELISA	Enzyme-linked immunosorbent assay
IUCN	International Union for Conservation of Nature
MALDI-TOF MS	Matrix-assisted laser desorption ionisation–time-of-flight mass spectrometry
MIC	Minimum inhibitory concentration
MS	Member State
OIE	Office International des Épizooties (World Organisation for Animal Health)
PCR	Polymerase chain reaction
PI	Potential impact
SD	Swine dysentery
ToR	Term of Reference

Appendix A – Criteria with certain outcome

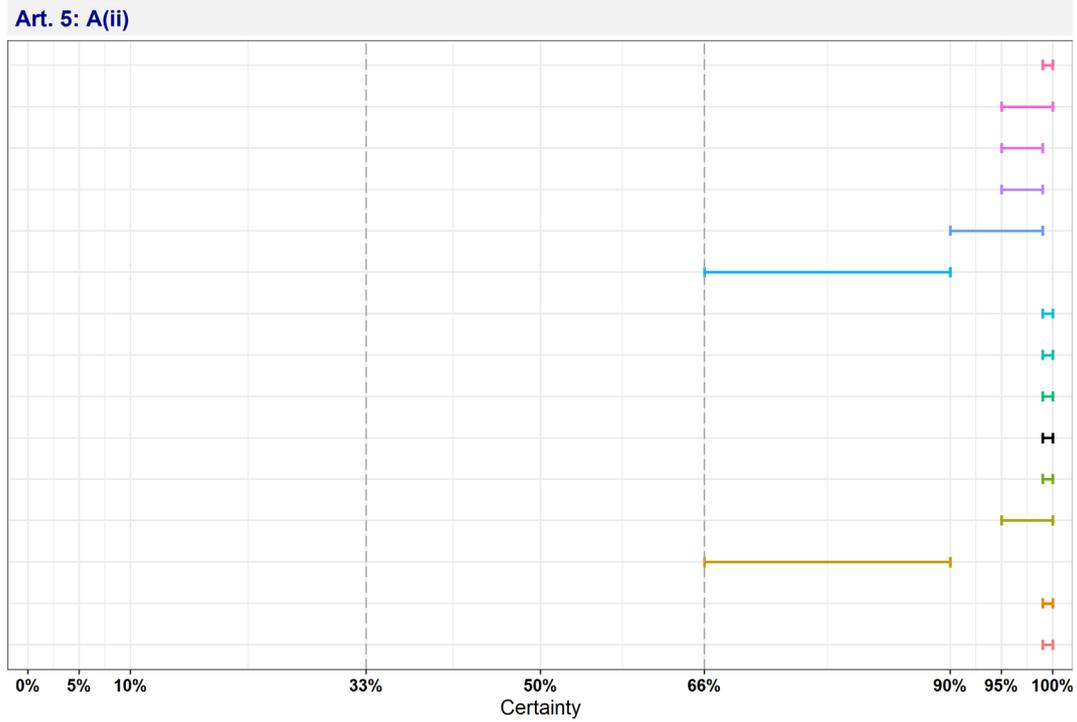
A.1. Article 5 criteria



The median range is displayed as a dashed line.

Figure A.1: Individual probability ranges reflecting fulfilment of Criterion A(i) (the disease is transmissible) after the collective judgement

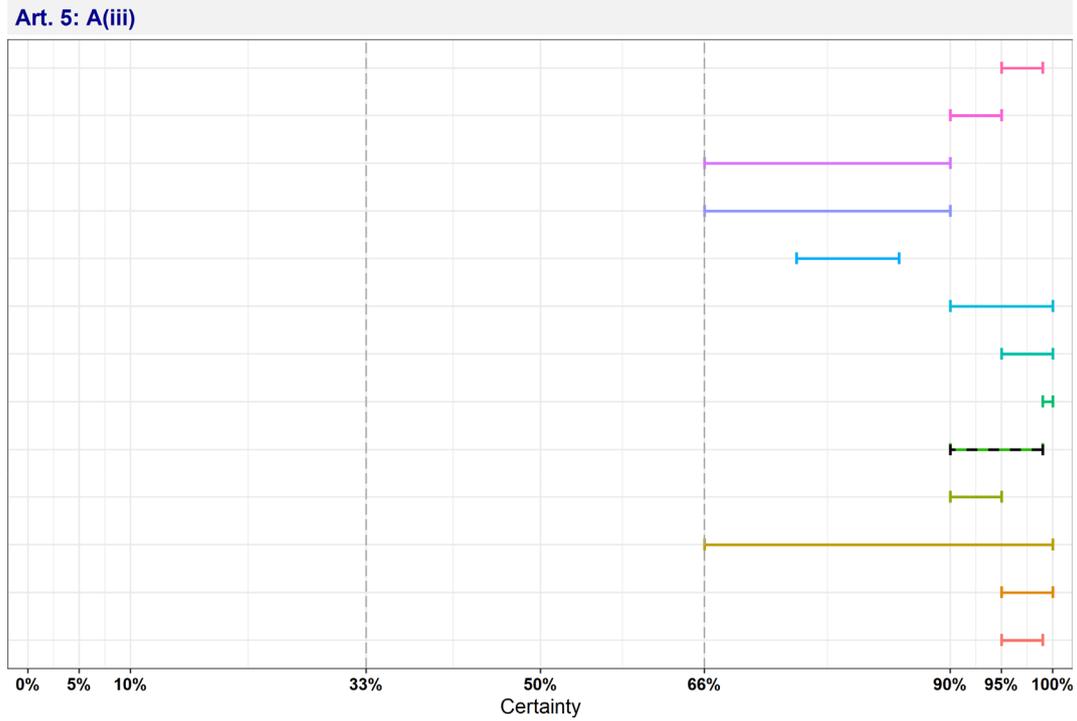
Collective Assessment



The median range is displayed as a dashed line.

Figure A.2: Individual probability ranges reflecting fulfilment of Criterion A(ii) (animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union) after the collective judgement

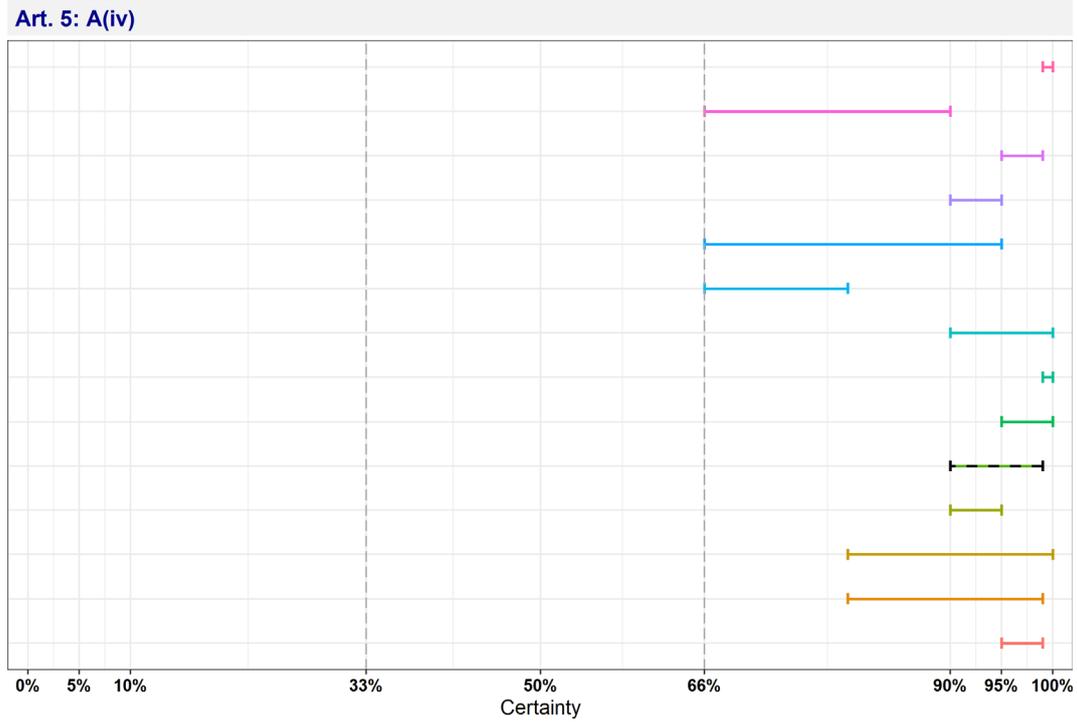
Collective Assessment



The median range is displayed as a dashed line.

Figure A.3: Individual probability ranges reflecting fulfilment of Criterion A(iii) (the disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character) after the collective judgement

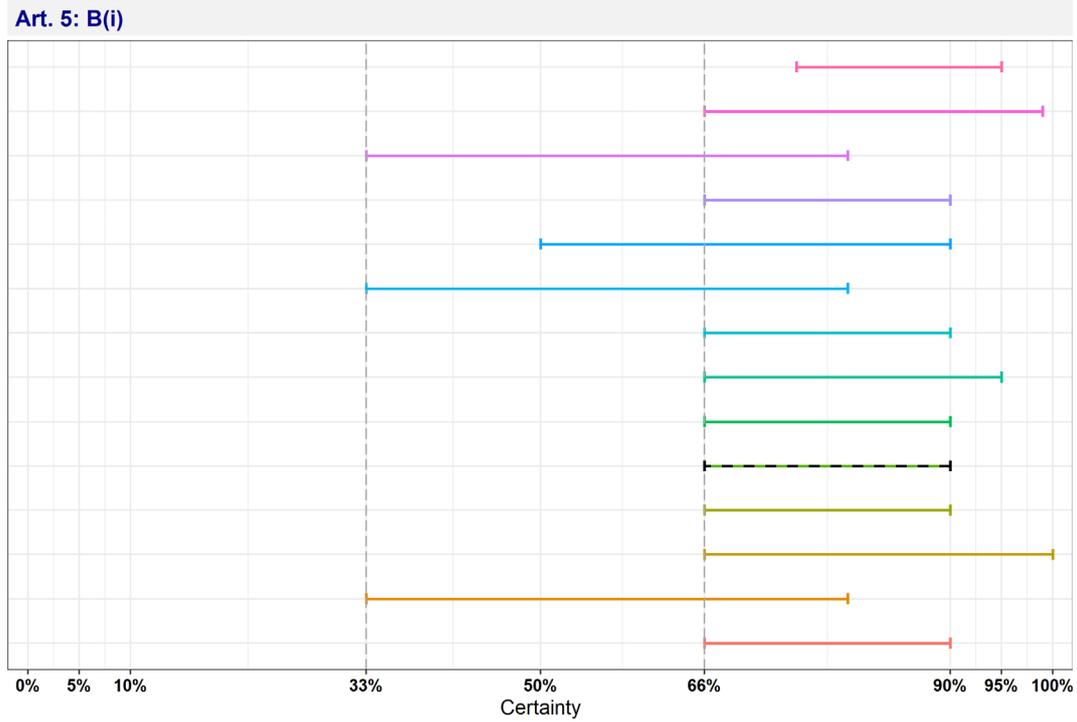
Collective Assessment



The median range is displayed as a dashed line.

Figure A.4: Individual probability ranges reflecting fulfilment of Criterion A(iv) (diagnostic tools are available for the disease) after the collective judgement

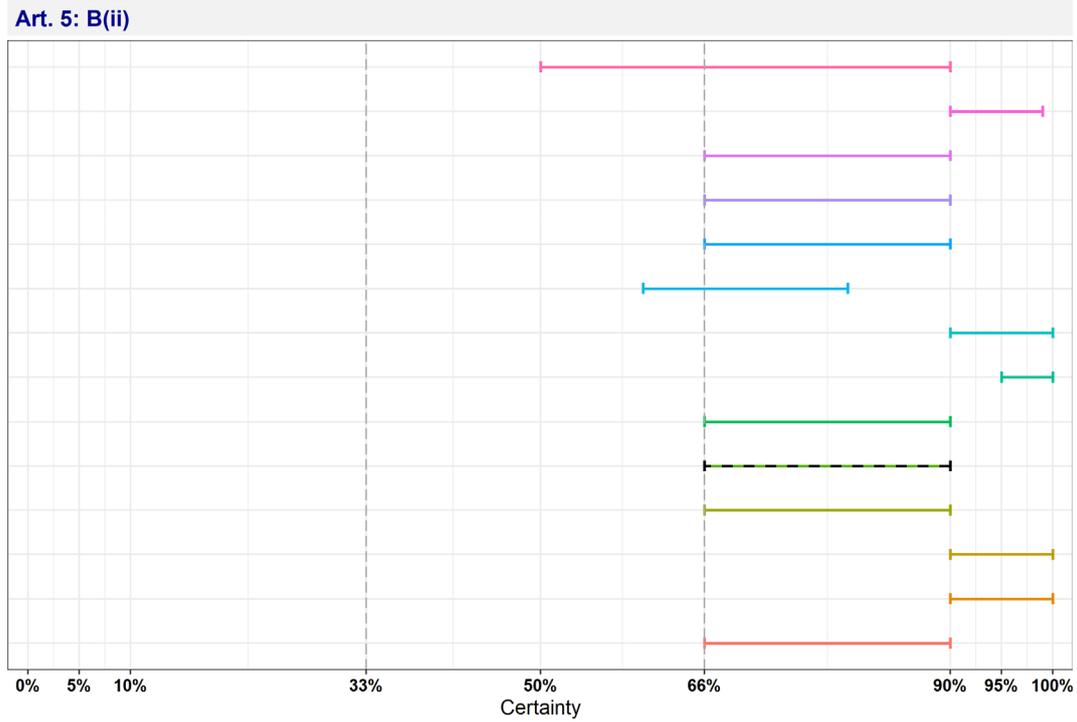
Collective Assessment



The median range is displayed as a dashed line.

Figure A.5: Individual probability ranges reflecting fulfilment of Criterion 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) after the collective judgement

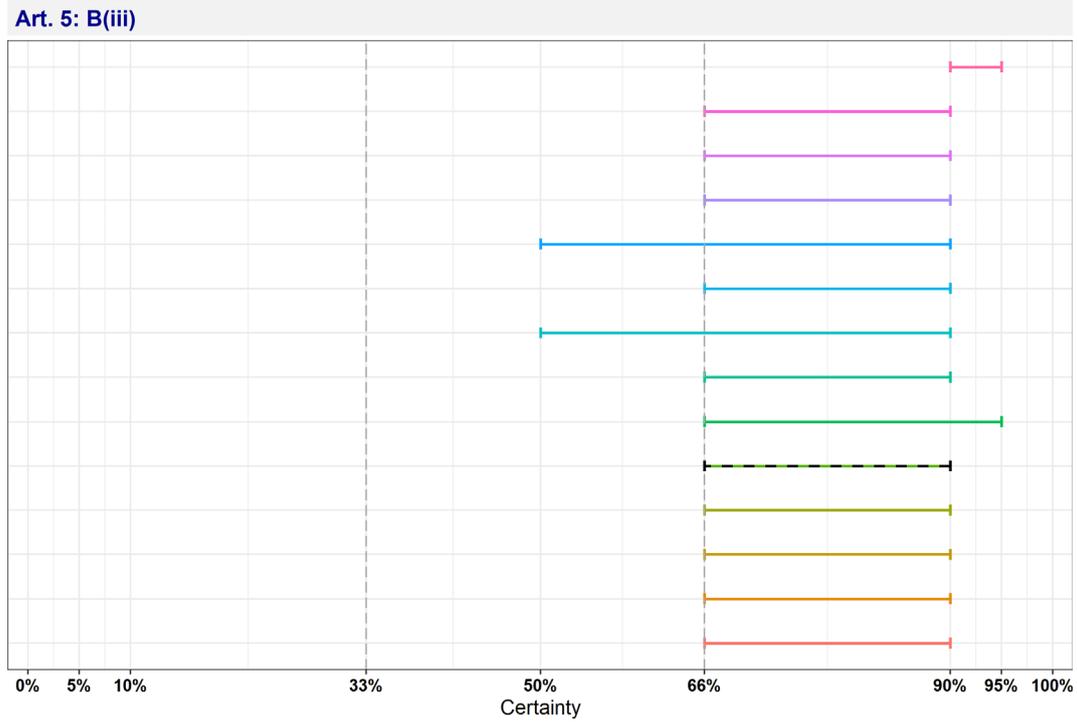
Collective Assessment



The median range is displayed as a dashed line.

Figure A.6: Individual probability ranges reflecting fulfilment of Criterion B(ii) (the disease agent has developed resistance to treatments which poses a significant danger to public and/or animal health in the Union) after the collective judgement

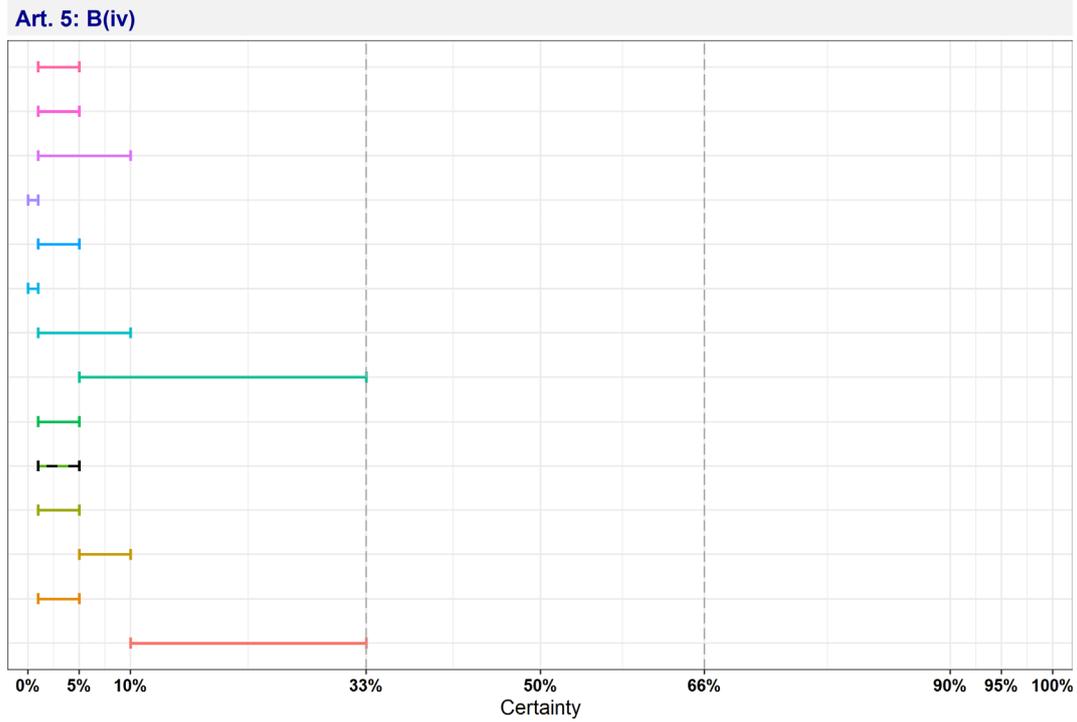
Collective Assessment



The median range is displayed as a dashed line.

Figure A.7: Individual probability ranges reflecting fulfilment of Criterion B(iii) (the disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union) after the collective judgement

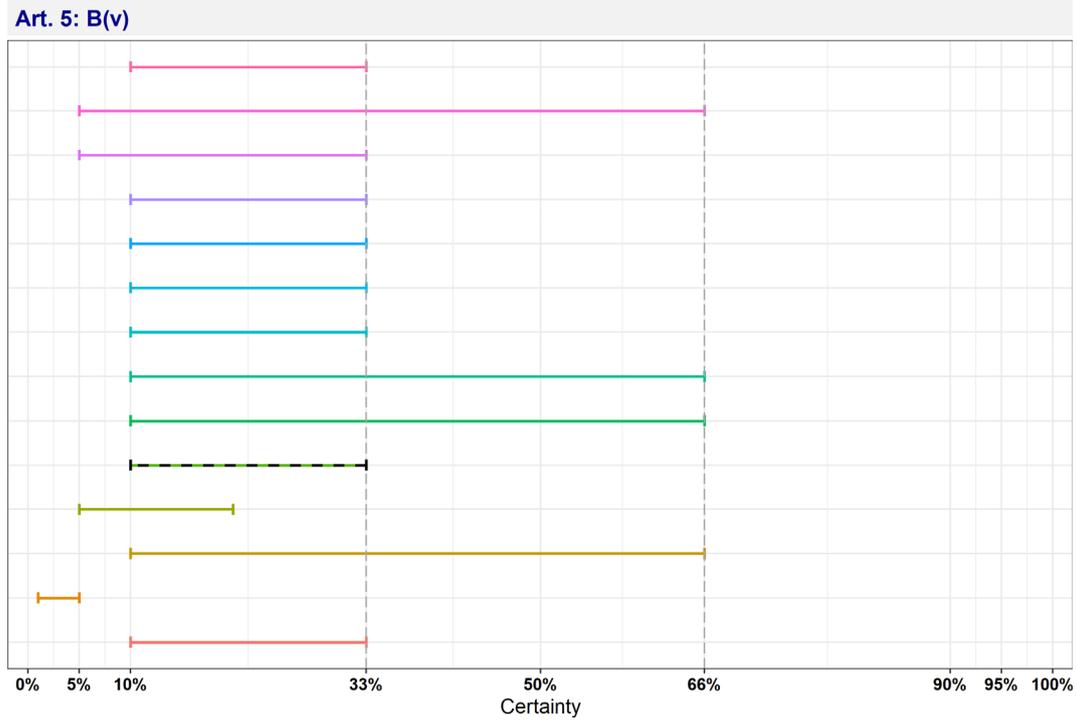
Collective Assessment



The median range is displayed as a dashed line.

Figure A.8: Individual probability ranges reflecting non-fulfilment of Criterion B(iv) (the disease has the potential to generate a crisis or the disease agent could be used for the purpose of bioterrorism) after the collective judgement

Collective Assessment

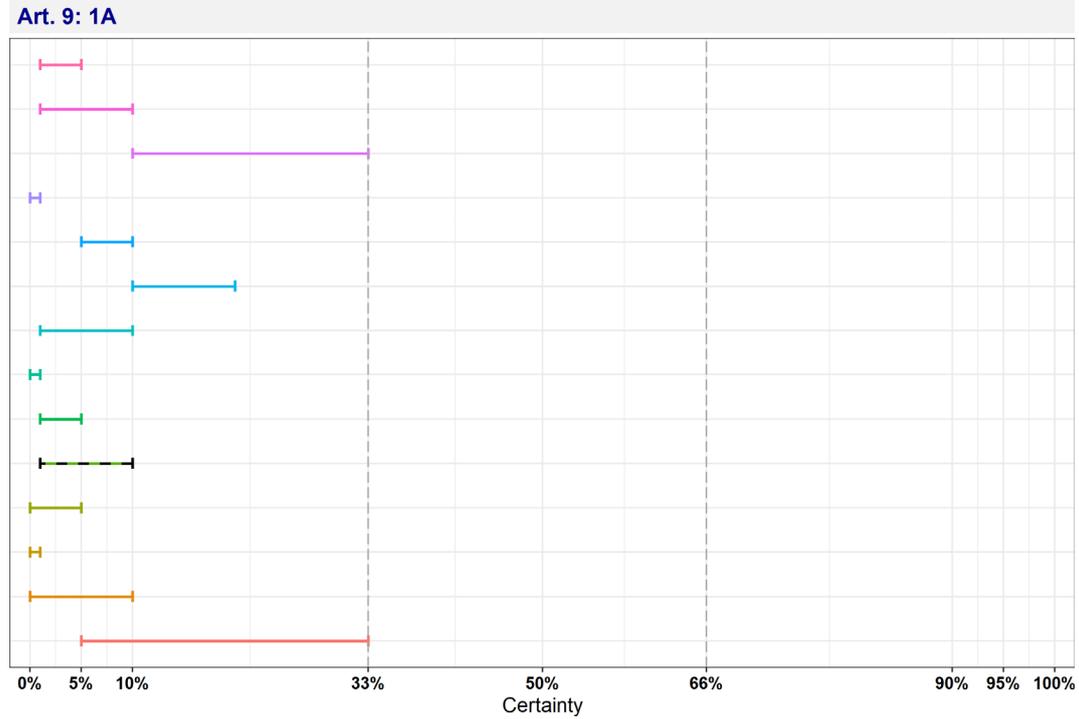


The median range is displayed as a dashed line.

Figure A.9: Individual probability ranges reflecting non-fulfilment of Criterion B(v) (the disease has or could have a significant negative impact on the environment, including biodiversity, of the Union) after the collective judgement

A.2. Article 9 criteria

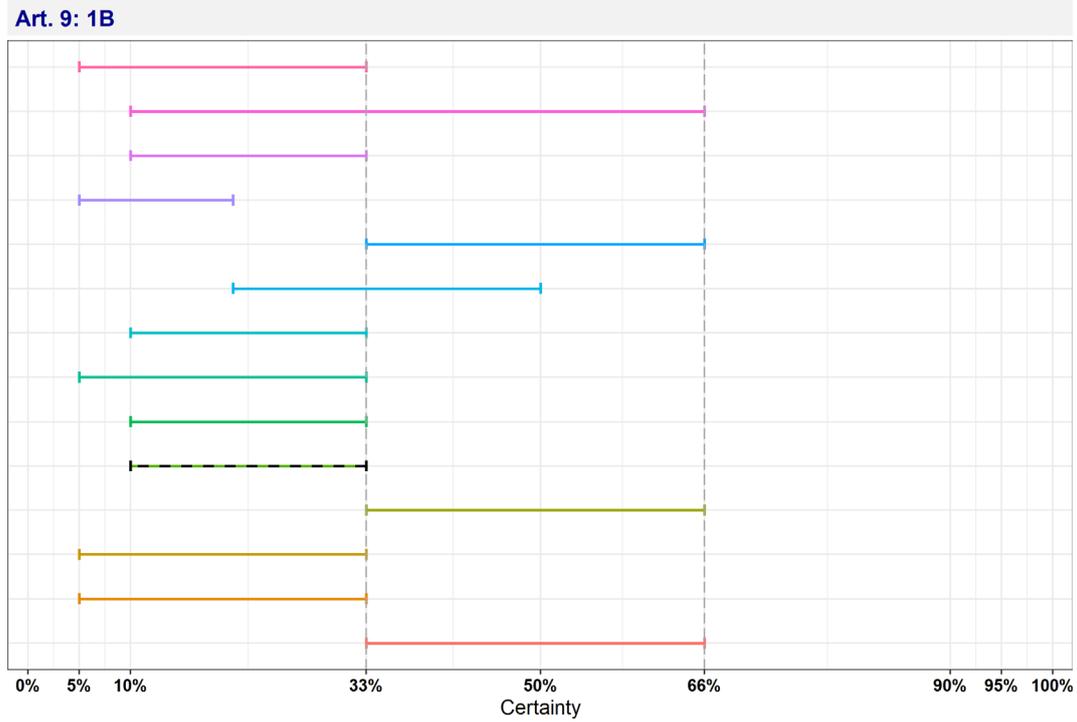
Collective Assessment



The median range is displayed as a dashed line.

Figure A.10: Individual probability ranges reflecting non-fulfilment of Criterion 1A (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) after the collective judgement

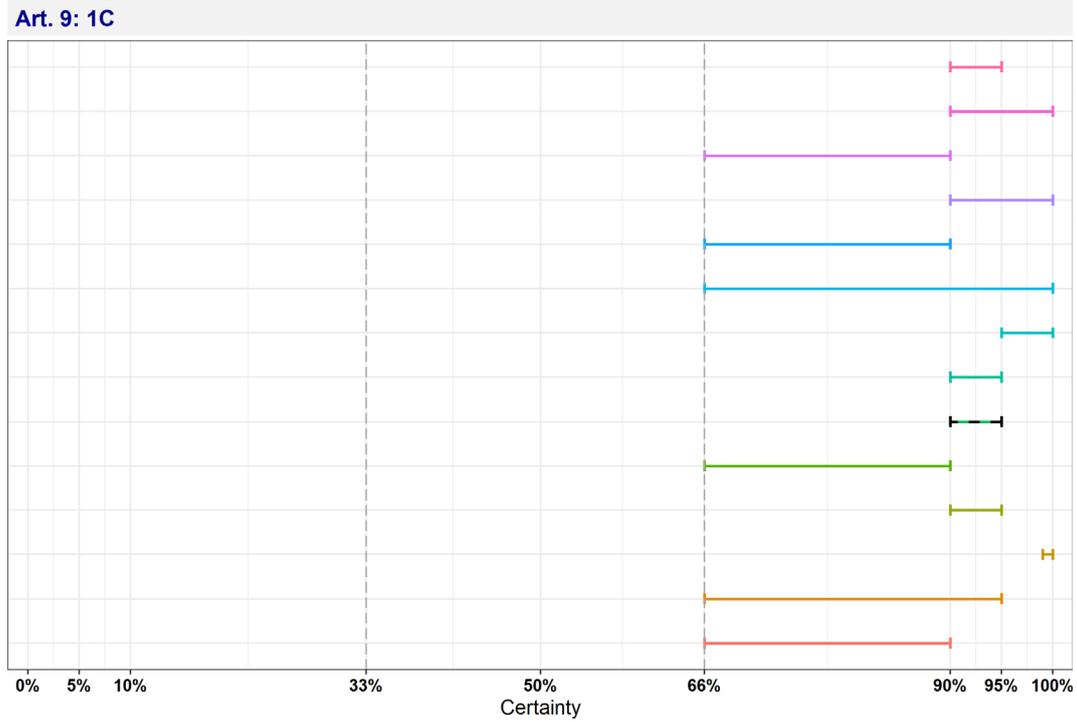
Collective Assessment



The median range is displayed as a dashed line.

Figure A.11: Individual probability ranges reflecting non-fulfilment of Criterion 1B (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) after the collective judgement

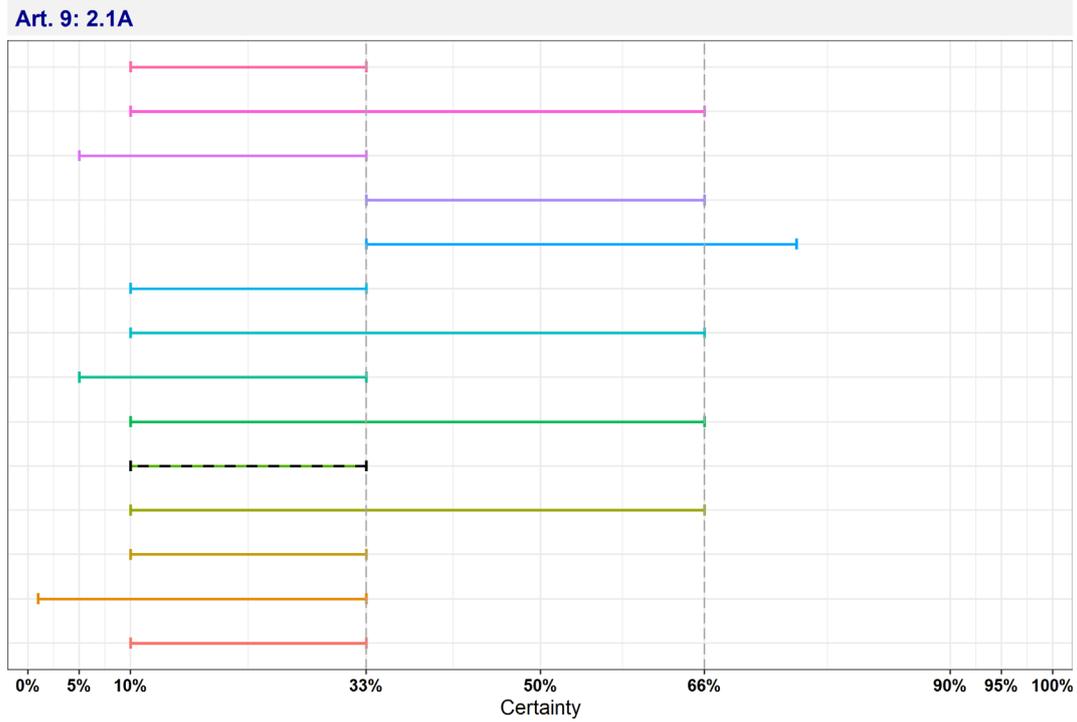
Collective Assessment



The median range is displayed as a dashed line.

Figure A.12: Individual probability ranges reflecting fulfilment of Criterion 1C (the disease is present in the whole or part of the Union territory with an endemic character) after the collective judgement

Collective Assessment

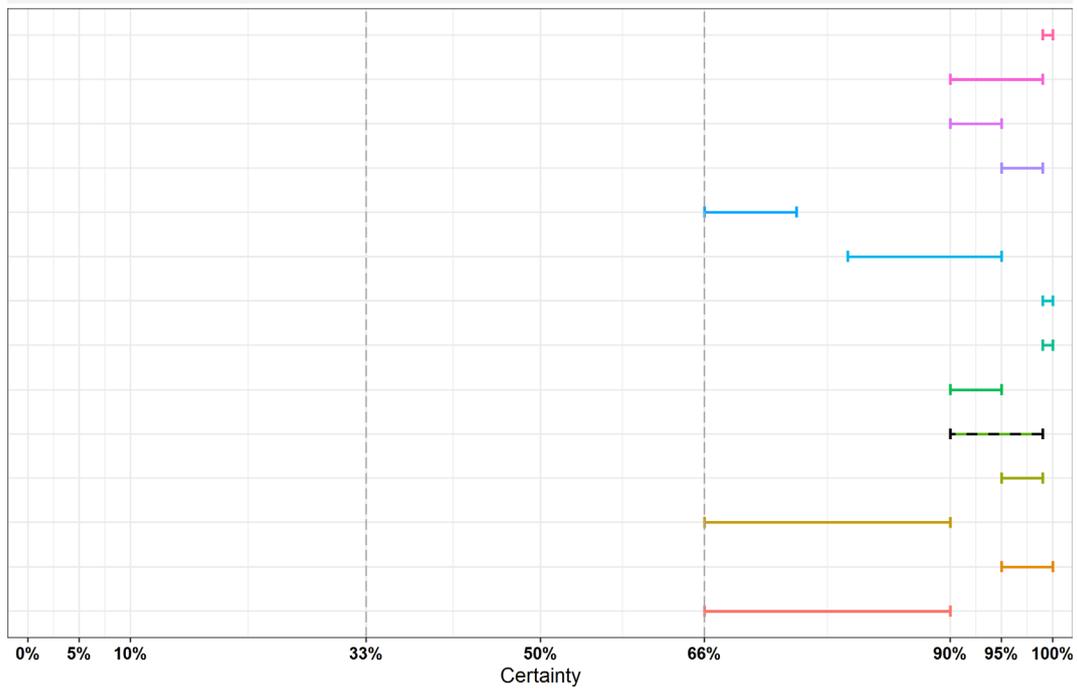


The median range is displayed as a dashed line.

Figure A.13: Individual probability ranges reflecting non-fulfilment of Criterion 2.1A (the disease is highly transmissible) after the collective judgement

Collective Assessment

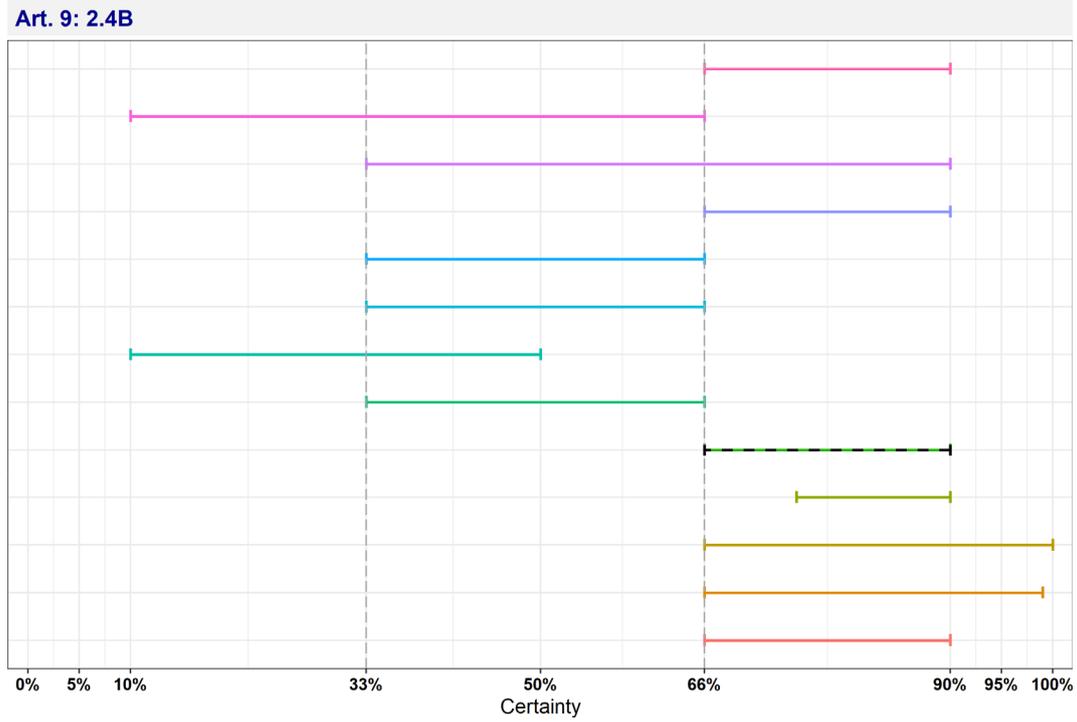
Art. 9: 2.3A



The median range is displayed as a dashed line.

Figure A.14: Individual probability ranges reflecting fulfilment of Criterion 2.3A (the disease affects multiple species of kept and wild animals or single species of kept animals of economic importance) after the collective judgement

Collective Assessment

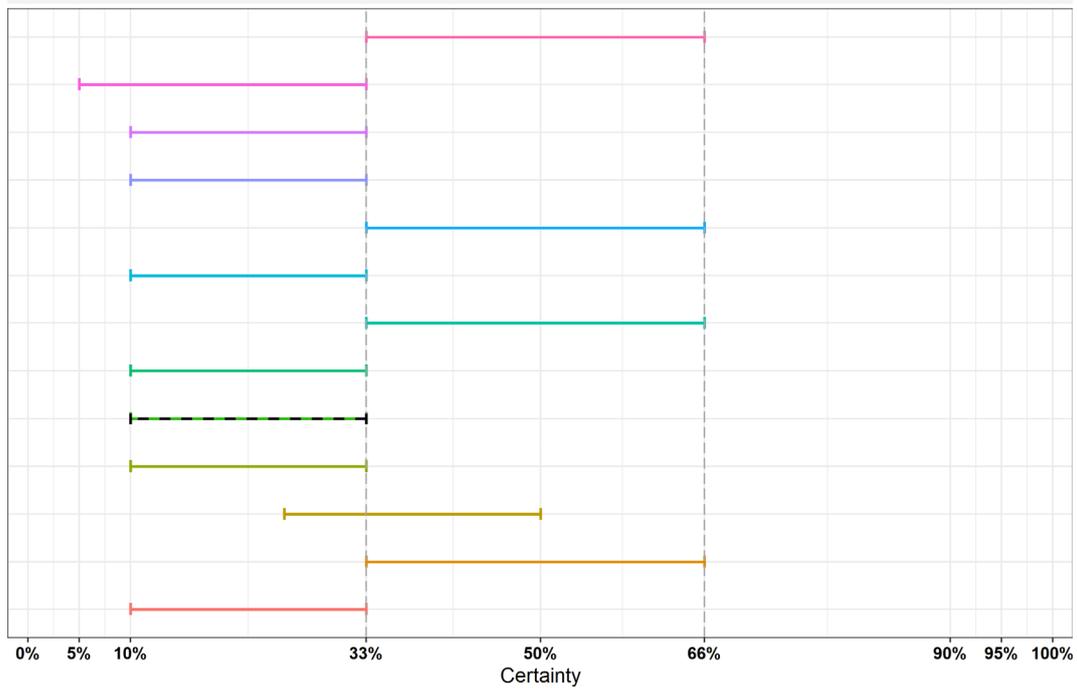


The median range is displayed as a dashed line.

Figure A.15: Individual probability ranges reflecting fulfilment of Criterion 2.4B (the disease may result in high morbidity with in general low mortality) after the collective judgement

Collective Assessment

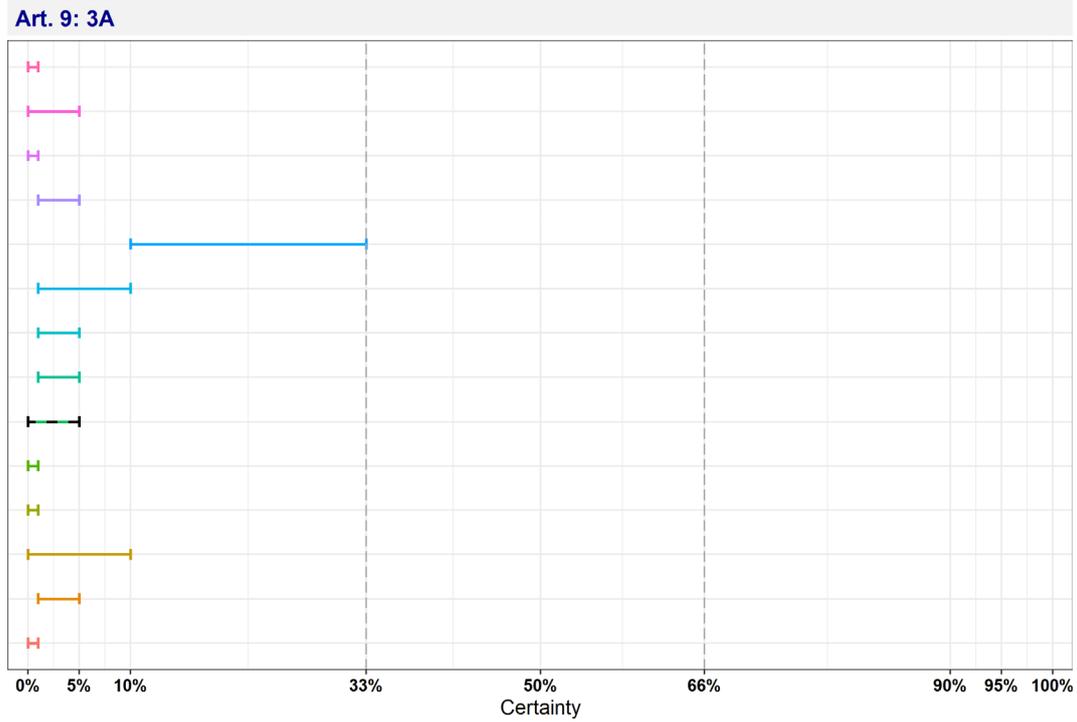
Art. 9: 2.4C



The median range is displayed as a dashed line.

Figure A.16: Individual probability ranges reflecting non-fulfilment of Criterion 2.4 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) after the collective judgement

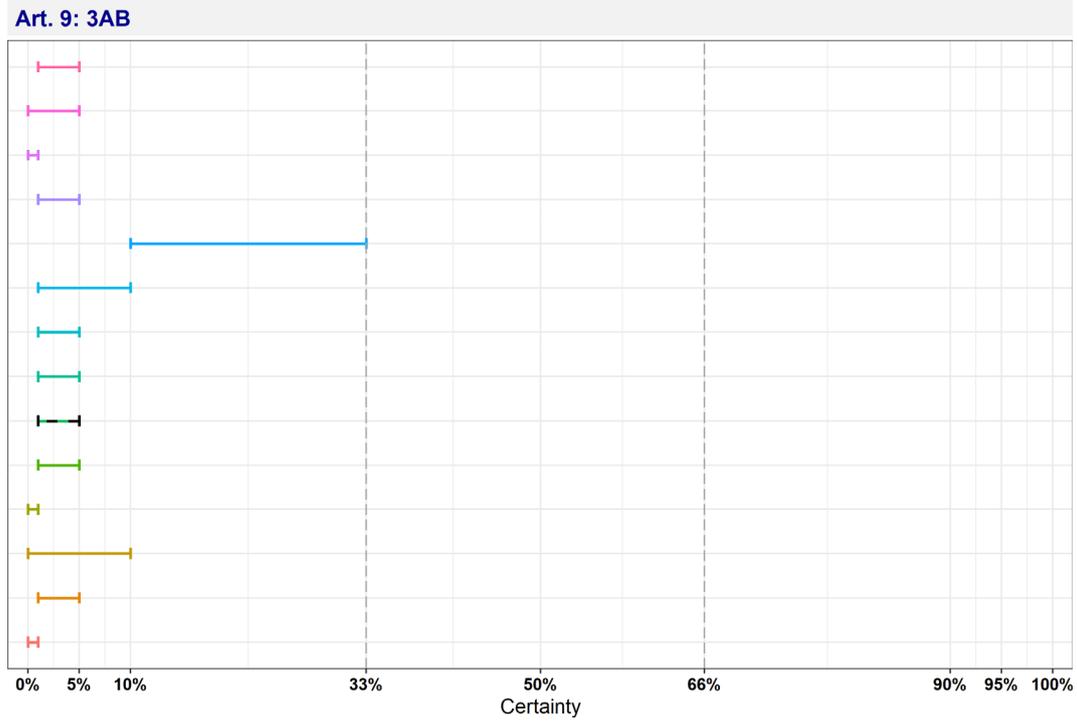
Collective Assessment



The median range is displayed as a dashed line.

Figure A.17: Individual probability ranges reflecting non-fulfilment of Criterion 3A (the disease has a zoonotic potential with significant consequences for public health, including epidemic or pandemic potential or possible significant threats to food safety) after the collective judgement

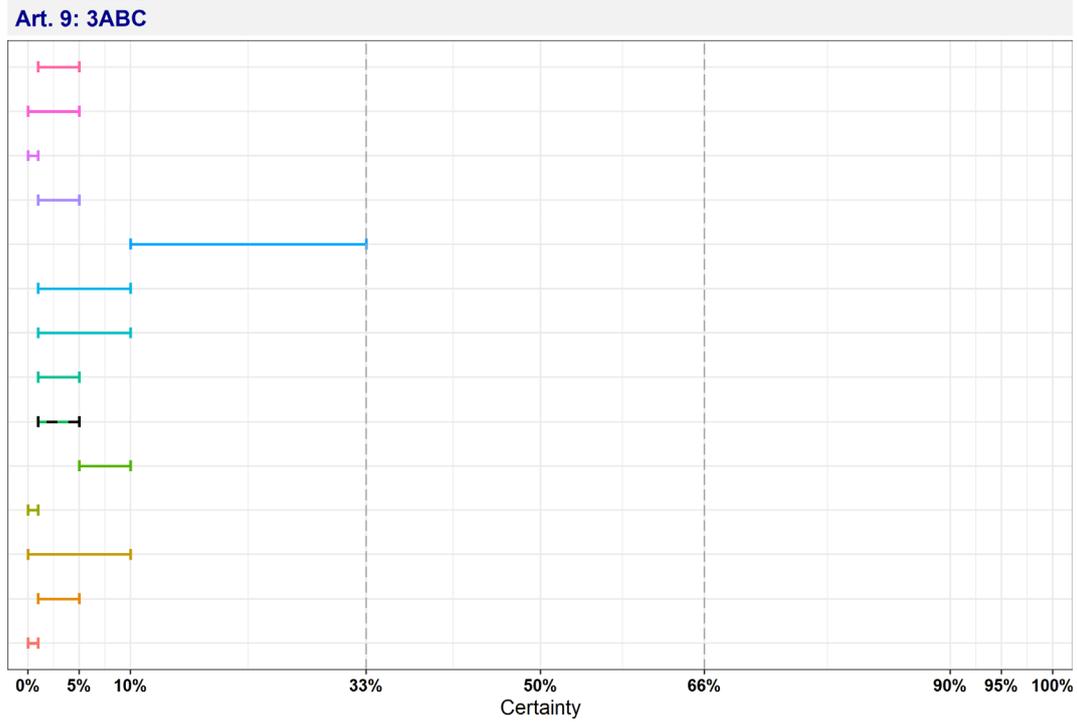
Collective Assessment



The median range is displayed as a dashed line.

Figure A.18: Individual probability ranges reflecting non-fulfilment of Criterion 3AB (the disease has a zoonotic potential with significant consequences for public health, including epidemic potential or possible significant threats to food safety) after the collective judgement

Collective Assessment

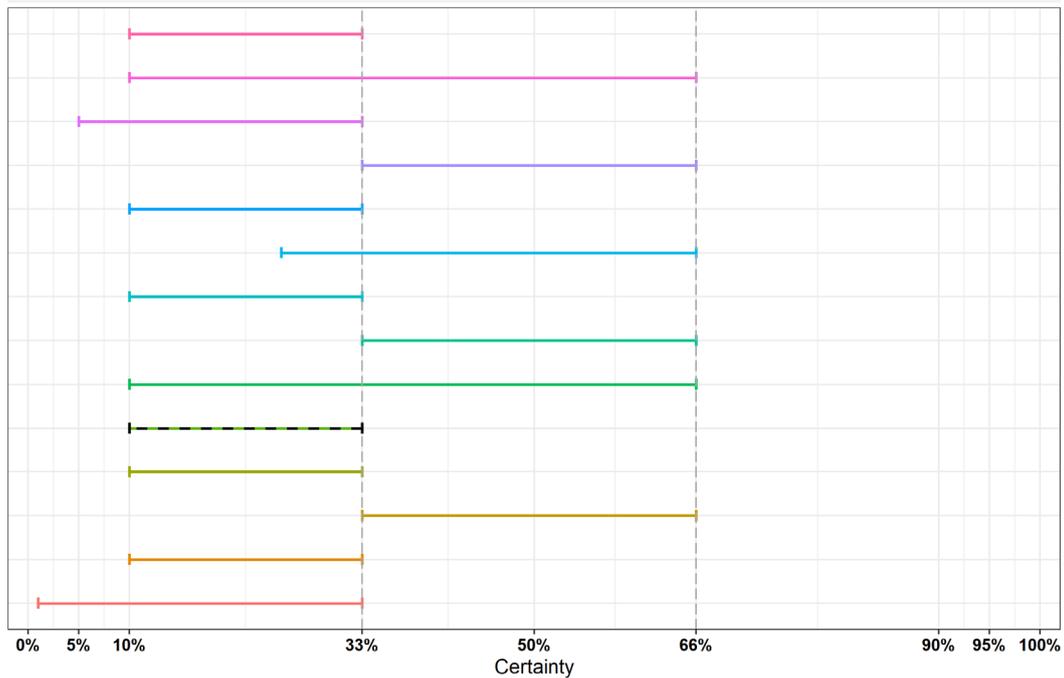


The median range is displayed as a dashed line.

Figure A.19: Individual probability ranges reflecting non-fulfilment of Criterion 3ABC (the disease has a zoonotic potential with significant consequences for public health or possible significant threats to food safety) after the collective judgement

Collective Assessment

Art. 9: 4AB (CI)



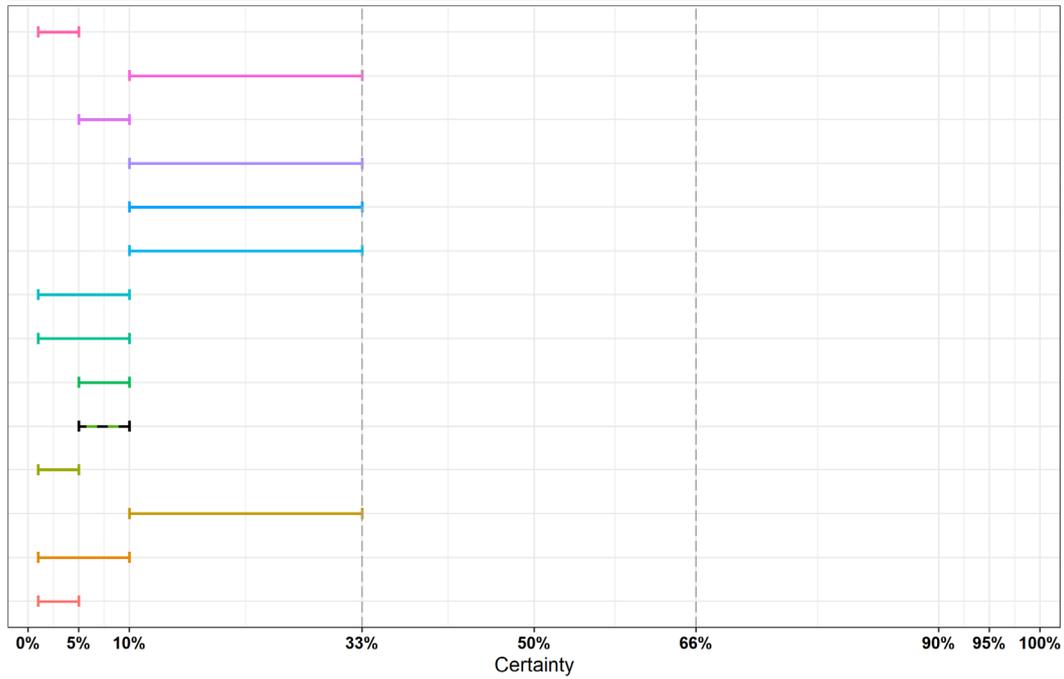
CI: current impact

The median range is displayed as a dashed line.

Figure A.20: Individual probability ranges reflecting non-fulfilment of Criterion 4AB (current impact) (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) after the collective judgement

Collective Assessment

Art. 9: 5(a) (CI)



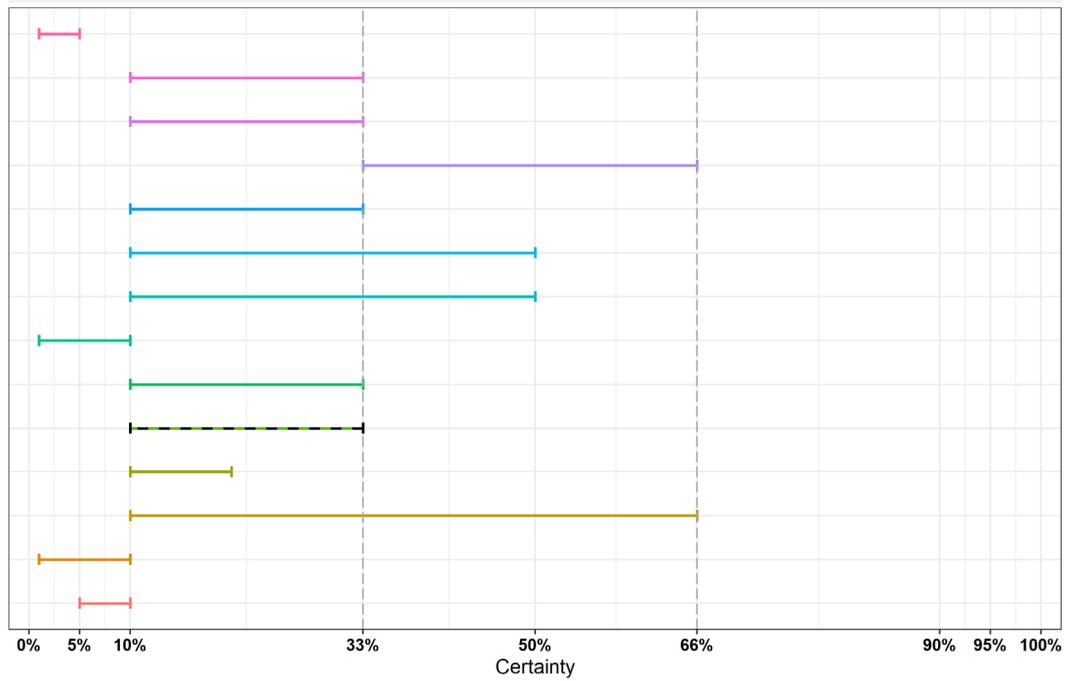
CI: current impact

The median range is displayed as a dashed line.

Figure A.21: Individual probability ranges reflecting non-fulfilment of Criterion 5(a) (current impact) (the disease has a significant impact on society, with in particular an impact on labour markets) after the collective judgement

Collective Assessment

Art. 9: 5(a) (PI)



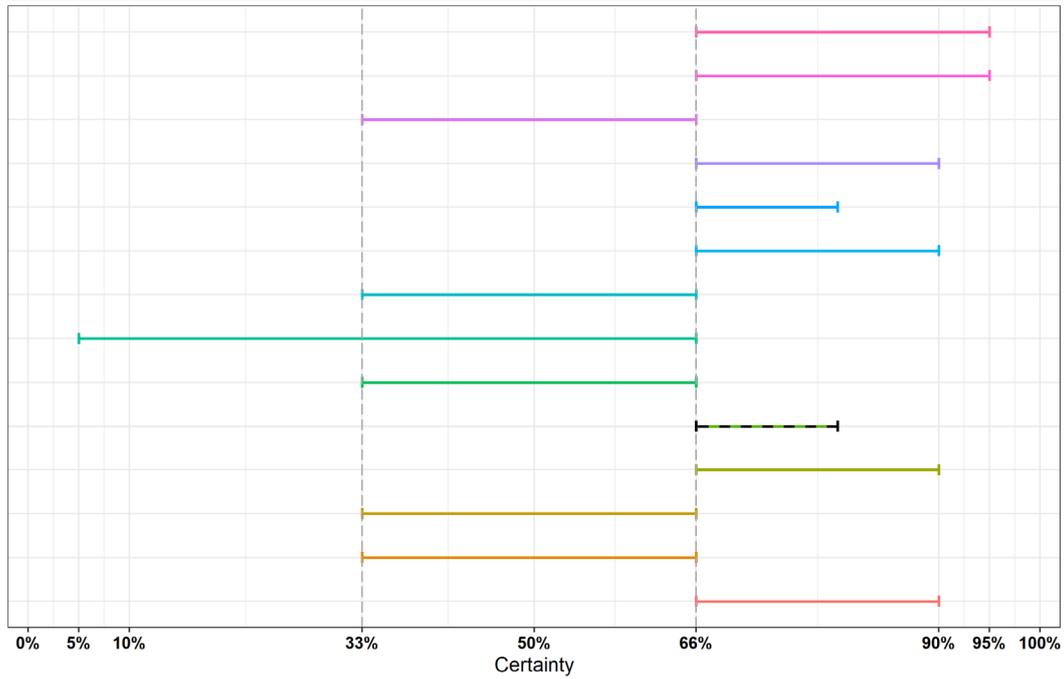
PI: potential impact

The median range is displayed as a dashed line.

Figure A.22: Individual probability ranges reflecting non-fulfilment of Criterion 5(a) (potential impact) (the disease has a significant impact on society, with in particular an impact on labour markets) after the collective judgement

Collective Assessment

Art. 9: 5(b) (CI)



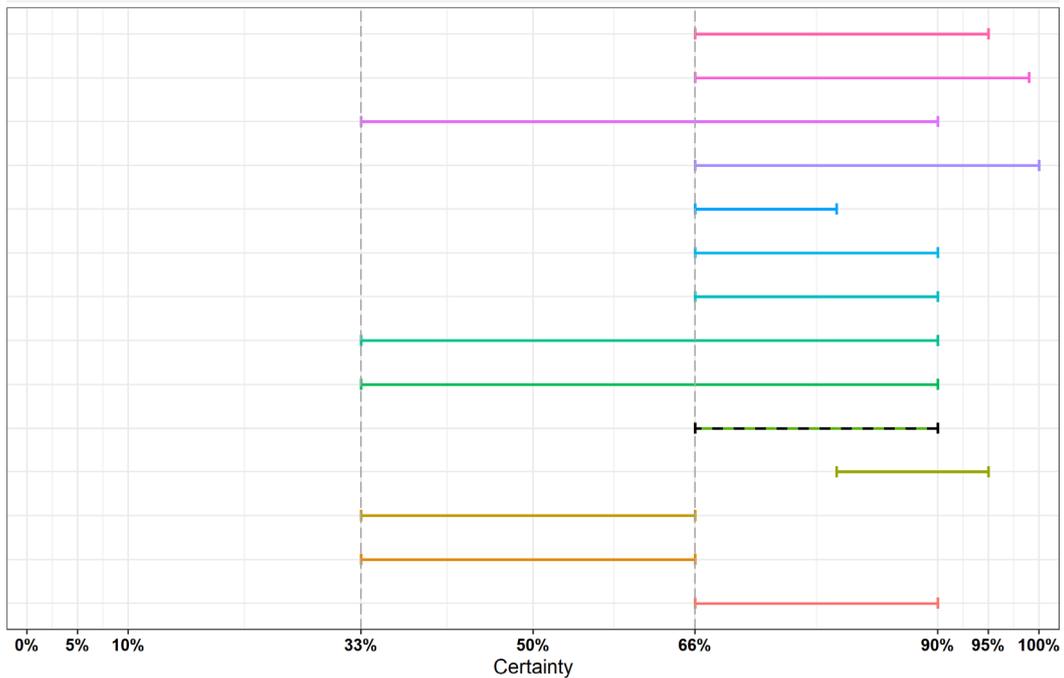
CI: current impact

The median range is displayed as a dashed line.

Figure A.23: Individual probability ranges reflecting fulfilment of Criterion 5(b) (current impact) (the disease has a significant impact on animal welfare, by causing suffering of large numbers of animals) after the collective judgement

Collective Assessment

Art. 9: 5(b) (PI)



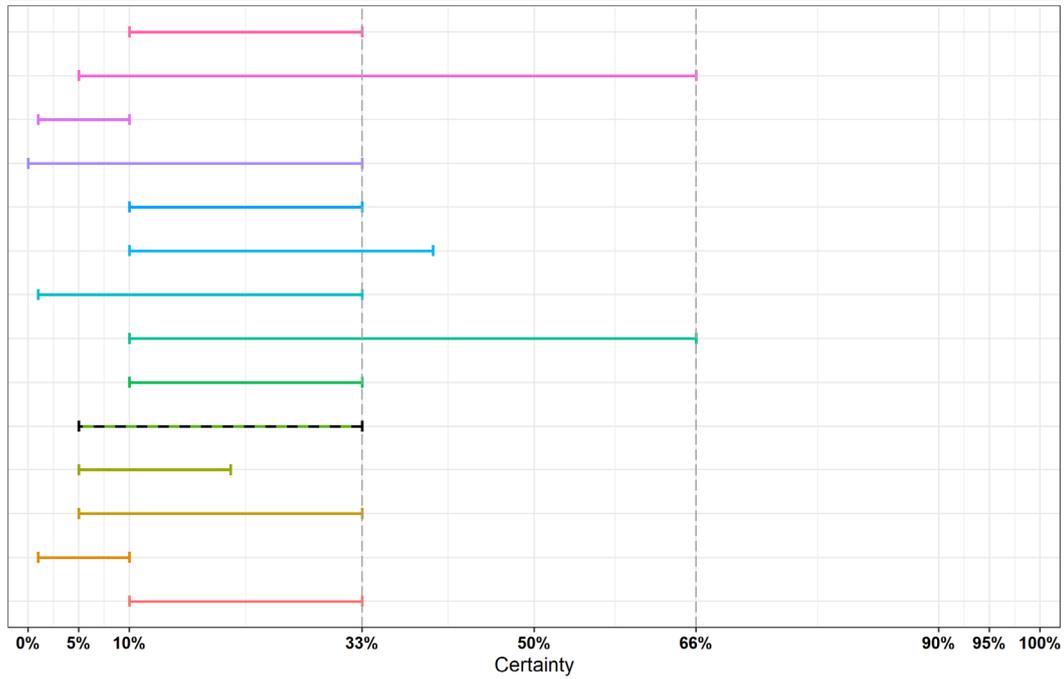
PI: potential impact

The median range is displayed as a dashed line.

Figure A.24: Individual probability ranges reflecting fulfilment of Criterion 5(b) (potential impact) (the disease has a significant impact on animal welfare, by causing suffering of large numbers of animals) after the collective judgement

Collective Assessment

Art. 9: 5(c) (CI)



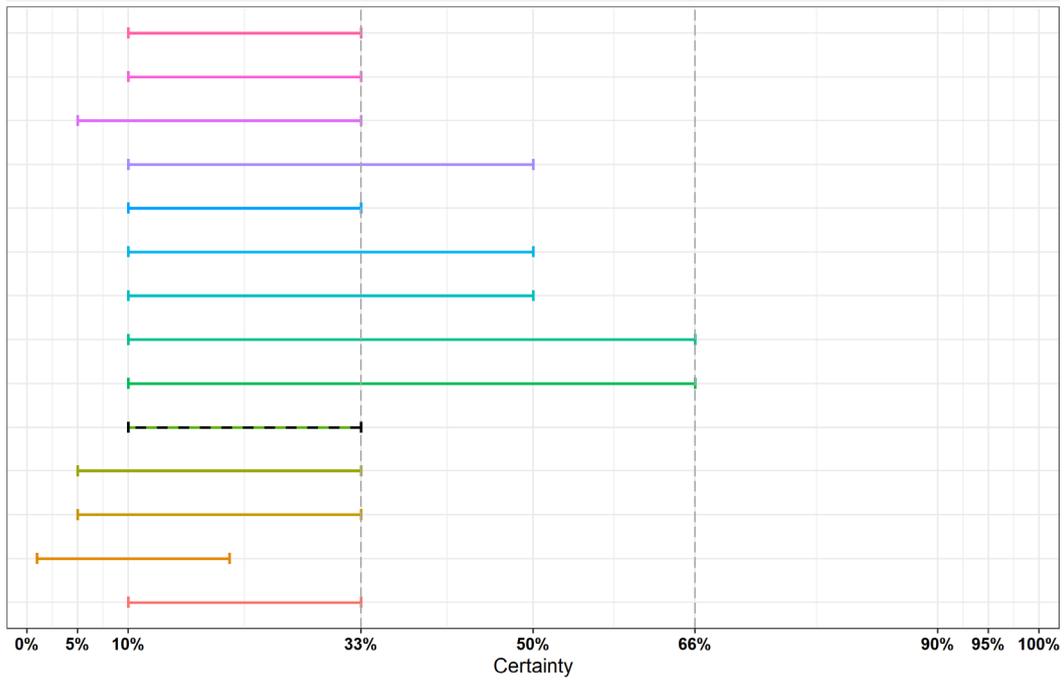
CI: current impact

The median range is displayed as a dashed line.

Figure A.25: Individual probability ranges reflecting non-fulfilment of Criterion 5(c) (current impact) (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) after the collective judgement

Collective Assessment

Art. 9: 5(c) (PI)



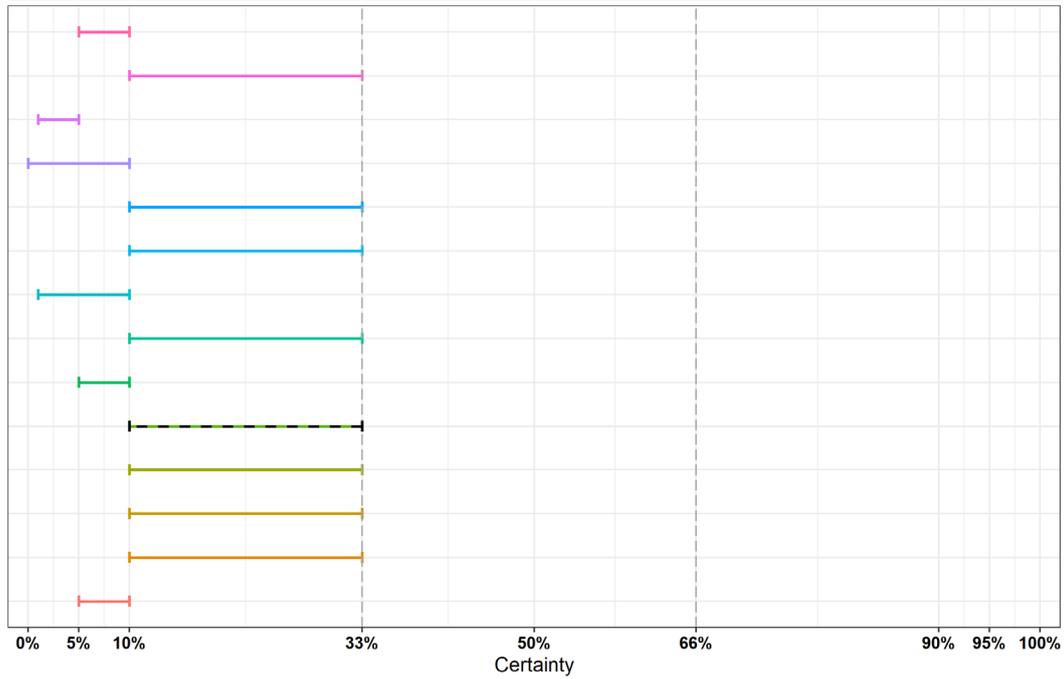
PI: potential impact

The median range is displayed as a dashed line.

Figure A.26: Individual probability ranges reflecting non-fulfilment of Criterion 5(c) (potential impact) (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) after the collective judgement

Collective Assessment

Art. 9: 5(d) (CI)



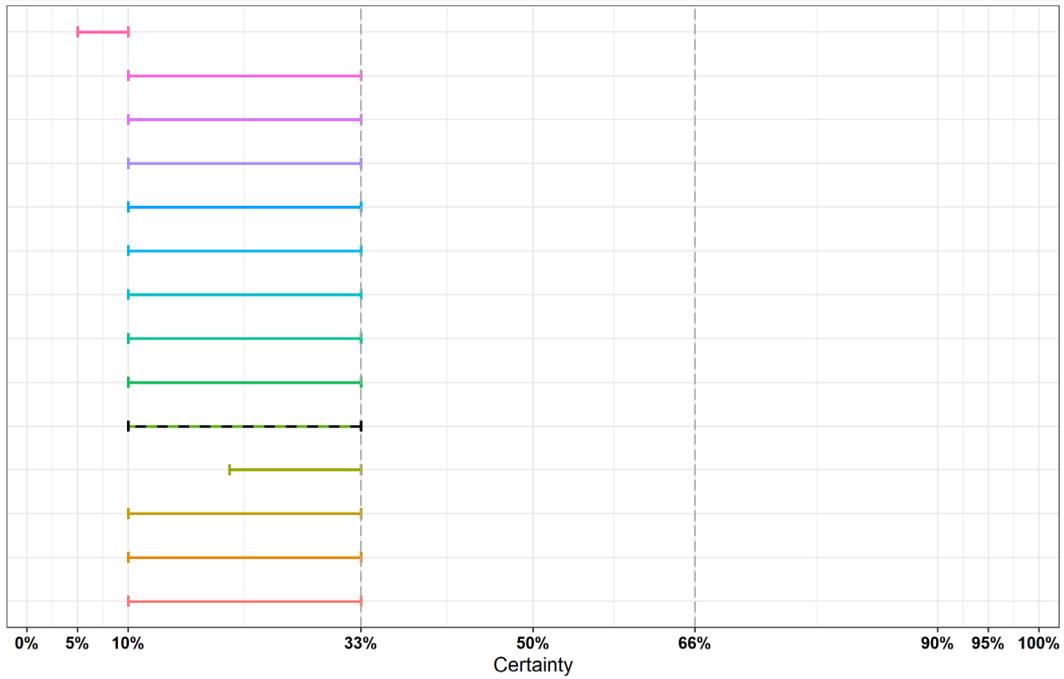
CI: current impact

The median range is displayed as a dashed line.

Figure A.27: Individual probability ranges reflecting non-fulfilment of Criterion 5(d) (current impact) (the disease has a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds) after the collective judgement

Collective Assessment

Art. 9: 5(d) (PI)



PI: potential impact

The median range is displayed as a dashed line.

Figure A.28: Individual probability ranges reflecting non-fulfilment of Criterion 5(d) (potential impact) (the disease has a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds) after the collective judgement

Appendix B – Criteria with uncertain outcome

B.1. Article 5 criteria

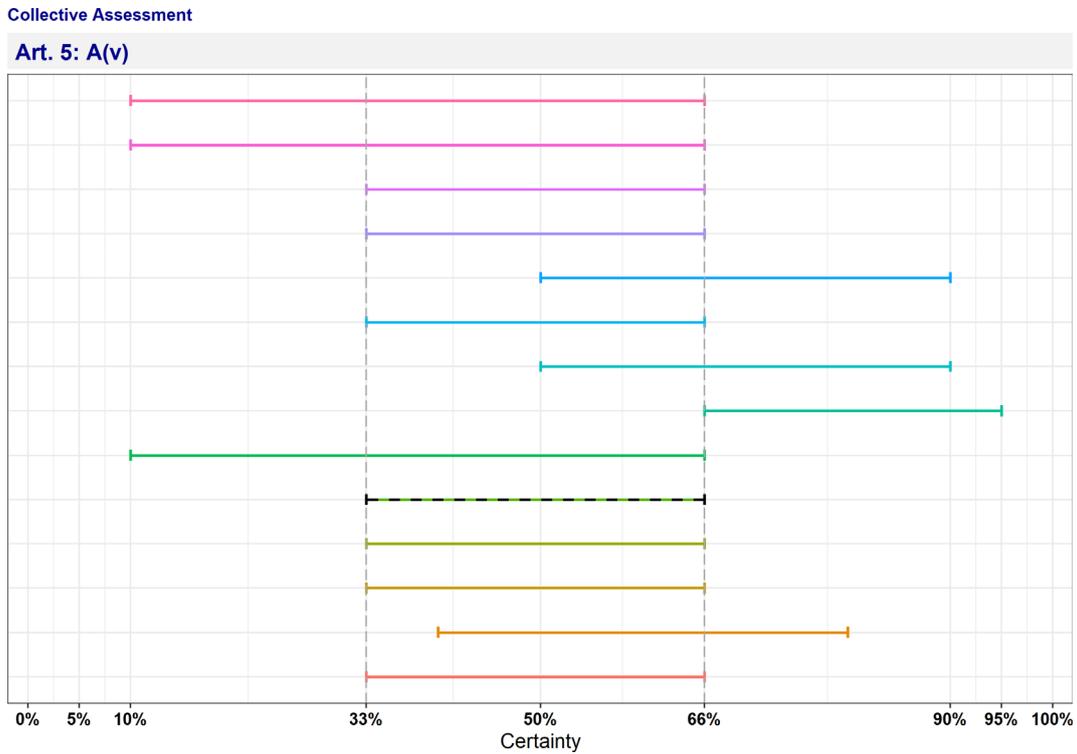


Figure B.1: Individual probability ranges reflecting uncertain outcome on Criterion A(v) (risk-mitigating measures and, where relevant, surveillance of the disease are effective and proportionate to the risks posed by the disease in the Union) after the collective judgement

B.2. Article 9 criteria

Collective Assessment

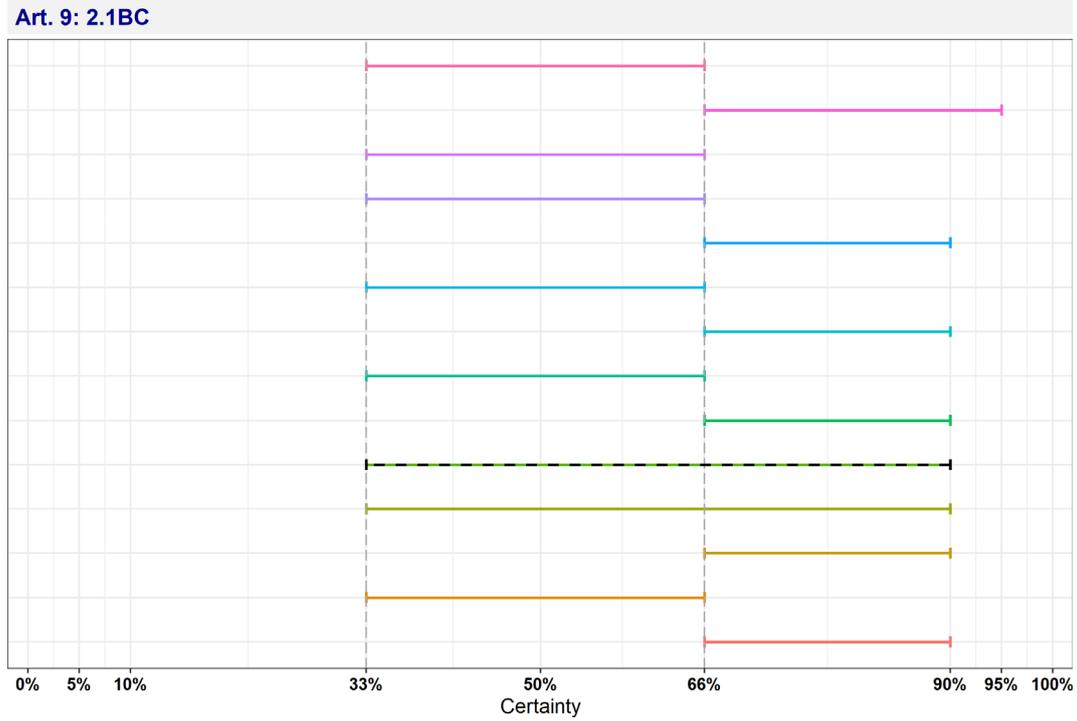
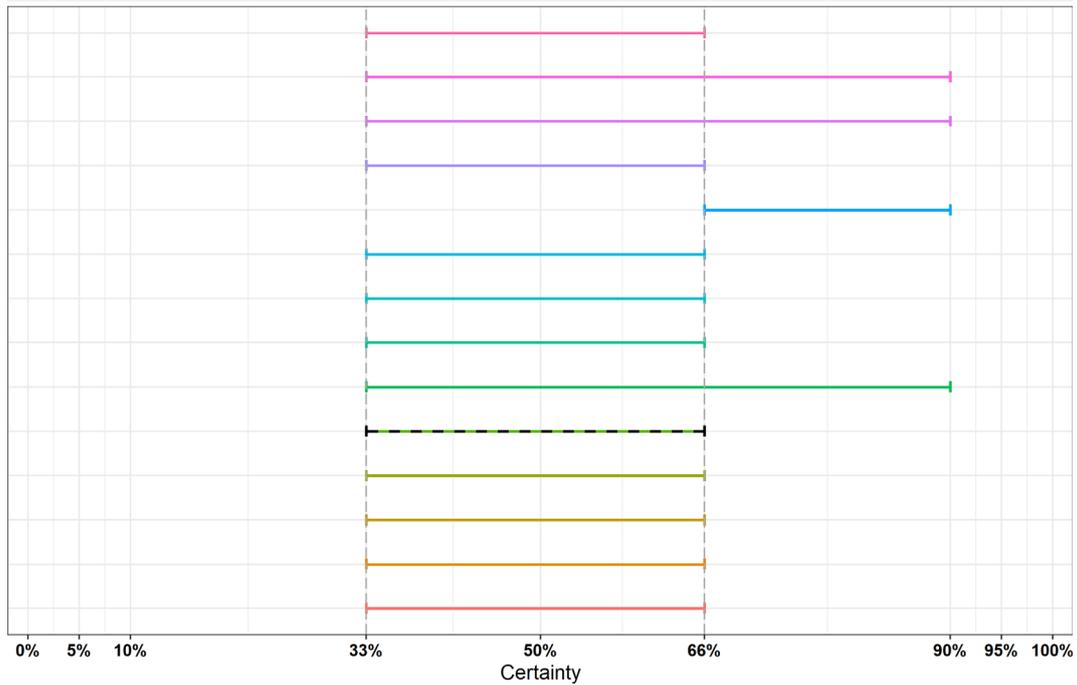


Figure B.2: Individual probability ranges reflecting uncertain outcome on Criterion 2.1BC (the disease is moderately to highly transmissible) after the collective judgement

Collective Assessment

Art. 9: 2.2AB

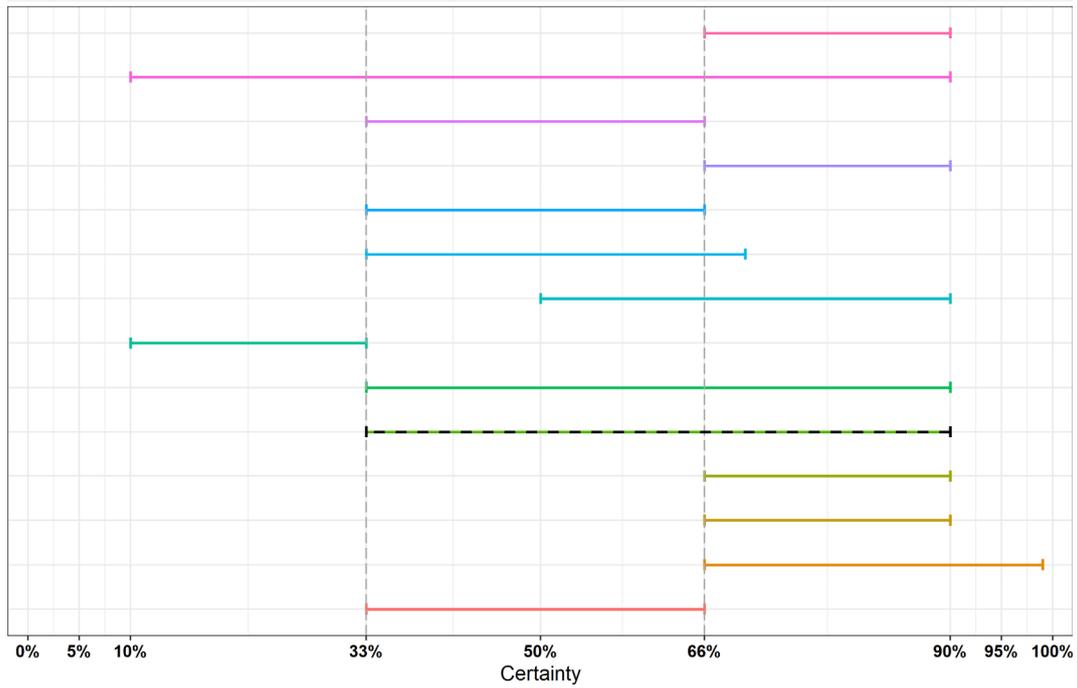


The median range is displayed as a dashed line.

Figure B.3: Individual probability ranges reflecting uncertain outcome on Criterion 2.2AB (there are possibilities of airborne or waterborne or vector-borne spread) after the collective judgement

Collective Assessment

Art. 9: 2.4A

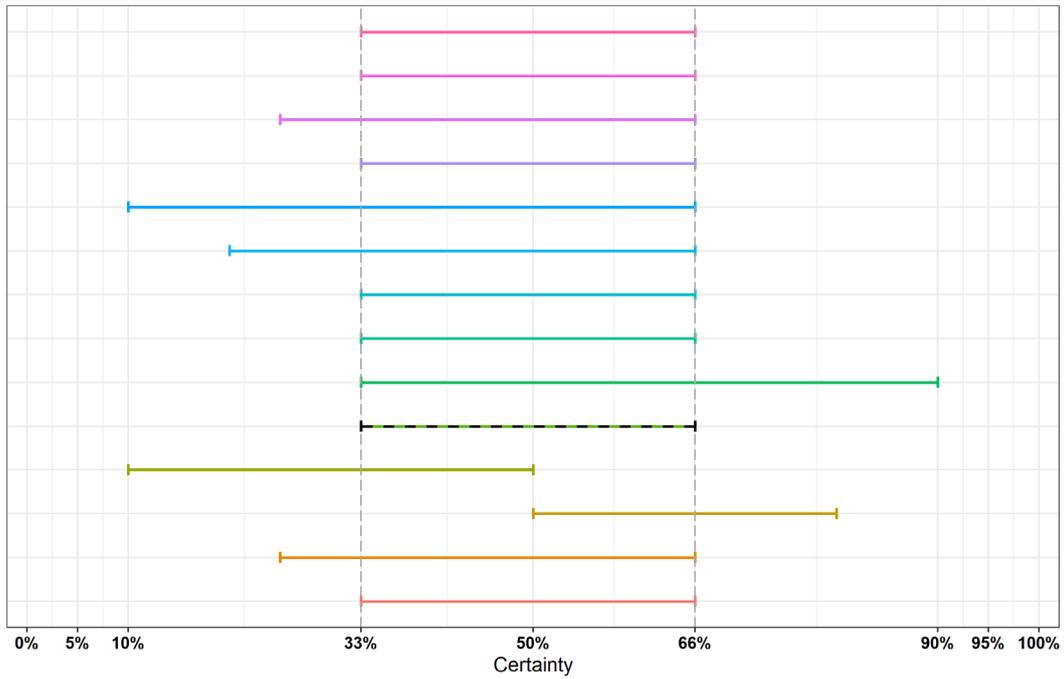


The median range is displayed as a dashed line.

Figure B.4: Individual probability ranges reflecting uncertain outcome on Criterion 2.4A (the disease may result in high morbidity and significant mortality rates) after the collective judgement

Collective Assessment

Art. 9: 4AB (PI)



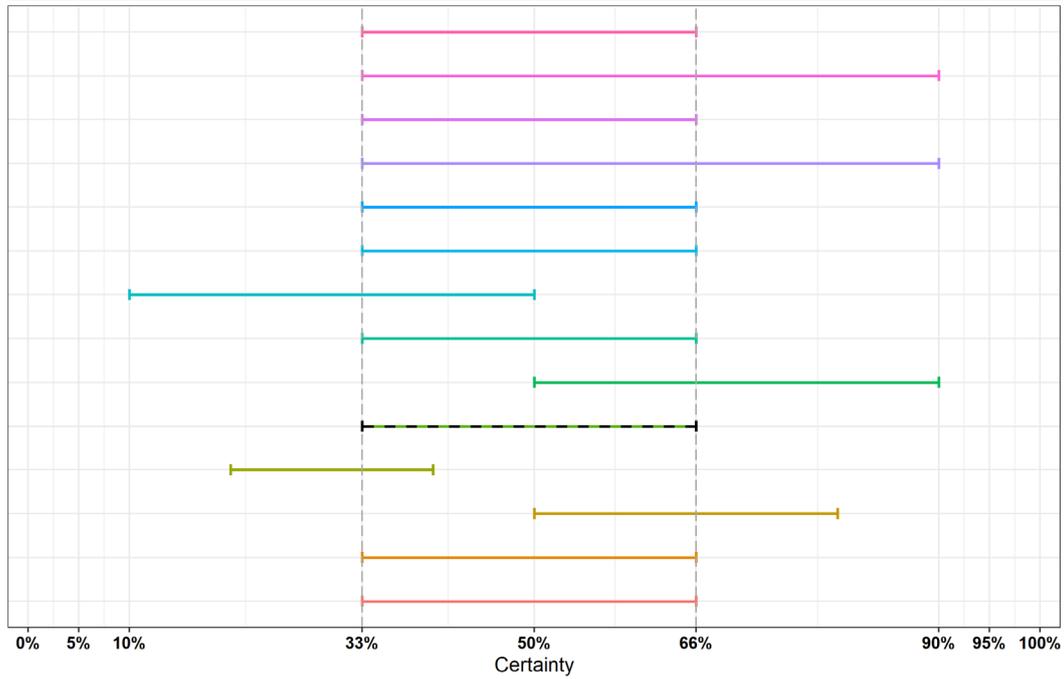
PI: potential impact

The median range is displayed as a dashed line.

Figure B.5: Individual probability ranges reflecting uncertain outcome on Criterion 4AB (potential impact) (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) after the collective judgement

Collective Assessment

Art. 9: 4C (CI)



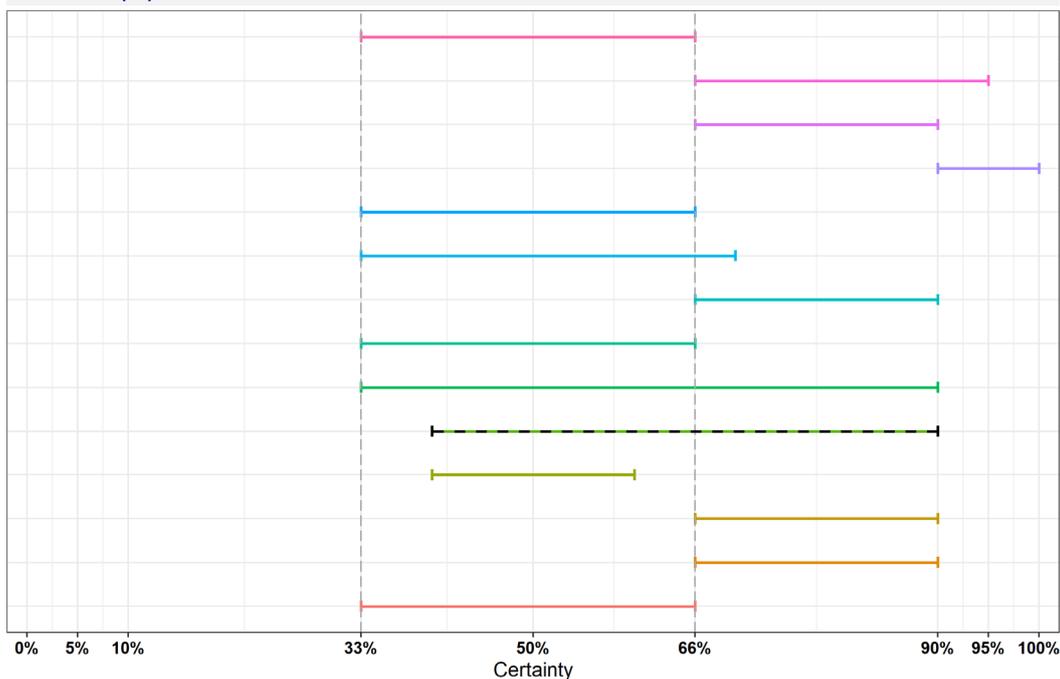
CI: current impact

The median range is displayed as a dashed line.

Figure B.6: Individual probability ranges reflecting uncertain outcome on Criterion 4C (current impact) (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) after the collective judgement

Collective Assessment

Art. 9: 4C (PI)

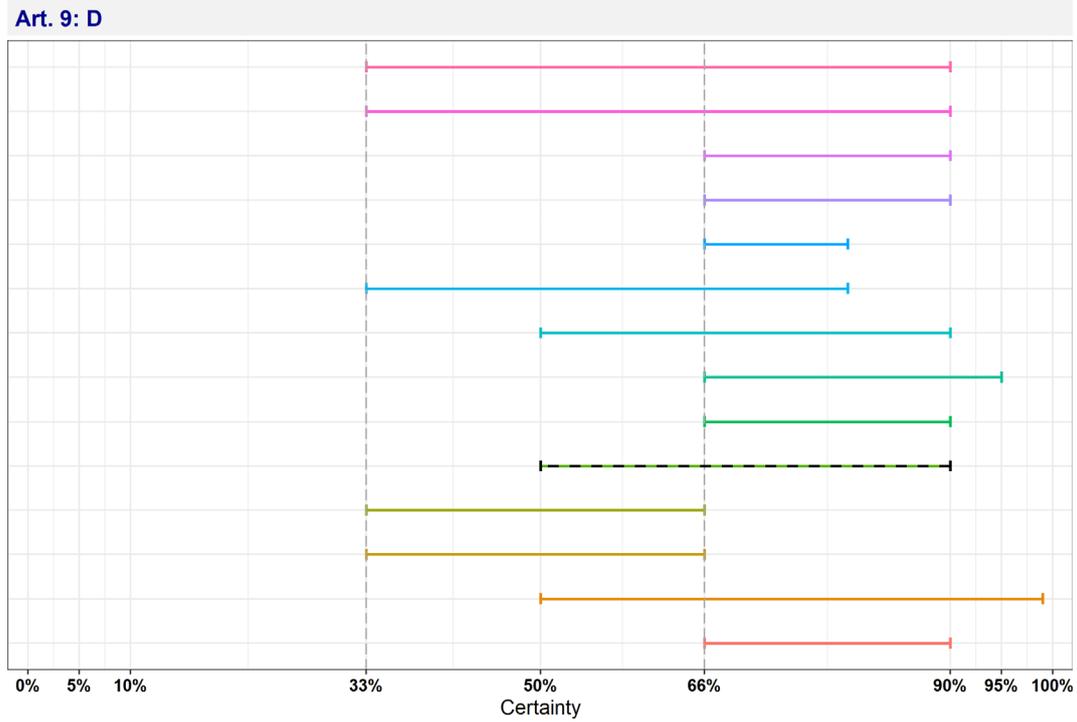


PI: potential impact

The median range is displayed as a dashed line.

Figure B.7: Individual probability ranges reflecting uncertain outcome on Criterion 4C (potential impact) (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) after the collective judgement

Collective Assessment



The median range is displayed as a dashed line.

Figure B.8: Individual probability ranges reflecting uncertain outcome on Criterion D (the risk posed by the disease can be effectively and proportionately mitigated by measures concerning movements of animals and products in order to prevent or limit its occurrence and spread) after the collective judgement