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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 *Staphylococcus pseudintermedius* in dogs and cats

EFSA Panel on Animal Health and Welfare (AHAW),
Søren Saxmose Nielsen, Dominique Joseph Bicout, Paolo Calistri, Elisabetta Canali, Julian Ashley Drewe, Bruno Garin-Bastuji, José Luis Gonzales Rojas, Christian Gortázar, Mette Herskin, Virginie Michel, Miguel Ángel Miranda Chueca, Barbara Padalino, Paolo Pasquali, Helen Clare Roberts, Hans Spoolder, Karl Ståhl, Antonio Velarde, Arvo Viltrop, Christoph Winckler, Francesca Baldinelli, Alessandro Broglia, Lisa Kohnle and Julio Alvarez

## Abstract

*Staphylococcus pseudintermedius* (*S. pseudintermedius*) was identified among the most relevant antimicrobial-resistant (AMR) bacteria in the EU for dogs and cats 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 *S. pseudintermedius* can be considered eligible to be listed for Union intervention according to Article 5 of the AHL (30–90% 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 4 (Categories A, B and D; 0–1%, 1–10% and 10–33% probability of meeting the criteria, respectively) and the AHAW Panel is uncertain whether it meets the criteria in Sections 3 and 5 (Categories C and E, 5–66% and 30–90% probability of meeting the criteria, respectively). The animal species to be listed for AMR *S. pseudintermedius* according to Article 8 criteria are mostly species belonging to the families of Canidae and Felidae, such as dogs and cats.



**Keywords:** antimicrobial resistance, *Staphylococcus pseudintermedius*, Animal Health Law, listing, categorisation, impact

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**Correspondence:** alpha@efsa.europa.eu

**Panel members:** Søren Saxmose Nielsen, Julio Alvarez, Dominique Joseph Bicout, Paolo Calistri, Elisabetta Canali, Julian Ashley Drewe, Bruno Garin-Bastuji, José Luis Gonzales Rojas, Christian Gortázar, Mette Herskin, Virginie Michel, Miguel Ángel Miranda Chueca, Barbara Padalino, Paolo Pasquali, Helen Clare Roberts, Hans Spoolder, Karl Ståhl, Antonio Velarde, Arvo Viltrop and Christoph Winckler.

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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 2016/429[1] 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 dogs and cats were published in a separate EFSA scientific opinion (EFSA AHAW Panel, 2021a).

According to the results of the assessment already conducted, *Staphylococcus pseudintermedius* (*S. pseudintermedius*) was identified among the most relevant AMR bacteria in the EU for dogs and cats due to its frequent implication in clinical disease in dogs and cats and to the high levels of resistance to clinically relevant antimicrobials – β-lactams, lincosamide and fluoroquinolones – both globally and in some cases also in the EU (Table 3 in EFSA AHAW Panel (2021a)). Also, its relevance as AMR pathogen is evidenced by the very large number of antimicrobial susceptibility testing results for the antimicrobials of interest (~ 83,000) that were retrieved through the extensive literature review conducted to address ToR 1 in EFSA AHAW Panel (2021a).

This scientific opinion presents the results of the assessment on AMR *S. pseudintermedius* in dogs and cats on its eligibility to be listed and categorised within the AHL framework. Special focus is placed on the animal health impact of AMR *S. pseudintermedius* in dogs and cats 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 *S. pseudintermedius* in dogs and cats according to the criteria of the AHL articles as follows:

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

[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.

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 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 *Staphylococcus pseudintermedius* according to Article 7 criteria of the AHL

### 3.1.1. Article 7(a) Disease profile

*S. pseudintermedius* are Gram-positive, non-motile, facultative anaerobic, coagulase-positive cocci belonging to the '*Staphylococcus intermedius* group', which also comprises *S. intermedius* and *S. delphini*. Information on antimicrobial resistance is almost only available in dogs and to a smaller extent in cats. For more detailed information on antimicrobial resistance in canine and feline isolates, we refer to other literature including the recent EFSA scientific opinion on the most relevant AMR bacteria in the EU for dogs and cats (EFSA AHAW Panel, 2021a), where this topic has been reviewed extensively with tables and figures showing proportion of resistance to all clinically relevant antibiotics in clinical *S. pseudintermedius* isolates from across the world.

When possible, information provided in this fact sheet has been specified for methicillin-resistant isolates (MRSP) or lincosamide-resistant isolates:

- MRSP is by definition resistant to all β-lactams, which constitute the most important and widely used antibiotic class for animals. MRSP emerged in dogs around 15 years ago and is nowadays globally disseminated. In Europe, the recent EFSA scientific opinion showed a weighted arithmetic mean of 5.8% methicillin resistance among canine and feline clinical *S. pseudintermedius* strains reported in Europe. Scandinavian countries generally have proportions around or less than 5%, whereas the proportion elsewhere in Europe is often higher, even above 40% in some countries (EFSA AHAW Panel, 2021a). The most prevalent MRSP clone in Europe, called ST71, is typically also – apart from β-lactams – resistant to several other drug classes (Perreten et al., 2010). In fact, ST71 may be impossible to treat with antibiotics registered for systemic use in animals. In the last decade, ST71 has become less dominant in Europe, since other less resistant clones have started to spread. Most of these belong to the genetic group CC258 (Pires Dos Santos et al., 2016).
- Resistance to lincosamides (e.g. lincomycin and clindamycin) is clinically important, as lincosamides are generally recommended as one of the first-choice options for canine skin infections (see Parameter 2 in Section 3.1.1.8). Despite large variations between countries, resistance to lincosamides is much more widespread than methicillin resistance with a weighted arithmetic mean of resistance among clinical canine and feline isolates reported in Europe being 22.5% (EFSA AHAW Panel, 2021a). Whenever information in the fact sheet on carriage rate (i.e. proportion of a population colonised or carrying the bacterium somewhere in

the body) is not further elaborated in terms of methicillin or lincosamide resistance, it is because the information available on carriage does not specify such antimicrobial resistance.

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

*S. pseudintermedius* is an opportunistic pathogen adapted to the family of Canidae, such as dogs (*Canis lupus familiaris*), which are the natural hosts. Dogs are also the most frequently infected animal species, where *S. pseudintermedius* mainly causes skin infections and otitis externa. A large study, performed in Germany on 16,103 clinical samples from different animal species, showed that 94.4% of the samples positive for *S. pseudintermedius* originated from dogs, and the remaining samples were from cats (3.0%) and horses (2.6%) (Ruscher et al., 2009). The same study also showed that the prevalence of MRSP isolates in clinical specimens was significantly higher in dogs (6.8%) and cats (6.6%) than in horses (2.7%) ($p < 0.001$). Domestic cats (*Felis catus*) are susceptible to this opportunistic pathogen but are not regarded as natural hosts due to the low carriage rates in healthy individuals. A recent study investigating the epidemiology of *S. pseudintermedius* in 595 healthy and 81 sick cats in Poland reported carriage rates of 2.5% and 7.6%, respectively, and showed that cats kept together with dogs are more frequently colonised (Bierowiec et al., 2021). The study found methicillin resistance in 5% and 46% of isolates from healthy and sick cats, respectively. The corresponding percentages for clindamycin resistance were 41% and 54%, respectively. Rare infections have been reported in horses and cattle, most likely as a consequence of exposure to dogs (Bannoehr and Guardabassi, 2012).

*Susceptible animal species*

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

There is very little information available in the scientific literature on the susceptibility of wild animal species to *S. pseudintermedius*. Sporadic reports suggest that infections can occur in wild animal species belonging to Canidae such as arctic foxes (*Vulpes lagopus*) (Iwata et al., 2018), and amongst Felidae such as Amur (Siberian) tigers (*Panthera tigris altaica*) (Jee et al., 2007). However, the two cases reported were in kept (probably exposed to contaminated environment) and stressed animals after transportation.

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

Mainly dogs (*Canis lupus familiaris*) and other members of Canidae, to a lesser extent cats (*Felis catus*) and other members of Felidae are naturally susceptible. Rare infections have been reported in horses and cattle, most likely as a consequence of exposure to dogs (Bannoehr and Guardabassi, 2012).

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

No information is available on experimentally susceptible wildlife species.

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

For laboratory animals, there is a model for cutaneous infections in the house mouse (*Mus musculus*) (Richards et al., 2018).

*Reservoir animal species*

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

Knowledge of *S. pseudintermedius* colonisation in wildlife is limited to a North American study performed on coyotes (*Canis latrans*), red foxes (*Vulpes vulpes*) and Gray foxes (*Urocyon cinereoargenteus*), which confirmed abundance of this staphylococcal species on the skin of these animals (DeCandia et al., 2019). A few other studies reported the occurrence of *S. pseudintermedius* in red foxes in Denmark (Guardabassi et al., 2012) and in an arctic fox imported from Norway (*Vulpes lagopus*) (Iwata et al., 2018). Altogether, it appears that for this staphylococcal species, wild species belonging to Canidae are likely reservoirs.

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

Dogs (*Canis lupus familiaris*) mainly and to a lesser extent cats (*Felis catus*) constitute the domestic reservoir.

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

*Morbidity*

Parameter 1 – Prevalence/incidence

Prevalence and incidence cannot be accurately measured for multiple reasons. First, *S. pseudintermedius* is a ubiquitous commensal bacterium of skin and mucosae in dogs. The high variability of carriage reported from cross-sectional studies (46–92%) is likely to reflect differences in study population, number and types of body sites sampled, and sampling methods (Bannoehr and Guardabassi, 2012). Longitudinal studies show that virtually any dog is colonised either transiently or permanently during the course of life (Bannoehr and Guardabassi, 2012). Second, *S. pseudintermedius* is not associated with a single disease as it is responsible for a large variety of opportunistic infections, mainly skin infections and otitis externa but also systemic infections of the urinary, respiratory and reproductive tract. Prevalence varies significantly depending on infection type and no reliable estimates are available on the prevalence of each type of infection at the population level. Third, all diseases associated with *S. pseudintermedius* can be caused by other bacterial species and the relative contribution by this opportunistic pathogen varies significantly between diseases as well as between studies of the same disease. For example, the isolation rates of *S. pseudintermedius* reported in the scientific literature for canine pyoderma (up to 92%), otitis externa (20–94%), urinary tract infections (6–95%), respiratory infections (9–60%) and pyometra (10–18%) are extremely variable across studies (Lynch and Helbig, 2021).

The occurrence of AMR infections has increased over the last decades, especially after the emergence of MRSP strains, which typically display a multidrug-resistant phenotype (van Duijkeren et al., 2011). MRSP prevalence varies significantly depending on geographical region and study population. Information on proportion of lincosamide and methicillin resistance in clinical *S. pseudintermedius* in dogs and cats is reported in Table 2.

**Table 2:** Weighted arithmetic mean, minimum and maximum proportions of resistance (%R or %R + I) and weighted standard deviation in *S. pseudintermedius* for the target antimicrobials on each continent (EFSA AHAW Panel, 2021a)

| Antibiotic | Continent | Number of papers | Number of isolates | Weighted arithmetic mean (% of resistance) | Minimum resistance (% observed) | Maximum resistance (% observed) | Standard deviation |
|---|---|---|---|---|---|---|---|
| Lincosamides | Africa | 1 | 278 | 31.7 | 31.7 | 31.7 | NA |
| | Asia | 3 | 493 | 46.9 | 20.1 | 78 | 26.7 |
| | Europe | 10 | 7,732 | 22.5 | 13 | 98.6 | 8.8 |
| | Oceania | 2 | 1,069 | 8.8 | 3.3 | 12.6 | 4.6 |
| Methicillin | Asia | 8 | 1,106 | 29.5 | 4 | 72.2 | 25.5 |
| | Europe | 23 | 19,909 | 5.8 | 0 | 41.4 | 4.2 |
| | North America | 3 | 274 | 32.2 | 21 | 41 | 8.8 |
| | Oceania | 1 | 629 | 12.9 | 12.9 | 12.9 | NA |
| | South America | 2 | 208 | 29.3 | 14.1 | 39.8 | 12.7 |

NA: standard deviation cannot be calculated because only one study was included.

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

No data are available to measure case-morbidity rate for *S. pseudintermedius*.

*Mortality*

Parameter 3 – Case-fatality rate

The mortality rates of life-threatening infections such as septicaemia, peritonitis and pneumonia are not well documented in dogs, and each of these infections can be caused by bacterial species other than *S. pseudintermedius*. Obviously, case-fatality rate depends on infection type. While the most common infections associated with *S. pseudintermedius* (e.g. pyoderma and otitis) are not a cause of

death, others such as neonatal septicaemia can result in outbreaks with fatality rates up to 75–90% (Pipan et al., 2019). Mortality specifically linked to AMR *S. pseudintermedius* has not been investigated.

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

Parameter 1 – Report of zoonotic human cases (anywhere)

*S. pseudintermedius* is not a normal coloniser of the human skin and mucosae, but individuals that live or work in close contact with dogs may be transiently colonised (Weese and van Duijkeren, 2010). Sharing of indistinguishable strains between people and dogs within the same household has been demonstrated, supporting the hypothesis of zoonotic transmission (Gómez-Sanz et al., 2013). It should be noted that human colonisation is likely transient or just contamination as indicated by a longitudinal study showing that MRSP-positive individuals were never positive more than once (Laarhoven et al., 2011).

Human infections due to *S. pseudintermedius* are rare and most cases are directly related to close contact with a pet dog (Somayaji et al., 2016a). As for any other opportunistic pathogen, the type of infection is extremely variable but most infections are mild to moderate. In the largest human case series to date, skin and soft tissue infections occurred in 18 of 20 patients, and the two remaining patients suffered bloodstream and prosthetic joint infection (Somayaji et al., 2016b). Three of the 20 patients were infected with an MRSP strain, whereas resistance to clindamycin appeared to be slightly more widespread. The same study reported a very low incidence rate of skin and soft tissue infections associated with *S. pseudintermedius* (0.025%) compared with *S. aureus* rates (30.0%) (Somayaji et al., 2016b).

As for the frequency of transmission, in a recent study where 108 dog owners were screened for nasal carriage of *S. pseudintermedius*, six of them (5.6%) were found to be positive (Walther et al., 2012). Of these six owners, one carried a *mecA*-positive isolate (MRSP), and another one carried a clindamycin-resistant isolate. Another owner shared an isolate genetically similar to the isolate of his/her dog (suggestive of possible transmission), and this isolate was resistant to penicillin. In another study performed on a sample of 122 households, *S. pseudintermedius* was isolated from the nasal cavity of eight (4.1%) of the dog owners (Hanselmann et al., 2009). One of the eight isolates was an MRSP. An older study found a significantly higher proportion of nasal or oral carriage of *S. intermedius* (likely *S. pseudintermedius*) in owners of dogs with deep pyoderma (7 of 13 owners positive) compared to people not in daily contact with dogs (1 of 13 persons positive). Six out of the 13 (46%) dog owners carried isolates genetically indistinguishable from those of their dogs (Guardabassi et al., 2004). Isolates showed variable resistance, with some isolates being resistant to up to five antimicrobial classes (penicillins, fusidic acid, macrolides/lincosamides, tetracycline and chloramphenicol).

Since the antimicrobial classes used in companion animals and humans largely overlap, the EU Committee for Medicinal Products for Veterinary Use has listed MRSP among the multidrug-resistant bacteria originating from companion animals that directly or indirectly may cause adverse health effects in humans (CVMP, 2013).

#### 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

Treatment of *S. pseudintermedius* infections has become increasingly difficult after the emergence and spread of methicillin-resistant MRSP since 2006 (van Duijkeren et al., 2011). Methicillin resistance is mediated by the *mecA* gene, which confers resistance to β-lactams. However, certain MRSP strains are typically pan-drug resistant, as they display resistance to virtually all antimicrobials authorised for veterinary use, including sulfonamides, lincosamides, macrolides, tetracyclines, aminoglycosides and fluoroquinolones in addition to β-lactams. These strains pose a serious challenge in small animal veterinary medicine because of the very limited therapeutic options, leading to increasing use of antimicrobials authorised only for human medicine. Fortunately, most MRSP infections are skin or soft tissue infections that can be managed successfully by topical treatment (Loeffler and Lloyd, 2018). As stated in the introduction to this fact sheet, the proportion of MRSP amongst clinical isolates varies considerably depending on the geographic region, but also depending on the dog population studied. Five MRSP clonal complexes (CC) are responsible for the vast majority of MRSP infections worldwide (CC71, CC68, CC258, CC45 and CC112) and differ substantially with regard to antimicrobial resistance profiles and geographical distribution (Pires Dos Santos et al., 2016). More information on AMR

*S. pseudintermedius* can be retrieved in the recent EFSA scientific opinion for dogs and cats (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

Although *S. pseudintermedius* is not responsible for transmissible disease, healthy and sick animals can transmit bacterial strains to other animals (see Section 3.1.1.6). Healthy carriers can be considered as persistent sources for transfer of the bacteria (not the disease) to other animals. Duration of the infectious period for sick animals depends on the specific disease. Some forms of deep skin pyoderma may persist for several weeks and require long treatment periods (4–6 weeks or 2 weeks beyond clinical resolution).

Parameter 2 – Presence and duration of latent infection period

There are no data to estimate duration of latent infection period for *S. pseudintermedius* infections.

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

Various cross-sectional studies have shown that 46–92% of healthy dogs carry *S. pseudintermedius* (Devriese and De Pelsmaecker, 1987; Griffeth et al., 2008; Hanselman et al., 2009; Rubin and Chirino-Trejo, 2011; Paul et al., 2012). This large variation is likely due to differences between studies concerning the number and types of sampling sites, sampling methods and methods used for microbiological culture. Longitudinal study designs have been used to investigate duration of carriage of *S. pseudintermedius* in healthy dogs. Such studies are also largely non-comparable due to differences in study design, but it appears that some dogs are non-carriers, whereas others are intermittent or persistent carriers. One study (Paul et al., 2012) showed that 15 of 16 dogs sampled 10 times over 1 year carried *S. pseudintermedius* in at least one sampling time. Six of the dogs (37%) were persistent carriers, and it was concluded that persistent colonisation of *S. pseudintermedius* in healthy dogs is relatively higher than that of *S. aureus* in humans (about 20%).

*Environment*

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

No studies are available about the length of survival of *S. pseudintermedius* in different matrices.

#### 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)

*S. pseudintermedius* can be transmitted both vertically from bitches to puppies and horizontally between individual animals via direct contact or environmental transmission (Bannoehr and Guardabassi, 2012). A recent study has confirmed transmission of *S. pseudintermedius* causing fatal sepsis in puppies through dam's milk (Pipan et al., 2019). A more recent study, based on a whole-genome sequencing approach, showed likely transmission of a multidrug-resistant MRSP isolate between a dog and cat visiting the same clinic 9 days apart (Papić et al., 2021). In that case, the clinic environment or the veterinary staff was likely contaminated causing indirect transmission of the strain. The same study showed that an environmental isolate from a clinic and a canine clinical isolate were indistinguishable. Importantly, bacterial transmission and colonisation are generally not causally related to disease occurrence, since these bacteria are harmless commensals of the skin and mucosae of the dog. Infections caused by this bacterium are not transmissible between diseased and healthy dogs. As for other opportunistic pathogens, disease is triggered by host factors and underlying conditions, and individuals usually become infected with a strain that they carry on their body (Bannoehr and Guardabassi, 2012).

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

Due to the rare occurrence of human infections caused by *S. pseudintermedius*, the routes of transmission between animals and humans have not been extensively investigated. Based on the ecology and epidemiology of this bacterial species, it is expected that transmission mainly occurs from dogs to humans either via direct contact and bites or indirectly through exposure to environments contaminated by dogs. There is no evidence that this bacterial species can be transmitted via contaminated food.

*Speed of transmission*

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

As for the frequency of transmission, in a recent study where 108 dog owners were screened for nasal carriage of *S. pseudintermedius*, six of them (5.6%) were found to be positive (Walther et al., 2012). Of these six owners, one carried a *mecA*-positive isolate (MRSP), and another one carried a clindamycin-resistant isolate. Another owner shared an isolate genetically similar to the isolate of his/her dog (suggestive of possible transmission), and this isolate was resistant to penicillin. In another study performed on a sample of 122 households, *S. pseudintermedius* was isolated from the nasal cavity of eight (4.1%) of the dog owners (Hanselmann et al., 2009). One of the eight isolates was an MRSP. An older study found a significantly higher proportion of nasal or oral carriage of *S. intermedius* (likely *S. pseudintermedius*) in owners of dogs with deep pyoderma (7 of 13 owners positive) compared to people not in daily contact with dogs (1 of 13 persons positive). Six out of the 13 (46%) dog owners carried isolates genetically indistinguishable from those of their dogs (Guardabassi et al., 2004). Isolates showed variable resistance, with some isolates being resistant to up to five antimicrobial classes (penicillins, fusidic acid, macrolides/lincosamides, tetracycline and chloramphenicol).

Parameter 4 – Transmission rate ($\beta$) (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

The distribution of *S. pseudintermedius*, including resistant variants, is clearly endemic, since this is a ubiquitous bacterial species worldwide. However, occurrence of disease is sporadic and limited to individuals predisposed to disease by underlying conditions such as allergy, hormonal dysfunctions, anatomical defects, immunosuppression, etc. MRSP is a recognised nosocomial pathogen associated with surgical wound infections (Bannoehr and Guardabassi, 2012); hence, it appears that these variants are more likely to spread in hospitals than methicillin-susceptible variants.

*Risk of introduction*

This section is not relevant due to the ubiquitous occurrence of this bacterial species in the EU.

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

*Diagnostic tools*

Parameter 1 – Existence of diagnostic tools

Routine diagnostics is based on bacterial culture of samples from animals presenting with clinical signs of bacterial infection. *S. pseudintermedius* cannot be distinguished clearly from related coagulase-positive staphylococcal species such as *S. intermedius* and *S. delphini* by phenotypic methods (Bannoehr and Guardabassi, 2012). Matrix-assisted laser desorption ionisation–time-of-flight mass spectrometry (MALDI-TOF MS) is the method of choice for species identification in diagnostic microbiology. An initial study estimated sensitivity and specificity of MALDI-TOF MS identification of *S. pseudintermedius* to be only 78% and 97%, respectively (Decristophoris et al., 2011). However,

improvement of the reference spectra library has allowed rapid and unambiguous identification of *S. pseudintermedius* by this method (Murugaiyan et al., 2014). Alternatively, various polymerase chain reaction (PCR)-based tests are available for species identification. The most widely used, a multiplex PCR targeting the thermonuclease (*nuc*) gene, has been shown to be both sensitive (99.8%) and specific (100%) for species identification of *S. pseudintermedius* (Sasaki et al., 2010). Recently, a novel real-time PCR assay targeting the *spsJ* gene was developed using an automated approach to compare genome sequences for PCR target selection, and showed to have 100% specificity for *S. pseudintermedius* identification (Verstappen et al., 2017).

Resistance to antibiotics can be detected in various ways, including by determination of the minimum inhibitory concentration (MIC) using broth or agar dilution, or using agar diffusion, e.g. by E-test. Antimicrobial resistance can also be detected using the disk diffusion method for which zone inhibition diameters are read. For specific detection of MRSP, oxacillin is known as the best indicator drug (Bemis et al., 2009). MRSP can be confirmed by the presence of *mecA*, typically revealed by PCR or sequencing. Alternatively, the product of *mecA*, namely penicillin-binding protein 2a (PBP2a), can be detected, e.g. by a latex agglutination test using antibodies specific for PBP2a.

Parameter 2 – Existence of control tools

No vaccines are available against *S. pseudintermedius*. Infections are controlled by antimicrobial treatment, which can be systemic or local depending on the infection type. The first choice of antibiotic also depends on the infection type. For systemic treatment of canine superficial bacterial folliculitis (most common skin infection of dogs and most often caused by *S. pseudintermedius*), recommendations by the International Society for Companion Animal Infectious Diseases have divided treatment options into first-, second- and third-tier options (Hillier et al., 2014). First-tier options include lincosamides (clindamycin, lincomycin), first-generation cephalosporins, amoxicillin-clavulanate and potentiated sulfonamides. Importantly, these are international recommendations, and individual countries may have local regulations and recommendations that are different depending on local occurrence of antimicrobial resistance and availability of drugs. For example, in a country with a high prevalence of MRSP, it would not make sense to recommend β-lactams, as MRSP is resistant to all drugs within this class. Superficial or surface pyoderma in dogs can often be treated topically with an antiseptic shampoo alone, thus lowering the risk of antimicrobial resistance selection compared to systemic treatment.

The measures to control and prevent *S. pseudintermedius* infection include surgical antimicrobial prophylaxis to prevent occurrence of surgical site infections, as well as personal hygiene, and environmental cleaning and disinfection to prevent spread in clinic and household environments (Morris et al., 2017).

### 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

Infections caused by *S. pseudintermedius* are present in all Member States and broadly in any country of the world due to the ubiquitous occurrence of this bacterial species in the commensal microbiota of dogs and other Canidae. As stated in the introduction to this fact sheet, antimicrobial resistance in *S. pseudintermedius*, including methicillin and lincosamide resistance, varies a lot between Member States (EFSA AHAW Panel, 2021a).

*The loss of production due to the disease*

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

Infectious diseases are the second most important cause of mortality in puppies, and among infectious causes, bacterial infections are the most common cause of neonatal mortality (Münnich and Küchenmeinster, 2014). *S. pseudintermedius* can cause neonatal septicaemia and mortality in breeding kennels (Pipan et al., 2019). However, no data are available to quantify the impact of *S. pseudintermedius* infections, including those caused by AMR strains, on the proportion of neonatal mortality in the dog breeding industry.

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

*Transmissibility between animals and humans*

Parameter 1 – Types of routes of transmission between animals and humans

Due to the rare occurrence of human infections caused by *S. pseudintermedius*, the routes of transmission between animals and humans have not been extensively investigated. Based on the ecology and epidemiology of this bacterial species, it is expected that transmission mainly occurs from dogs to humans either via direct contact and bites, or indirectly through exposure to environments contaminated by dogs. There is no evidence that this bacterial species can be transmitted via contaminated food. There is no reason to believe that resistant variants are more likely to be transmitted to humans than variants susceptible to antibiotics.

Parameter 2 – Incidence of zoonotic cases

Human infections are rare and most cases are directly related to close contact with a pet dog (Somayaji et al., 2016a). As for any other opportunistic pathogen, the type of infection is extremely variable but most infections are mild to moderate. In the largest human case series to date, skin and soft tissue infections occurred in 18 of 20 patients, and the two remaining patients suffered bloodstream and prosthetic joint infection (Somayaji et al., 2016b). The same study reported a very low incidence rate of skin and soft tissue infections associated with *S. pseudintermedius* (0.025%) compared with *S. aureus* rates (30.0%) (Somayaji et al., 2016b).

As for the frequency of transmission, in a recent study where 108 dog owners were screened for nasal carriage of *S. pseudintermedius*, six of them (5.6%) were found to be positive (Walther et al., 2012). Of these six owners, one carried a *mecA*-positive isolate (MRSP), and another one carried a clindamycin-resistant isolate. Another owner shared an isolate genetically similar to the isolate of his/her dog (suggestive of possible transmission), and this isolate was resistant to penicillin. In another study performed on a sample of 122 households, *S. pseudintermedius* was isolated from the nasal cavity of eight (4.1%) of the dog owners (Hanselmann et al., 2009). One of the eight isolates was an MRSP. An older study found a significantly higher proportion of nasal or oral carriage of *S. intermedius* (likely *S. pseudintermedius*) in owners of dogs with deep pyoderma (7 of 13 owners positive) compared to people not in daily contact with dogs (1 of 13 persons positive). Six out of the 13 (46%) dog owners carried isolates genetically indistinguishable from those of their dogs (Guardabassi et al., 2004). Isolates showed variable resistance, with some isolates being resistant to up to five antimicrobial classes (penicillins, fusidic acid, macrolides/lincosamides, tetracycline and chloramphenicol).

*Transmissibility between humans*

Parameter 3 – Human-to-human transmission is sufficient to sustain sporadic cases or community-level outbreak

There is no evidence that *S. pseudintermedius* can be transmitted between humans. Due to the host specificity of this staphylococcal species, human-to-human transmission is unlikely sufficient to sustain sporadic cases or certainly insufficient to result in community-level outbreaks.

Parameter 4 – Sporadic, epidemic or pandemic potential

Human infections caused by *S. pseudintermedius* are sporadic and have no potential for epidemic or pandemic spread.

*The severity of human forms of the disease*

Parameter 5 – Disability-adjusted life year (DALY)

There are no data to assess DALY attributable to *S. pseudintermedius* infections in humans.

*The availability of effective prevention or medical treatment in humans*

Parameter 6 – Availability of medical treatment and their effectiveness (therapeutic effect and any resistance)

As for animals, human *S. pseudintermedius* infections are treated using antimicrobials when necessary. Rare cases of human infections caused by MRSP strains have been reported in the scientific literature (Stegmann et al., 2010). Severe human infections can potentially be treated using a larger

repertoire of antimicrobial classes, including drugs that are not authorised for veterinary use and for which resistance has not been reported in MRSP (e.g. linezolid, quinupristin/dalfopristin and vancomycin).

Parameter 7 – Availability of vaccines and their effectiveness (reduced morbidity)

No vaccines are available.

#### 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

The impact of *S. pseudintermedius* infections on animal health and welfare clearly depends on the type of infection. This bacterial species is uncommonly associated with life-threatening infections. An Italian retrospective study investigating infectious causes of death in young dogs did not detect *S. pseudintermedius* among the most common bacterial species (Cardillo et al., 2020). *S. pseudintermedius* is usually isolated from skin infections and otitis externa, which are usually mild to moderate, although sporadic cases of rapidly progressive and rare conditions of fatal necrotising fasciitis have been reported in dogs (Weese et al., 2009). However, these mild and moderate infections of the integumentary system are widespread in the dog population and can result in long periods of disease, during which patients are subjected to pain and discomfort (e.g. pain, pruritus, scratching, etc.). Thus, skin and ear disease conditions have a considerable impact on animal welfare based on prevalence, duration and severity of discomfort. In a recent UK study assessing the comparative health-related welfare impact of eight common, breed-related disorders, otitis externa and dermatitis demonstrated amongst the highest overall severity scores, although had lower prevalence and duration scores compared to dental disorder, osteoarthritis and overweight/obese conditions, which resulted as the most impacting disorders (Summers et al., 2019). Based on the isolation rates of *S. pseudintermedius* from various infections, it appears that this bacterium may be involved as causative agent for otitis externa and pyoderma in up to 90% of clinical cases (Lynch and Helbig, 2021).

Antimicrobial resistance contributes to increase the impact of *S. pseudintermedius* infections on animal health and welfare. Multidrug-resistant MRSP infections may result in treatment failure, prolonging discomfort and pain in patients that do not respond to antimicrobial therapy. For example, a case of canine obstructive struvite urolithiasis associated with MRSP was reported to relapse for over 18 months and was eventually resolved with off-label treatment with vancomycin (Aizawa et al., 2017). Similarly, cases of persistent MRSP pyoderma may last over long periods of time during which the dogs experience numerous episodes of relapse or reinfection due to the limited number of effective and available antimicrobials (Bell et al., 2016). A study comparing treatment outcome of dogs with MRSP and non-MRSP pyoderma reported treatment failure in 3 of 88 (3%) MRSP infections treated with first-line agents (e.g. cephalexin or cefovecin) and in 7 of 76 (9%) MRSP infections treated with second-line antibiotics such as chloramphenicol and doxycycline (Bryan et al., 2012). The study showed that the majority of pyodermas resolved regardless of methicillin resistance, although some cases of MRSP pyoderma took longer to treat and adverse effects were frequently observed in dogs treated with chloramphenicol (Bryan et al., 2012). Adverse effects associated with use of chloramphenicol has been documented in approximately one-third of treatments, and consist mainly of gastrointestinal signs and hind limb weakness (Short et al., 2014). Similarly, parenterally administered vancomycin has been associated with cases of acute kidney injury, although this adverse effect could not definitely be attributed to the antibiotic because of illness severity and additional nephrotoxic treatments (DeStefano et al., 2019). Overall, adverse effects due to treatment with second-line antimicrobials should also be considered when assessing the impact of MRSP infections on animal welfare.

Antimicrobial resistance is also a factor predisposing to infection. MRSP carriage has been identified as a main risk for developing surgical site infections (Nazarali et al., 2015; Välkki et al., 2020). This is because MRSP is by definition resistant to cefazolin and other β-lactam antibiotics that are used for surgical prophylaxis in small animals.

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

There are no studies assessing the impact of *S. pseudintermedius* (including antibiotic-susceptible and resistant variants) on biodiversity and the environment. However, such impact is limited to the few animal species that are susceptible to this opportunistic pathogen, mainly dogs and other members of the Canidae.

*Biodiversity*

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

No studies are available on the impact of *S. pseudintermedius* on endangered wild species.

Parameter 2 – Mortality in wild species

Sporadic reports of fatal infections such as meningoencephalitis and nephritis in arctic fox (*Vulpes lagopus*) (Iwata et al., 2018) and Amur (Siberian) tiger (*Panthera tigris altaica*) (Jee et al., 2007) indicate that *S. pseudintermedius* can be a cause of death in wild species belonging to Canidae and Felidae.

*Environment*

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

No information is available on the persistence of *S. pseudintermedius* in natural environments. A longitudinal study showed that household environmental samples can be contaminated with MRSP in the absence of MRSP-positive animals or humans, indicating that MRSP can survive in household environments for prolonged periods of time (Laarhoven et al., 2011). A longitudinal study performed in a veterinary hospital showed an increase in contamination with coagulase-positive staphylococci (including *S. pseudintermedius*) associated with higher patient caseload and stable levels of contamination on surfaces that were less frequently cleaned, suggesting that persistence of contamination in the clinic environment could be secondary to lack of or inappropriate cleaning and disinfection (Hunter et al., 2021). The study found too few MRSP isolates to conclude anything about persistence of this resistant variant.

Potentially, antimicrobial resistance genes may also persist in the environment, but detection of e.g. *mecA* in the environment (without necessarily being present in a bacterium) would not explain anything about bacterial origin, as resistance genes may occur in many different bacterial species apart from *S. pseudintermedius*.

### 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

There are no officially/internationally recognised diagnostic tests. Diagnosis of *S. pseudintermedius* infection is based on clinical signs and standard bacterial culture and identification. Detection of resistance is based on the previously mentioned tools, namely MIC testing, disk diffusion and PCR for detection of resistance genes or products thereof.

*Effectiveness*

Parameter 2 – Sensitivity and specificity of diagnostic tests

There are no officially/internationally recognised diagnostic tests. As mentioned earlier, a study estimated sensitivity and specificity of MALDI-TOF MS identification of S. *pseudintermedius* to be only 78% and 97%, respectively (Decristophoris et al., 2011).

*Feasibility*

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

The type of sample matrix used for bacterial culture depends on the infection type. For example, for skin infections, swabs or biopsies of skin lesions (e.g. pustules) would be relevant.

#### 3.1.4.2. Article 7(d)(ii) Vaccination

No vaccines are available for preventing any of the diseases caused by *S. pseudintermedius*.

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

*Availability*

Parameter 1 – Types of drugs available on the market

Various antimicrobial agents are available on the market for treatment of *S. pseudintermedius* infections. The specific drugs used depend on the type of disease. For example, the antibiotics recommended for treatment of skin infections include lincosamides (e.g. clindamycin), amoxicillin-clavulanate or first-generation cephalosporins (e.g. cephalexin). Topical products containing antiseptics (e.g. chlorhexidine) such as shampoos, gels, etc., are recommended as the sole antimicrobial treatment for superficial skin infections. Similarly, topical products containing antibiotics or antiseptics are used for treatment of otitis externa. At present, no effective alternatives to antimicrobials are available for curing systemic infections caused by *S. pseudintermedius*.

*S. pseudintermedius*, and in particular certain MRSP clones like ST71, can be resistant to most or even all antibiotics licensed for systemic treatment of infections in animals. In these cases, veterinarians would have to try local antiseptic treatment (e.g. with shampoo) or use of systemic antibiotics not licensed or available for veterinary use (e.g. chloramphenicol, linezolid, vancomycin). The latter scenario would be relevant for infections that cannot be treated topically, such as deep pyoderma or urinary tract infection. An alternative would be to abstain from antimicrobial treatment and leave the cure to the immune system of the animal. In that regard, MRSP and clindamycin-resistant isolates are not necessarily more virulent than methicillin-susceptible isolates, and focusing on the removal of primary factors predisposing patients to infections (e.g. allergy, endocrine disorders, immune disorders, parasite infestation, etc., predispose to canine integumentary infections) might in some cases be sufficient for patients to recover.

Parameter 2 – Availability/production capacity (per year)

Antimicrobial drugs for treatment of *S. pseudintermedius* infections are widely available in the market worldwide.

*Effectiveness*

Parameter 3 – Therapeutic effects in the field (effectiveness)

Antimicrobial therapy is generally effective, although it is likely that in most cases treatment would fail or have reduced efficacy if a strain causing infection is resistant to the antimicrobial drug used. However, there are no data to assess the frequency and impact of treatment failure, and as mentioned above patients may recover even without an effective systemic antimicrobial regimen.

*Feasibility*

Parameter 4 – Way of administration

Systemic antimicrobials are usually administered orally to enhance treatment at home by animal owners. Skin infections can be treated topically without the need for systemic antimicrobial therapy. Parenteral administration is limited to perioperative antimicrobial prophylaxis or treatment of severe infections in hospitalised animals.

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

*Availability*

Parameter 1 – Available biosecurity measures

Various disinfectant products are available for prevention and control of *S. pseudintermedius* infections in veterinary settings. Regular cleaning and disinfection of environmental surfaces and

medical equipment (e.g. stethoscopes, thermometers, etc.) is important to prevent hospital-acquired infections. Such products are available as wipes, ready-to-use sprays or dilutable concentrates for larger areas.

*Effectiveness*

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

Biosecurity measures based on disinfection are effective against *S. pseudintermedius*. Also, MRSP strains can be killed by common disinfectants such as quaternary ammonium chloride- or hydrogen peroxide-containing products (Sohoo et al., 2020). Regular hand washing was shown to be a protective factor for *S. pseudintermedius* colonisation in humans (Hanselman et al., 2009).

*Feasibility*

Parameter 3 – Feasibility of biosecurity measures

Biosecurity measures based on disinfection are feasible and inexpensive.

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

*Availability*

Parameter 1 – Available movement restriction measures

Isolation of known MRSP patients and carriers is recommended to prevent spread and contamination within veterinary hospitals (Morris et al., 2017). It may involve housing a patient in a dedicated isolation ward or using enhanced precautions in a general ward.

*Effectiveness*

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

Physical separation in isolation units is considered to be more effective than procedural separation alone (Morris et al., 2017). The choice depends on various factors including availability and size of the isolation unit, ability to perform patient care activities in isolation, number of animals to be isolated and hospital type.

*Feasibility*

Parameter 3 – Feasibility of restriction of animal movement

Feasibility of isolation procedures depends on size and structure of the veterinary hospital.

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

*Availability*

Parameter 1 – Available methods for killing animals

Veterinarians may recommend euthanasia of patients affected by severe MRSP infections that have poor prognosis and cannot be treated effectively with veterinary antimicrobials.

*Effectiveness*

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

Animal euthanasia is not a measure for reducing spread of *S. pseudintermedius* infections but a way to end animal suffering in untreatable cases.

*Feasibility*

Parameter 3 – Feasibility of killing animals

Feasibility depends on acceptance by animal owners.

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

Bodies of dead animals infected with *S. pseudintermedius* do not pose any special risks to public or animal health, and are disposed using the same methods (e.g. burial, incineration, etc.) as for companion animals that died from other diseases.

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

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

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

Cost of treatment impacts dog owners and can increase when infections are caused by AMR strains (e.g. MRSP or clindamycin-resistant strains), as they may result in treatment failure with the consequence of increasing veterinary expenditures due to prolonged hospitalisation or additional visits, diagnostic tests and therapies. However, specific information on actual costs are not available.

Parameter 2 – Cost of eradication (culling, compensation)

The cost of euthanising pet animals varies between veterinary clinics.

Parameter 3 – Cost of surveillance and monitoring

There are no data to estimate the costs of surveillance. In Europe, national passive surveillance programmes on antimicrobial resistance in *S. pseudintermedius* are only available in few countries such as Norway (NORM-VET), Sweden (Swedres-Svarm), Finland (FINRES-Vet), France (RESAPATH) and Germany (GERM-Vet). Cost of surveillance also includes active surveillance programmes that can be implemented at the clinic level, e.g. when environmental or staff contamination is suspected due to increased frequency of surgical site and other hospital-acquired infections.

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

This section is not relevant for companion animals. Even if *S. pseudintermedius* infection may affect export of e.g. puppies, it would not be due to a ban, embargo or sanction.

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

Economic losses due to *S. pseudintermedius* infection have not been estimated.

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

Disease control measures are likely to be acceptable to society, except that some animal owners may not be able to sustain the veterinary expenditures associated with prolonged treatment of multidrug-resistant infections. Furthermore, some owners may be reluctant to accept euthanasia of their pets in the lack of any effective antimicrobial drug approved for veterinary use. On the other hand, use of critically important antimicrobials that are not authorised for veterinary use is controversial, even if limited to rare cases where it could be justified by animal health and welfare, and in some countries is prohibited by law.

#### 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

Animal welfare can be affected if disease conditions are prolonged by treatment failure. Anecdotal evidence suggests that severe infections caused by multidrug-resistant *S. pseudintermedius* can result in poor treatment outcomes such as limb amputation, organ failure, death or euthanasia in companion animals.

Multidrug-resistant MRSP infections may result in treatment failure, prolonging discomfort and pain in patients that do not respond to antimicrobial therapy. For example, a case of canine obstructive struvite urolithiasis associated with MRSP was reported to relapse for over 18 months and was eventually resolved with off-label treatment with vancomycin (Aizawa et al., 2017). Similarly, cases of persistent MRSP pyoderma may last over long periods of time during which the dogs experience numerous episodes of relapse or reinfection due to the limited number of effective and available

antimicrobials (Bell et al., 2016). A study comparing treatment outcome of dogs with MRSP and non-MRSP pyoderma reported treatment failure in 3 of 88 (3%) MRSP infections treated with first-line agents (e.g. cephalexin or cefovecin) and in 7 of 76 (9%) MRSP infections treated with second-line antibiotics such as chloramphenicol and doxycycline (Bryan et al., 2012). The study showed that the majority of pyodermas resolved regardless of methicillin resistance, although some cases of MRSP pyoderma took longer to treat and adverse effects were frequently observed in dogs treated with chloramphenicol (Bryan et al., 2012). Adverse effects associated with use of chloramphenicol has been documented in approximately one-third of treatments, and consist mainly of gastrointestinal signs and hindlimb weakness (Short et al., 2014). Similarly, parenterally administered vancomycin has been associated with cases of acute kidney injury, although this adverse effect could not definitely be attributed to the antibiotic because of illness severity and additional nephrotoxic treatments (DeStefano et al., 2019). Overall, adverse effects due to treatment with second-line antimicrobials should also be considered when assessing the impact of MRSP infections on animal welfare.

Antimicrobial resistance is also a factor predisposing to infection. MRSP carriage has been identified as a main risk for developing surgical site infections (Nazarali et al., 2015; Välkki et al., 2020). This is because MRSP is by definition resistant to cefazolin and other β-lactam antibiotics that are used for surgical prophylaxis in small animals.

Parameter 2 – Wildlife depopulation as control measure

Wildlife depopulation is not a measure for control of *S. pseudintermedius* infections.

#### 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)

There are no data to quantify the environmental impact caused by the measures for control and prevention of *S. pseudintermedius* infections in companion animals. It is, however, known that active drug residues derived from antimicrobial therapy can be introduced into the environment via urine and faeces from treated animals, contributing to selection and spread of antimicrobial resistance in different ecosystems (Polianciuc et al., 2020). The amount, persistence and bioavailability of residues released into the environment depends on drug pharmacokinetics and chemical structure. Some antimicrobial drugs (e.g. fluoroquinolones) are chemically stable in the environment, and can interfere with photosynthetic pathways and cause morphological deformities in higher plants (Polianciuc et al., 2020).

*Biodiversity*

Parameter 1 – Mortality in wild species

There are no reports on mortality in wildlife species due to control measures for control and prevention of *S. pseudintermedius* infections in companion animals.

## 3.2. Assessment of AMR *Staphylococcus pseudintermedius* 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 3 and Figure 1, the results of the expert judgement on the Article 5 criteria of the AHL for AMR *S. pseudintermedius* in dogs and cats are presented.

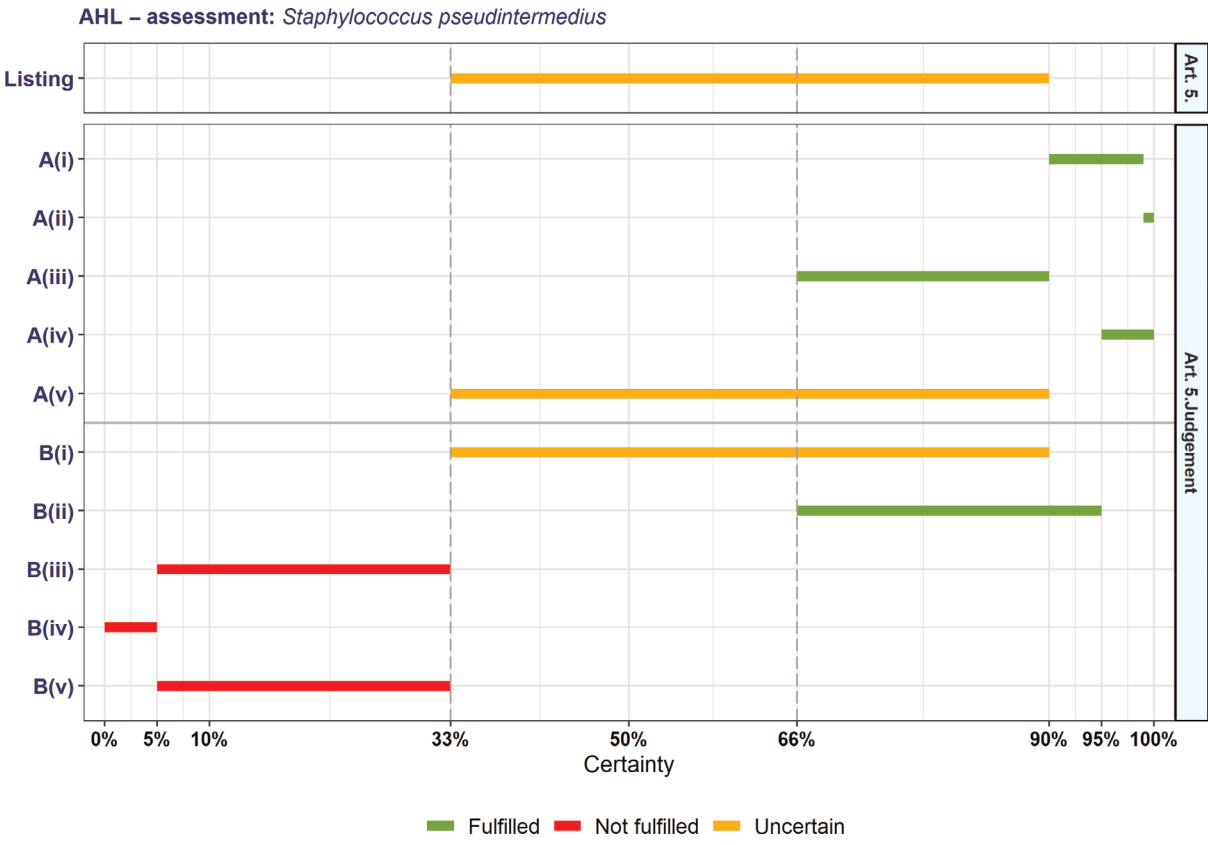
The distribution of the individual answers (probability ranges) provided by each expert for each criterion are reported in Sections A.1 and A.2 of Annex A.

**Table 3:** 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 | 90–99 | 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 | 16 |
| A(iii) | The disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character | 66–90 | Fulfilled | 0 | 14 |
| A(iv) | Diagnostic tools are available for the disease | 95–100 | Fulfilled | 0 | 14 |
| 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 | 33–90 | Uncertain | 0 | 14 |
| **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 | 33–90 | Uncertain | 0 | 14 |
| B(ii) | The disease agent has developed resistance to treatments which poses a significant danger to public and/or animal health in the Union | 66–95 | Fulfilled | 0 | 14 |
| B(iii) | The disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union | 5–33 | Not fulfilled | 0 | 14 |
| B(iv) | The disease has the potential to generate a crisis or the disease agent could be used for the purpose of bioterrorism | 0–5 | Not fulfilled | 0 | 16 |
| B(v) | The disease has or could have a significant negative impact on the environment, including biodiversity, of the Union | 5–33 | Not fulfilled | 0 | 14 |

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 *S. pseudintermedius* 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)*

- The bacterium is a commensal and ubiquitous worldwide, and therefore present in the EU. This makes its risk and the effectiveness of risk-mitigating measures difficult to assess.
- Treatment (antibiotics) is available, effective and proportionate (considering the disease caused by the bacterium), but can be complicated by multidrug resistance.
- Other risk-mitigating measures such as surgical antimicrobial prophylaxis, personal hygiene, cleaning and disinfection can be used.
- Surveillance for AMR *S. pseudintermedius* is sporadic and not harmonised.
- There are no vaccines or officially/internationally recognised diagnostic tests available.

*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):*

- The bacterium is opportunistic and only sporadically causes disease.
- Diseases caused by the bacterium are not solely attributable to *S. pseudintermedius*.
- There is a lack of precise prevalence/incidence estimates, in particular for AMR strains.
- The bacterium can cause skin infections and otitis externa in dogs. It can also cause systemic infections of the urinary, respiratory and reproductive tract in dogs.
- Dogs experience long periods of disease associated with pain and discomfort.
- Life-threatening infections including mortality have been reported in dogs.
- *S. pseudintermedius* is one of the main pathogens in small animal medicine and methicillin-resistant *S. pseudintermedius* has been described as emerging.
- The zoonotic potential is low.

### 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 3, AMR *S. pseudintermedius* complies with four criteria of the first set (A(i)–A(iv)), but there is uncertainty (33–90% probability) on the assessment on compliance with criterion A(v). Therefore, it is uncertain whether AMR *S. pseudintermedius* 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 33–90% (Figure 1).

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

In Tables 4–8 and related graphs (Figures 2–4), the results of the expert judgement on AMR *S. pseudintermedius* in dogs and cats 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 Annex B.

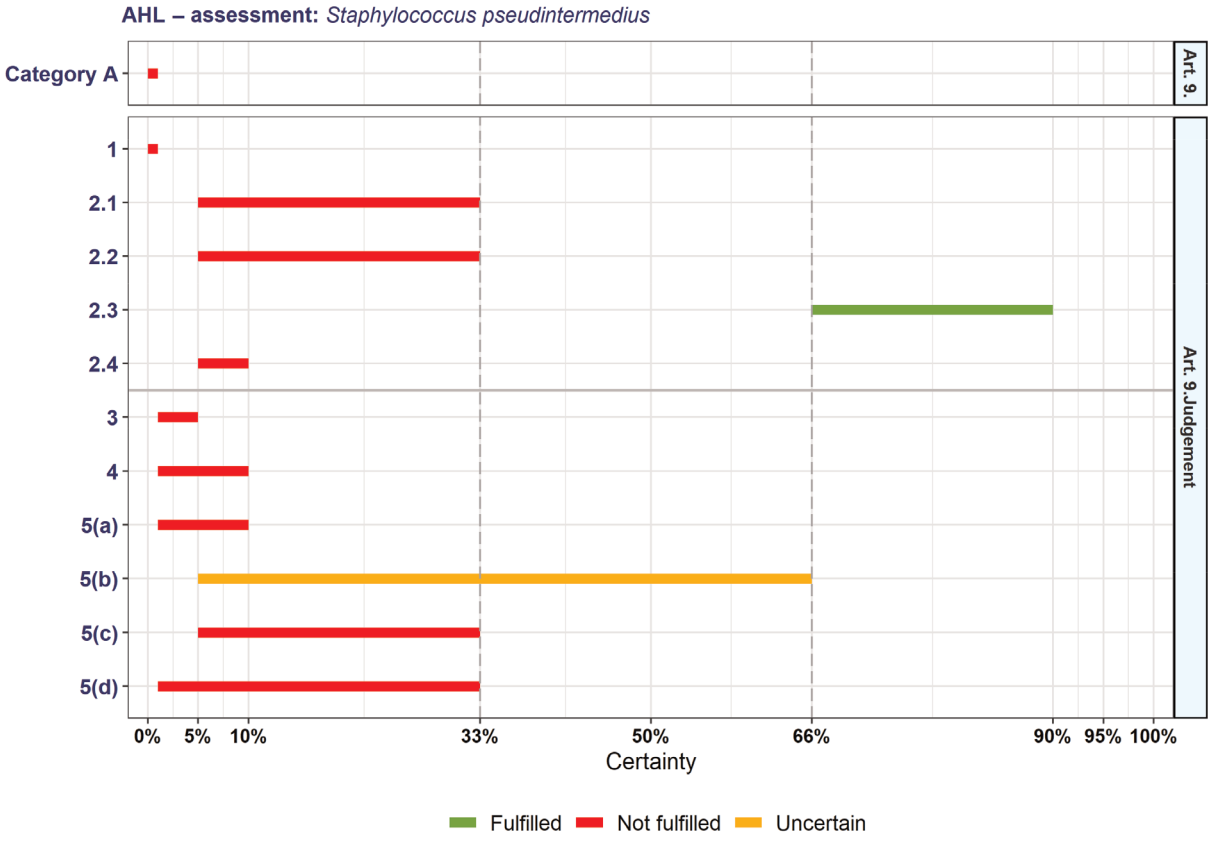
### 3.3.1. Detailed outcome on Category A criteria

**Table 4:** 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 | 0–1 | Not fulfilled | 0 | 14 |
| 2.1 | The disease is highly transmissible | 5–33 | Not fulfilled | 0 | 14 |
| 2.2 | There are possibilities of airborne or waterborne or vector-borne spread | 5–33 | Not fulfilled | 0 | 14 |
| 2.3 | The disease affects multiple species of kept and wild animals or single species of kept animals of economic importance | 66–90 | Fulfilled | 0 | 14 |
| 2.4 | The disease may result in high morbidity and significant mortality rates | 5–10 | Not fulfilled | 0 | 14 |
| **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 | 1–5 | Not fulfilled | 0 | 16 |
| 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 | 1–10 | Not fulfilled | 0 | 14 |
| 5(a) | The disease has a significant impact on society, with in particular an impact on labour markets | 1–10 | Not fulfilled | 0 | 14 |
| 5(b) | The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals | 5–66 | Uncertain | 0 | 14 |

| 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 |
| 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 | 14 |
| 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 | 1–33 | Not fulfilled | 0 | 14 |

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 5(b) (the disease has a significant impact on animal welfare, by causing suffering of large numbers of animals)*

- It is difficult to interpret 'large' numbers of animals.
- Diseases caused by the bacterium are not solely attributable to *S. pseudintermedius*.
- There is a lack of precise prevalence/incidence estimates, in particular for AMR strains.
- The bacterium causes suffering to individual animals, due to long periods of disease associated with pain and discomfort (e.g. pruritus, scratching).

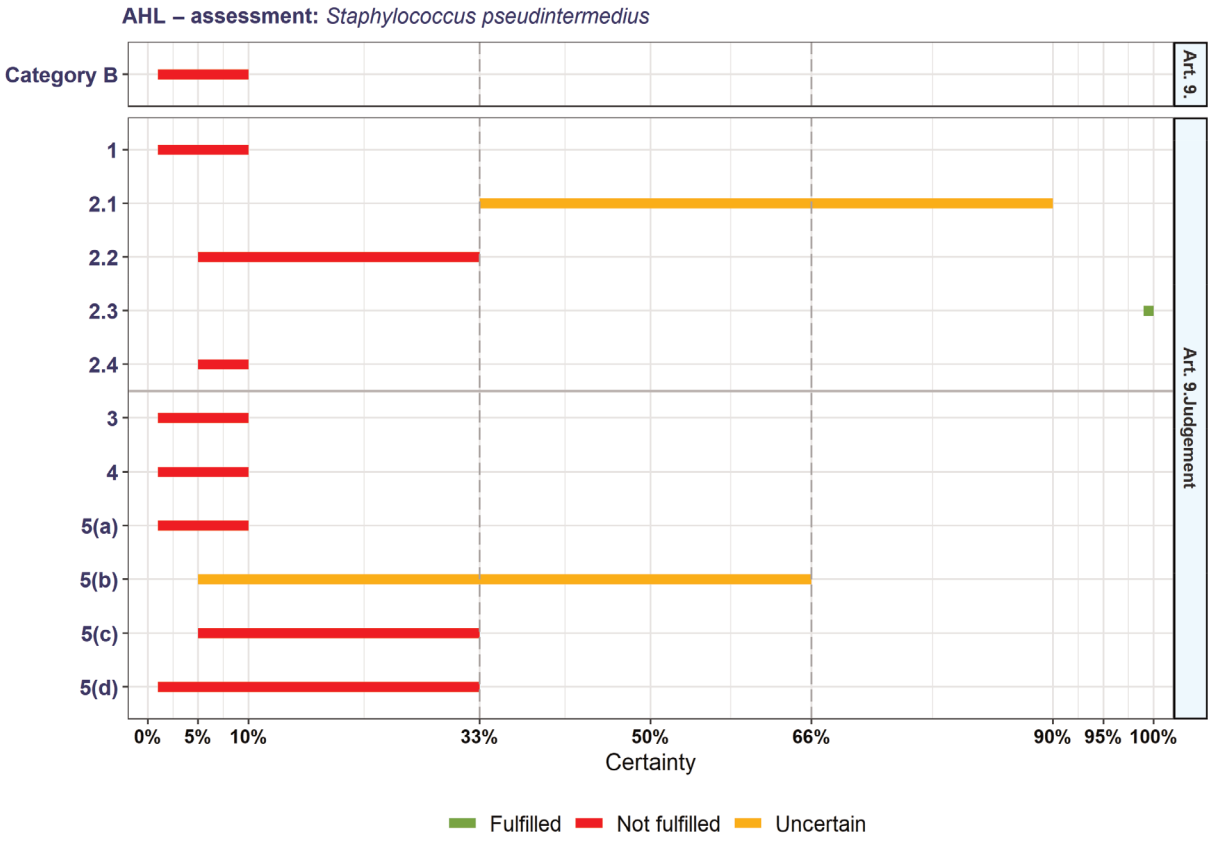
- Pain and suffering in dogs may be more common than recognised, due to the complex nature of infection and co-infection.

### 3.3.2. Detailed outcome on Category B criteria

**Table 5:** 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 | 1–10 | Not fulfilled | 0 | 14 |
| 2.1 | The disease is moderately to highly transmissible | 33–90 | Uncertain | 0 | 14 |
| 2.2 | There are possibilities of airborne or waterborne or vector-borne spread | 5–33 | Not fulfilled | 0 | 14 |
| 2.3 | The disease affects single or multiple species | – | Fulfilled | 0 | 14 |
| 2.4 | The disease may result in high morbidity with in general low mortality | 5–10 | Not fulfilled | 0 | 14 |
| **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 | 1–10 | Not fulfilled | 0 | 16 |
| 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 | 1–10 | Not fulfilled | 0 | 14 |
| 5(a) | The disease has a significant impact on society, with in particular an impact on labour markets | 1–10 | Not fulfilled | 0 | 14 |
| 5(b) | The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals | 5–66 | Uncertain | 0 | 14 |
| 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 | 14 |
| 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 | 1–33 | Not fulfilled | 0 | 14 |

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

#### 3.3.2.1. Reasoning for uncertain outcome on Category B criteria

*Criterion 2.1 (the disease is moderately to highly transmissible)*

- The bacterium is a commensal and ubiquitous.
- The bacterium is transmissible, but not the diseases caused by it.
- It seems to be at least moderately transmissible (based on the prevalence of 45–90%).
- If it was highly transmissible, there would be more cases.
- Information is scarce (e.g. on transmission rate).
- *S. pseudintermedius* has been described as an emerging AMR bacterium and has spread in the last couple of years.

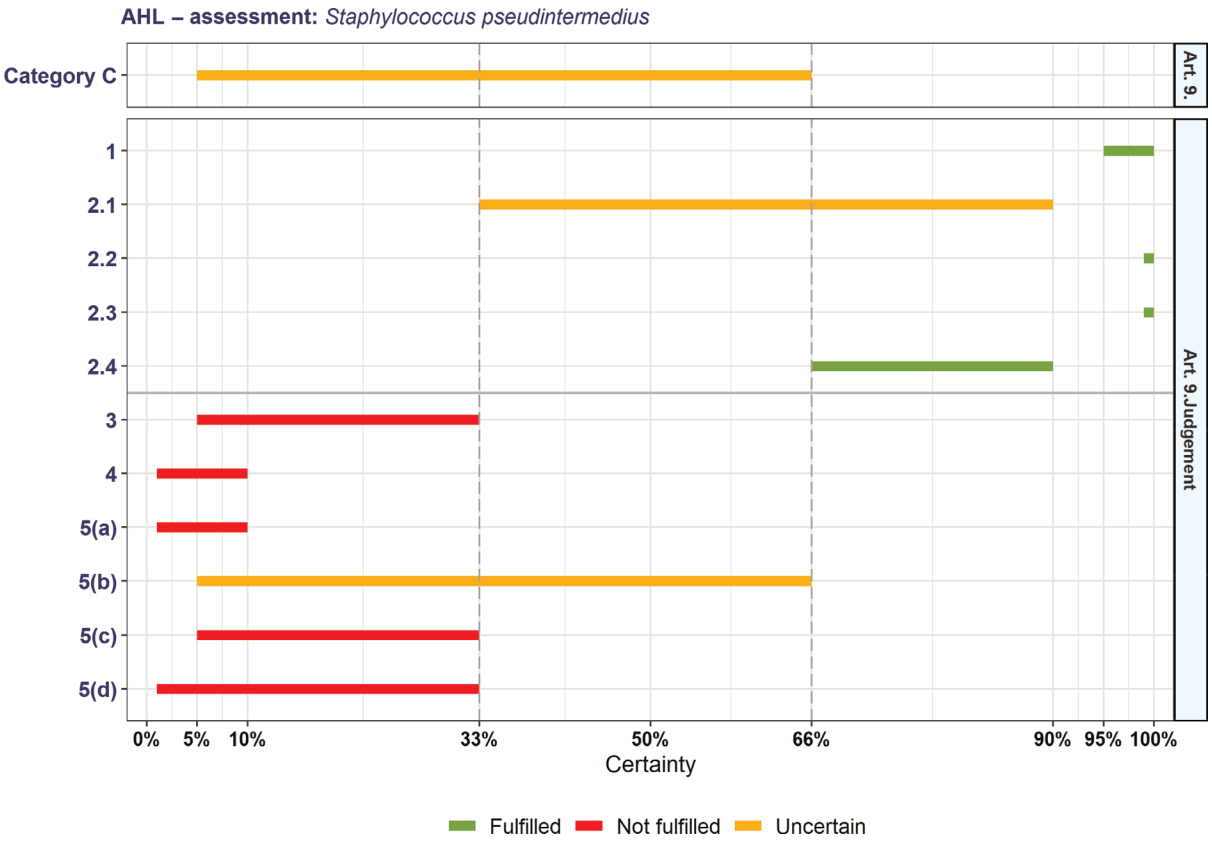
*Criterion 5(b) (the disease has a significant impact on animal welfare, by causing suffering of large numbers of animals):* See above in Section 3.3.1.1.

### 3.3.3. Detailed outcome on Category C criteria

**Table 6:** 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 | 95–100 | Fulfilled | 0 | 16 |
| 2.1 | The disease is moderately to highly transmissible | 33–90 | Uncertain | 0 | 14 |
| 2.2 | The disease is transmitted mainly by direct or indirect transmission | - | Fulfilled | 0 | 14 |
| 2.3 | The disease affects single or multiple species | - | Fulfilled | 0 | 14 |
| 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 | 66–90 | Fulfilled | 3 | 11 |
| **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 | 5–33 | 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 | 1–10 | Not fulfilled | 0 | 14 |
| 5(a) | The disease has a significant impact on society, with in particular an impact on labour markets | 1–10 | Not fulfilled | 0 | 14 |
| 5(b) | The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals | 5–66 | Uncertain | 0 | 14 |
| 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 | 14 |
| 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 | 1–33 | Not fulfilled | 0 | 14 |

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.

*Criterion 5(b) (the disease has a significant impact on animal welfare, by causing suffering of large numbers of animals):* See above in Section 3.3.1.1.

### 3.3.4. Detailed outcome on Category D criteria

**Table 7:** 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 Sections 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 | 10–33 | Not fulfilled | 0 | 12 |

na: not applicable.

### 3.3.5. Detailed outcome on Category E criteria

**Table 8:** 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 Sections 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<br>(If a disease fulfils the criteria as in Article 5, thus being eligible to be listed, consequently Category E would apply.) | 33–90 | 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 4–8. 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 *S. pseudintermedius* as in Article 9, is presented in Table 9 and Figure 5.

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

| | **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)** |
| **Category** | **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 | 0–1 | 5–33 | 5–33 | 66–90 | 5–10 | 1–5 | 1–10 | 1–10 | 5–66 | 5–33 | 1–33 |
| B | 1–10 | 33–90 | 5–33 | – | 5–10 | 1–10 | 1–10 | 1–10 | 5–66 | 5–33 | 1–33 |
| C | 95–100 | 33–90 | – | – | 66–90 | 5–33 | 1–10 | 1–10 | 5–66 | 5–33 | 1–33 |
| D | 10–33 | | | | | | | | | | |
| E | 33–90 | | | | | | | | | | |

Probability ranges (% certainty) (green: fulfilled; red: not fulfilled; orange: uncertain).

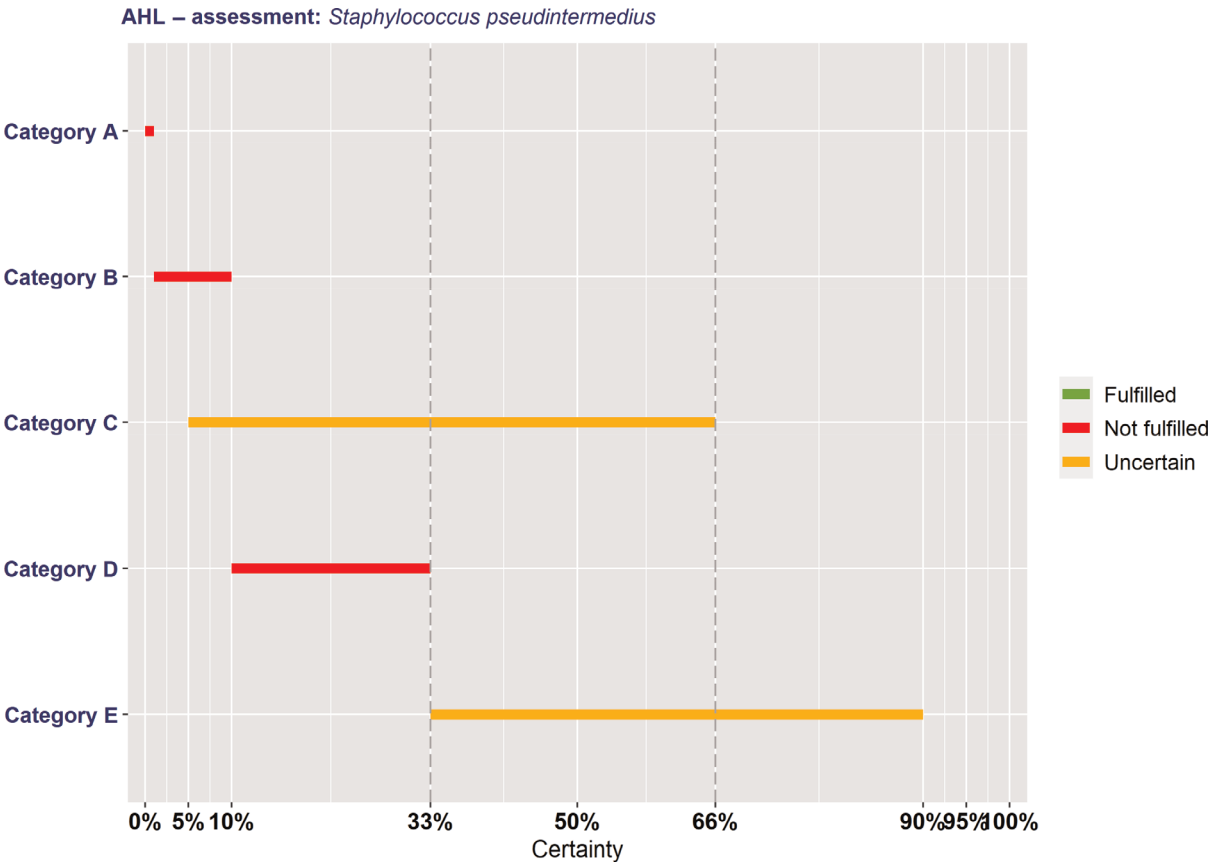



**Figure 5:** Outcome of the expert judgement on criteria in Annex IV and overall probabilities for categorisation of the AMR bacterium in accordance with Article 9

According to the assessment here performed, AMR *S. pseudintermedius* 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 *S. pseudintermedius* complies only with criterion 2.3 (66–90% 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 *S. pseudintermedius* does not comply with any apart from criterion 5(b), for which the assessment was inconclusive (5–66% probability). Overall, it was assessed with 0–1% probability that AMR *S. pseudintermedius* 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 *S. pseudintermedius* complies only with criterion 2.3. The assessment was inconclusive on compliance with criterion 2.1 (33–90% 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 *S. pseudintermedius* does not comply with any apart from criterion 5(b), for which the assessment was inconclusive (5–66% probability). Overall, it was assessed with 1–10% probability that AMR *S. pseudintermedius* 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 *S. pseudintermedius* complies with criteria 1 (95–100% probability), 2.2, 2.3 and 2.4 (66–90% probability). 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 *S. pseudintermedius* does not comply with any apart from criterion

5(b), for which the assessment was inconclusive (5–66% probability). Overall, it was assessed with 5–66% probability that AMR *S. pseudintermedius* 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 Sections 1, 2, 3 or 5 of Annex IV of the AHL and with the specific criterion D of Section 4, with which AMR *S. pseudintermedius* does not comply (10–33% 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 with a large uncertainty (33–90% probability of fulfilling the criteria).

## 3.4. Assessment of AMR *Staphylococcus pseudintermedius* 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 *S. pseudintermedius* 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 *S. pseudintermedius* according to the criteria of Article 8(3) of the AHL are as displayed in Table 10 (elaborated from information reported in Section 3.1.1.1 of the present document).

**Table 10:** Animal species to be listed for AMR *S. pseudintermedius* according to the criteria of Article 8

| | Class/order | Family | Genus/species |
|---|---|---|---|
| Susceptible | Carnivora | Canidae | Domestic dog (*Canis lupus familiaris*) |
| | | | Red fox (*Vulpes vulpes*) |
| | | | Gray fox (*Urocyon cinereoargenteus*) |
| | | | Arctic fox (*Vulpes lagopus*) |
| | | | Coyote (*Canis latrans*) |
| | | Felidae | Domestic cat (*Felis catus*) |
| | | | Amur (Siberian) tiger (*Panthera tigris altaica*) |
| | Perissodactyla | Equidae | Horse (*Equus ferus caballus*) |
| | Artiodactyla | Bovidae | Cattle (*Bos taurus*) |
| | Rodentia | Muridae | House mouse (*Mus musculus*) |
| Reservoir | Carnivora | Canidae | All |
| | | Felidae | Domestic cat (*Felis catus*) |
| Vector | None | | |

[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.

The table contains all animal species in which AMR *S. pseudintermedius* 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.

## 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.

**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 (30–90% probability, from 'as likely as not' to 'likely') whether AMR *S. pseudintermedius* 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 0–1% probability ('almost impossible') that AMR *S. pseudintermedius* 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 1–10% probability (from 'extremely unlikely' to 'very unlikely') that AMR *S. pseudintermedius* 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 was uncertain (5–66% probability, from 'very unlikely' to 'as likely as not') whether AMR *S. pseudintermedius* 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 considered with 10–33% probability ('unlikely') that AMR *S. pseudintermedius* 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 (30–90% probability, from 'as likely as not' to 'likely') whether AMR *S. pseudintermedius* 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 animal species that can be considered to be listed for AMR *S. pseudintermedius* according to Article 8(3) of the AHL are mainly species belonging to Canidae and Felidae, as reported in Table 10 in Section 3.4 of the present document.

The AHAW Panel highlights that monitoring of antimicrobial resistance in opportunistic bacteria could help to assess their impacts. Therefore, even though the assessment on AMR *S. pseudintermedius* is inconclusive on its eligibility to be listed for Union intervention, specific initiatives (e.g. monitoring or applied research) into various aspects of AMR *S. pseudintermedius* 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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## Abbreviations

| | |
|---|---|
| AHAW | Animal Health and Welfare |
| AHL | Animal Health Law |
| AMR | Antimicrobial-resistant |
| CC | Clonal complex |
| CFSPH | Center for Food Security and Public Health |

| | |
|---|---|
| CI | Current impact |
| CITES | Convention on International Trade in Endangered Species |
| DALY | Disability-adjusted life year |
| IUCN | International Union for Conservation of Nature |
| MALDI-TOF MS | Matrix-assisted laser desorption ionisation–time-of-flight mass spectrometry |
| MIC | Minimum inhibitory concentration |
| MRSP | Methicillin-resistant *S. pseudintermedius* |
| MS | Member State |
| OIE | Office International des Épizooties (World Organisation for Animal Health) |
| PCR | Polymerase chain reaction |
| PBP2a | Penicillin-binding protein 2a |
| PI | Potential impact |
| ToR | Term of Reference |

# Annex A – Criteria with certain outcome

## A.1. Article 5 criteria

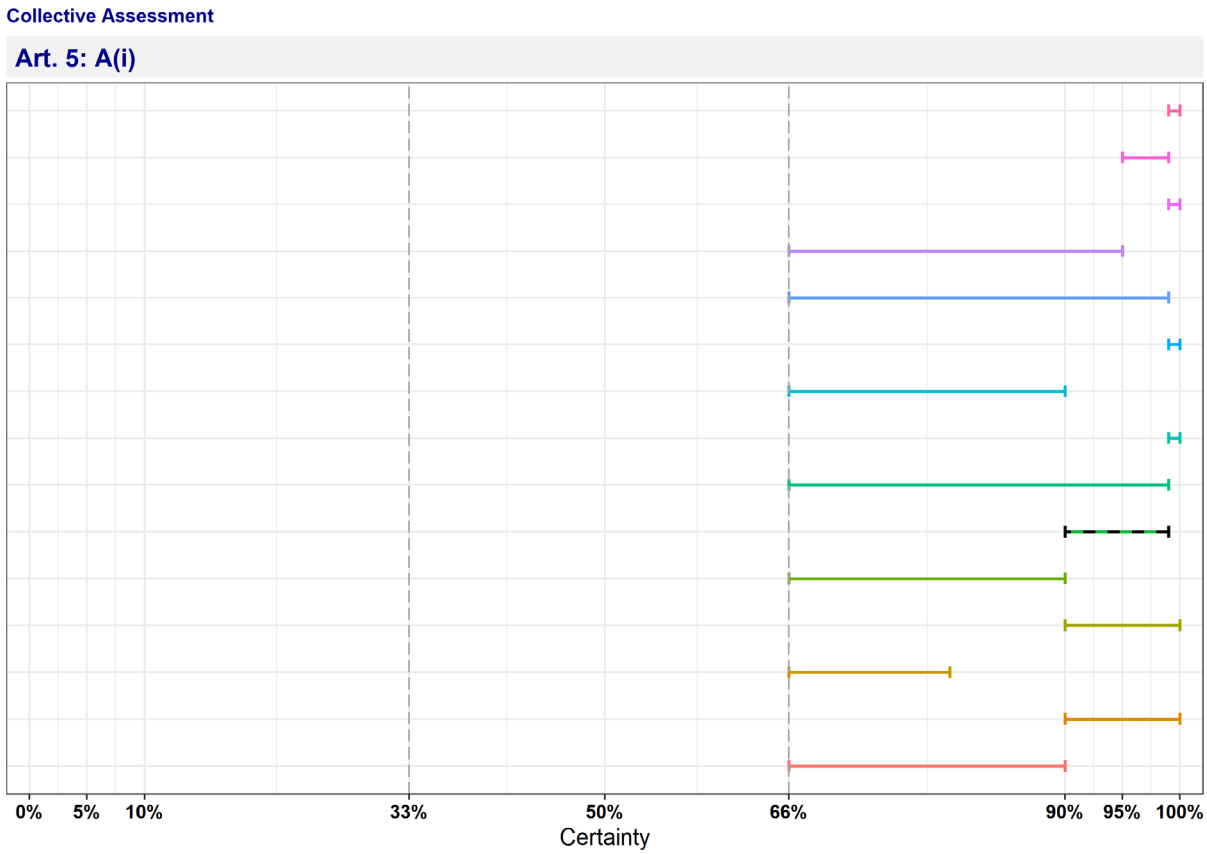


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**Figure A.1:** Individual probability ranges reflecting fulfilment of criterion A(i) (the disease is transmissible) after the collective judgement

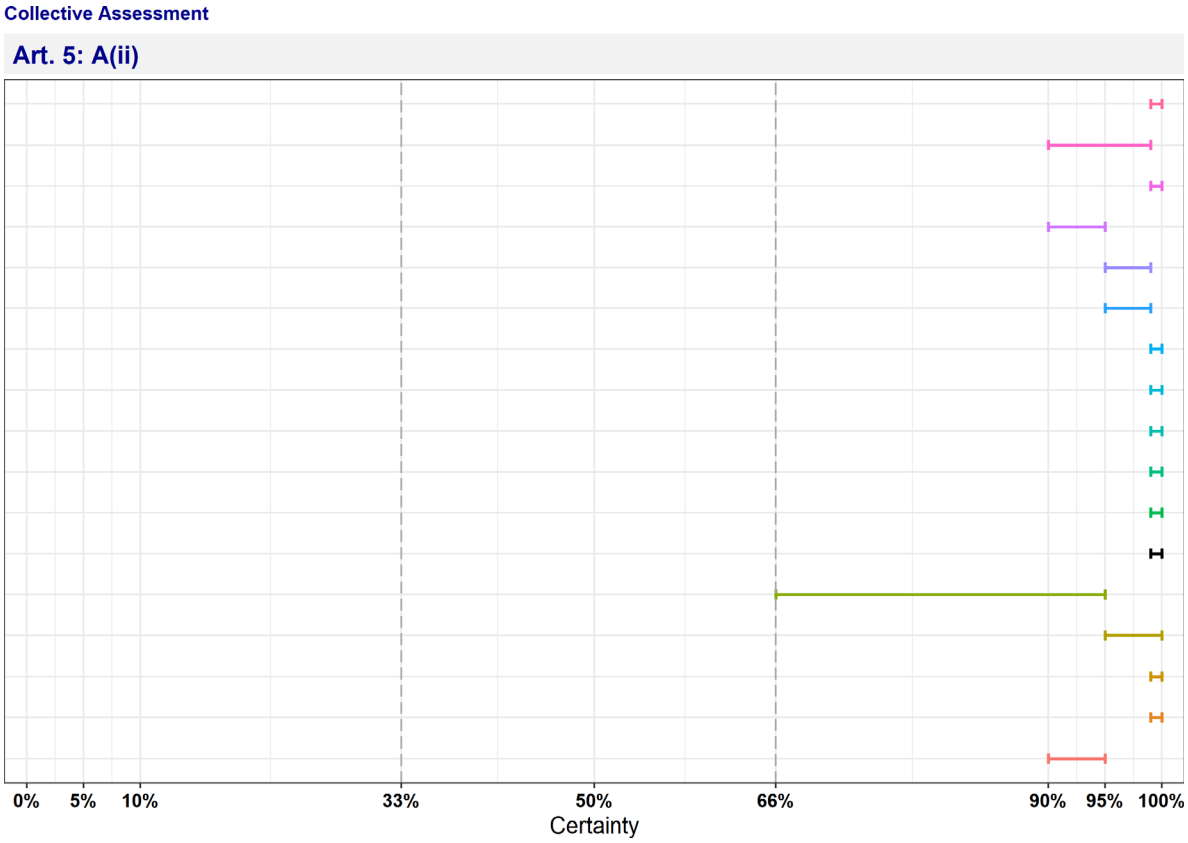


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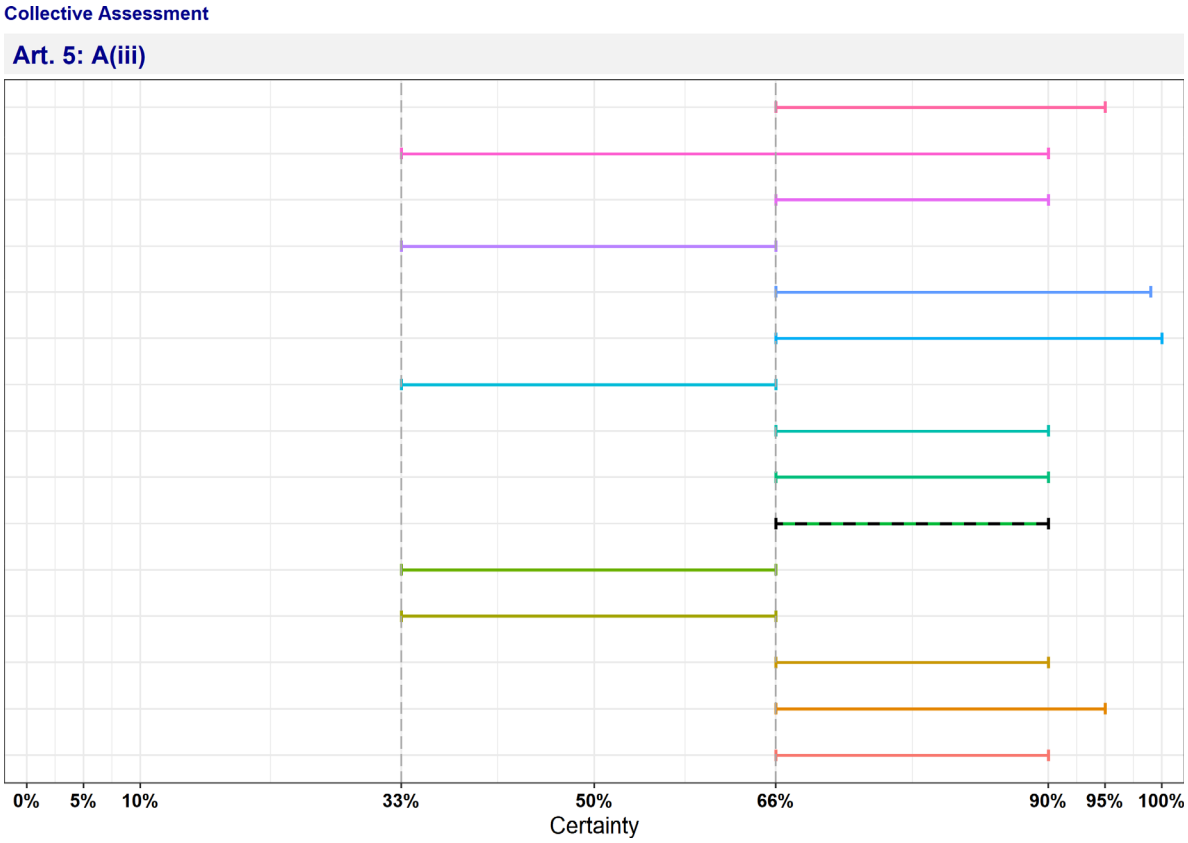
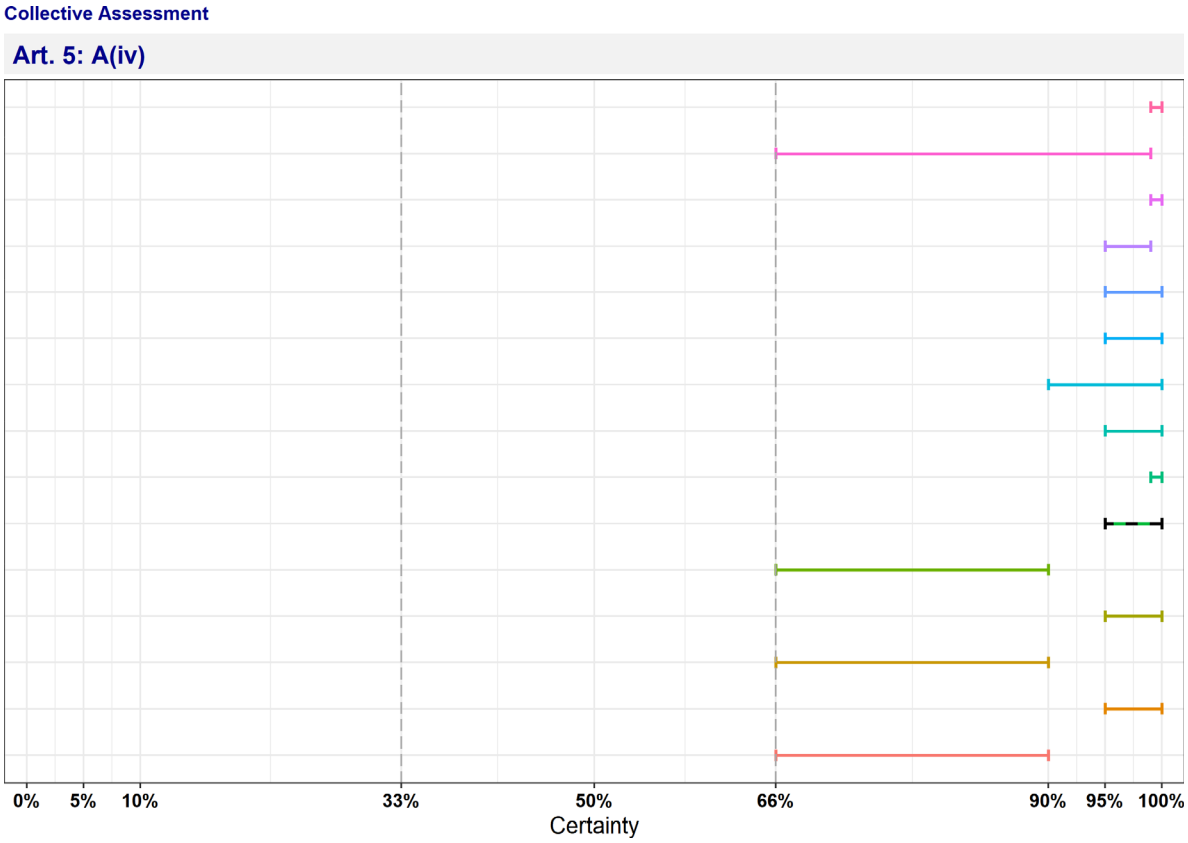
**Figure A.2:** Individual probability ranges reflecting fulfilment of criterion A(ii) (animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union) after the collective judgement



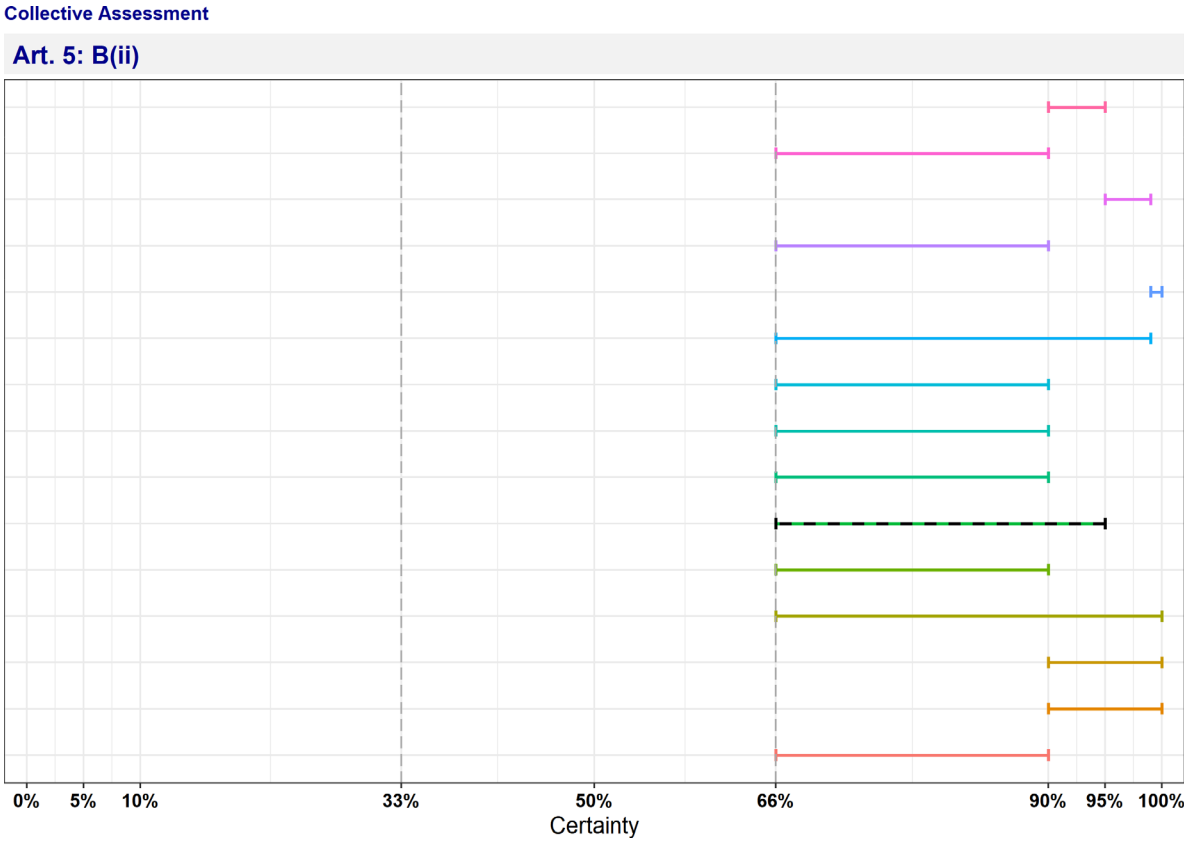

The median range is displayed as a dashed line.

**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



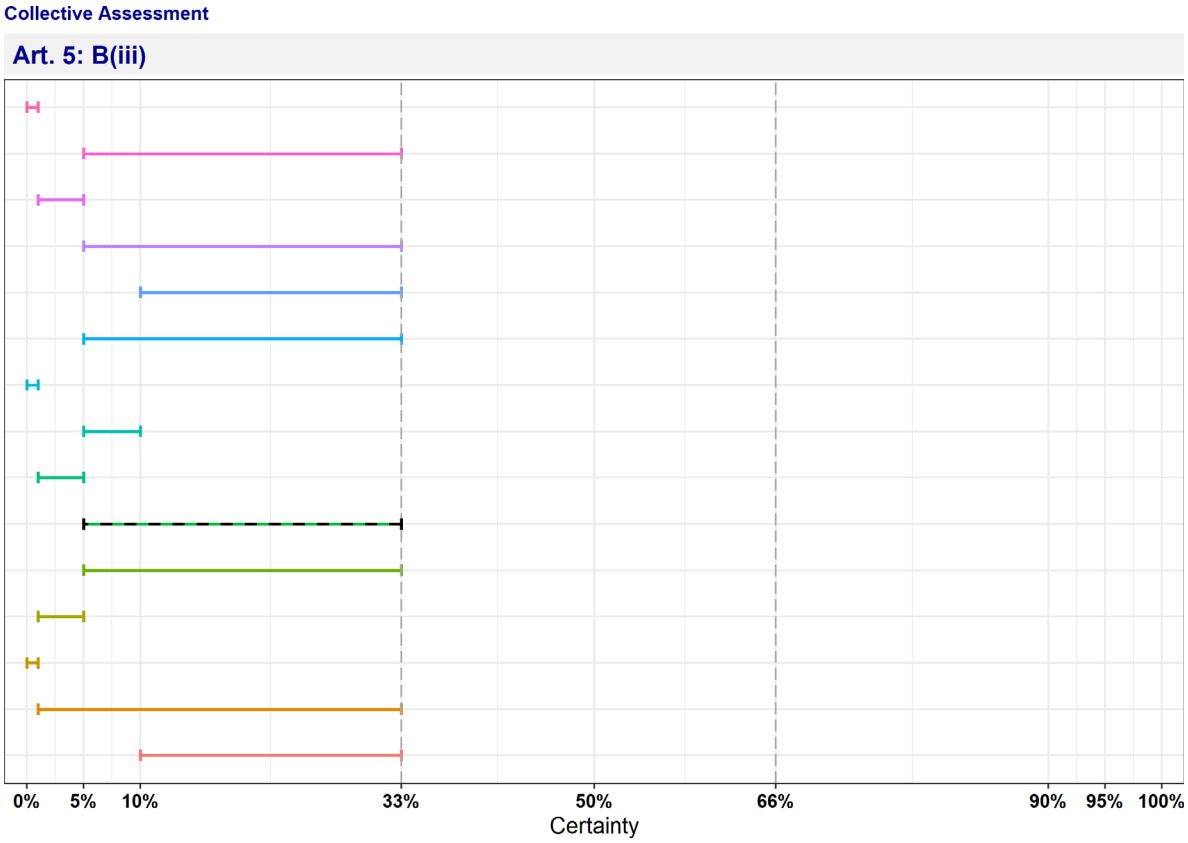

The median range is displayed as a dashed line.

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



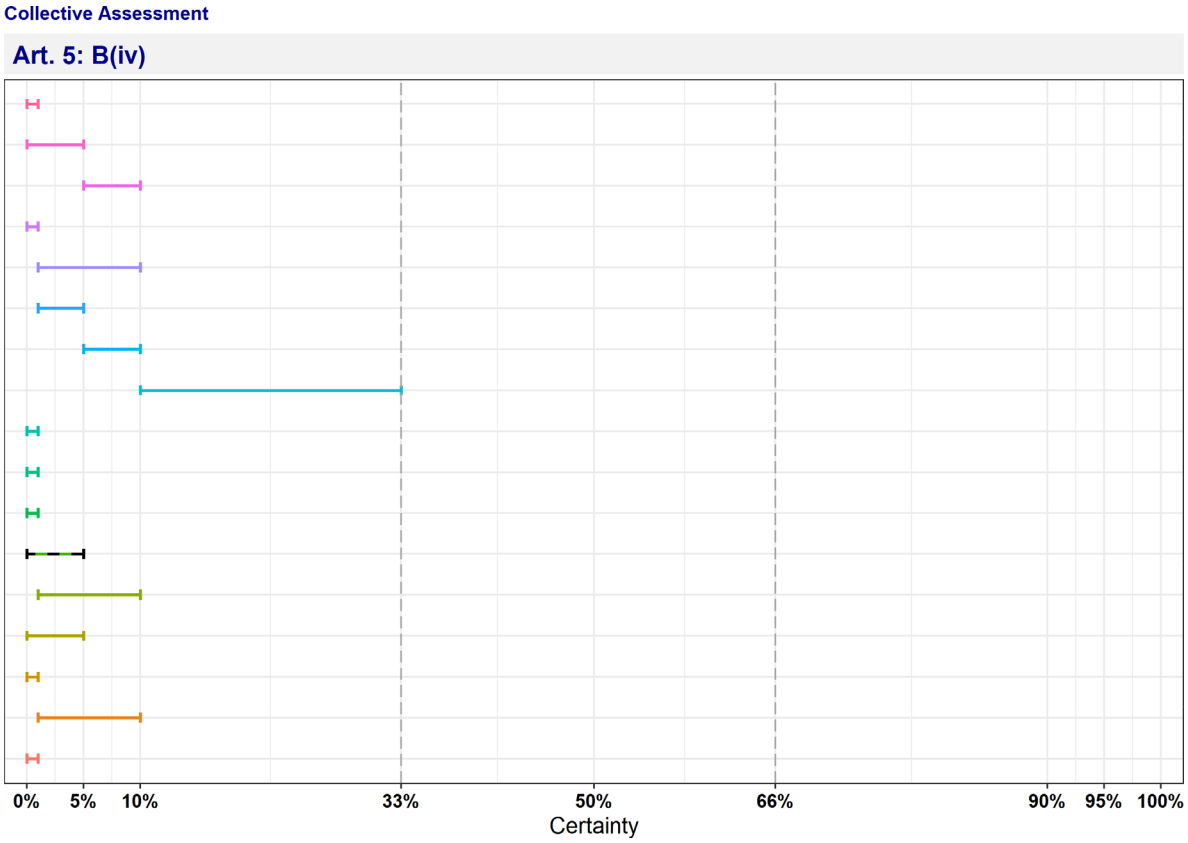

The median range is displayed as a dashed line.

**Figure A.5:** 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



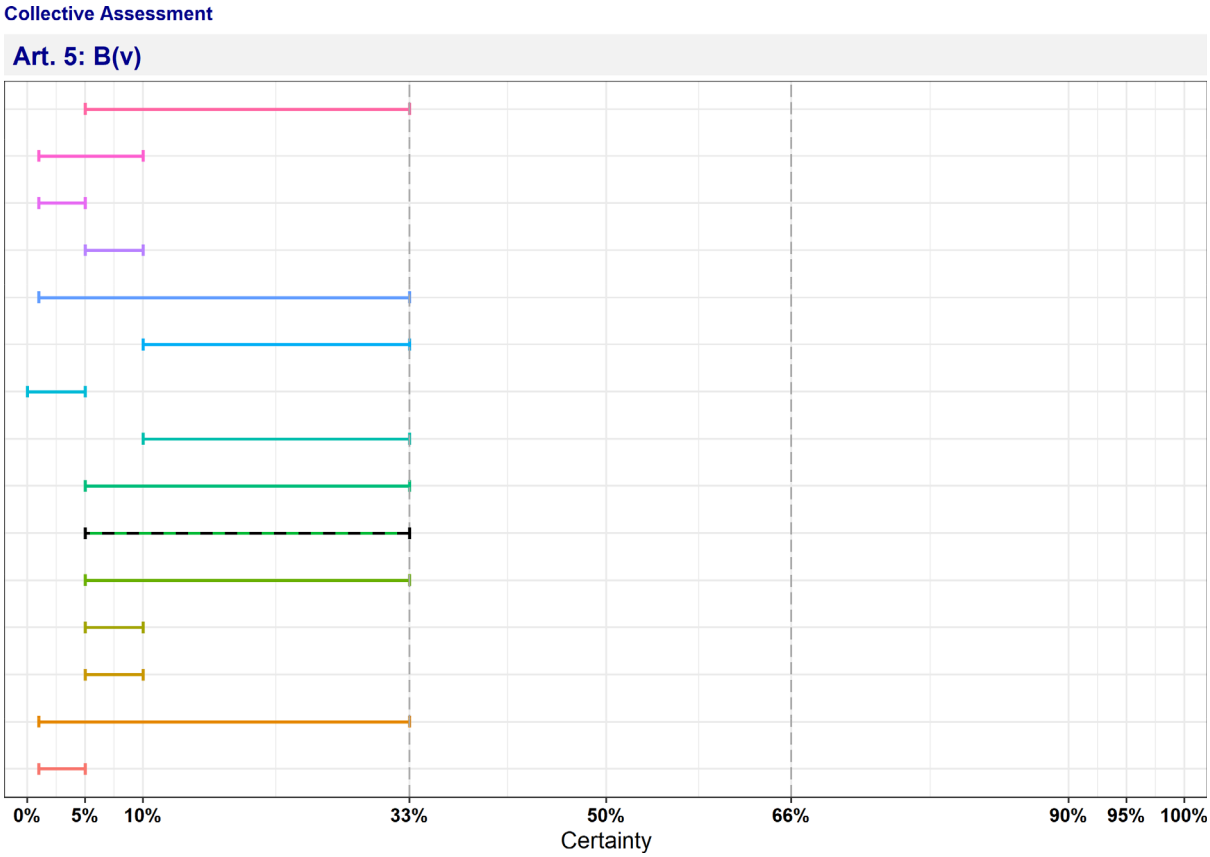

The median range is displayed as a dashed line.

**Figure A.6:** Individual probability ranges reflecting non-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




The median range is displayed as a dashed line.

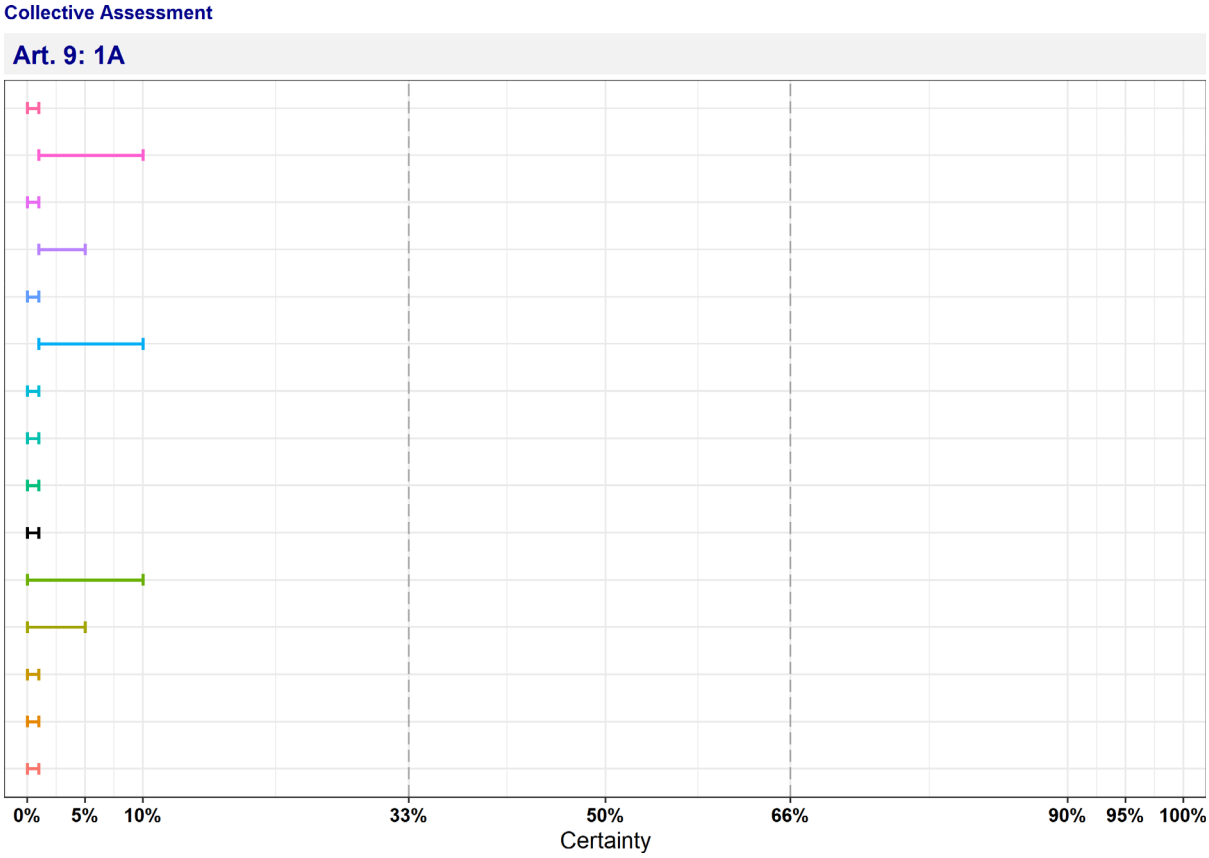
**Figure A.7:** Individual probability ranges reflecting non-fulfilment of criterion B(iv) (the disease has the potential to generate a crisis or the disease agent could be used for the purpose of bioterrorism) after the collective judgement




The median range is displayed as a dashed line.

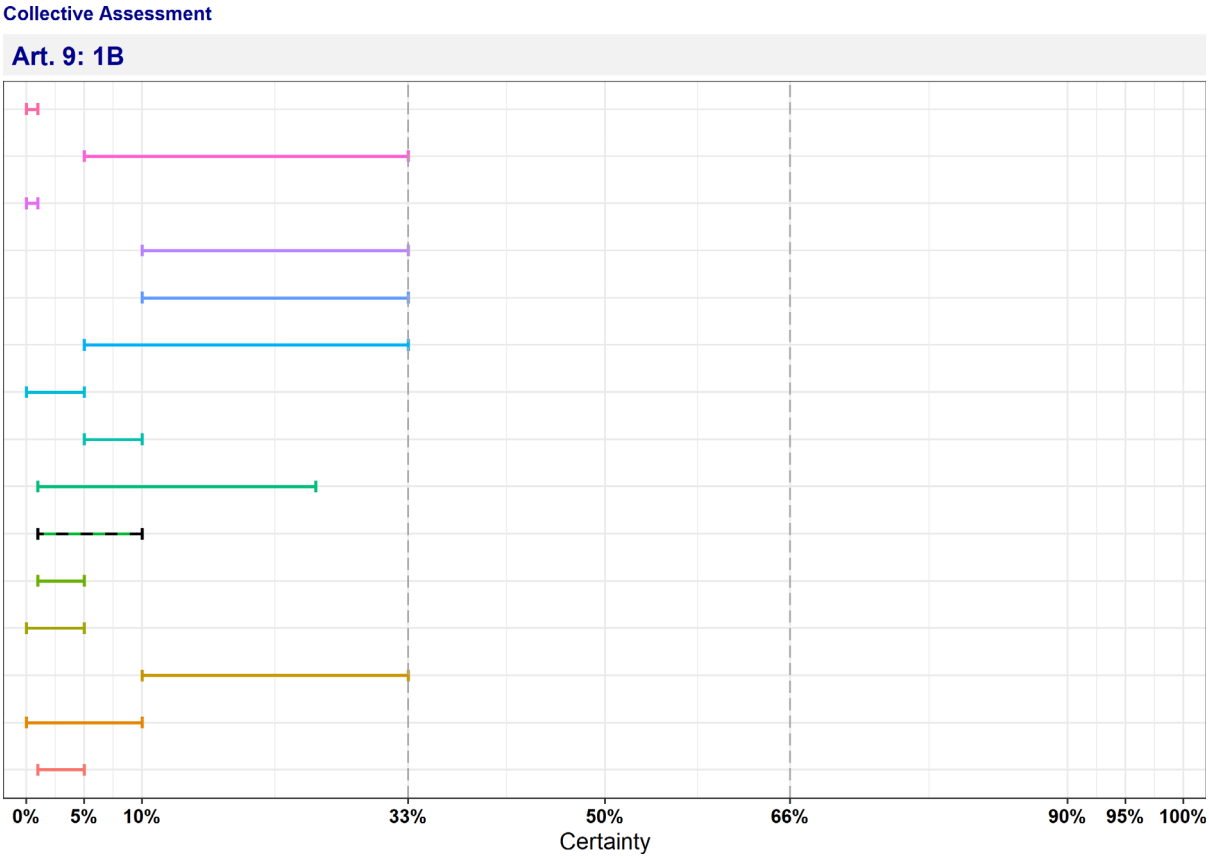
**Figure A.8:** Individual probability ranges reflecting non-fulfilment of criterion B(v) (the disease has or could have a significant negative impact on the environment, including biodiversity, of the Union) after the collective judgement

## A.2. Article 9 criteria



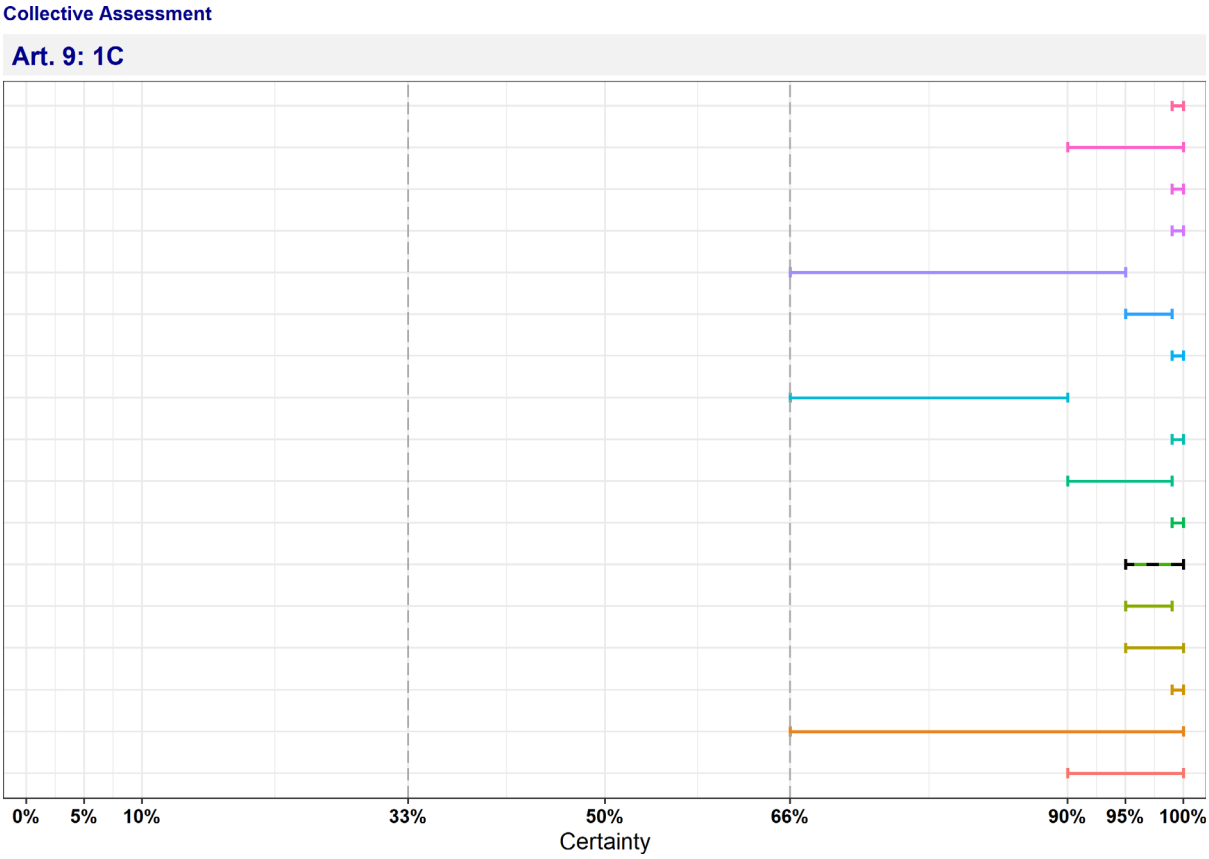

The median range is displayed as a dashed line.

**Figure A.9:** 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



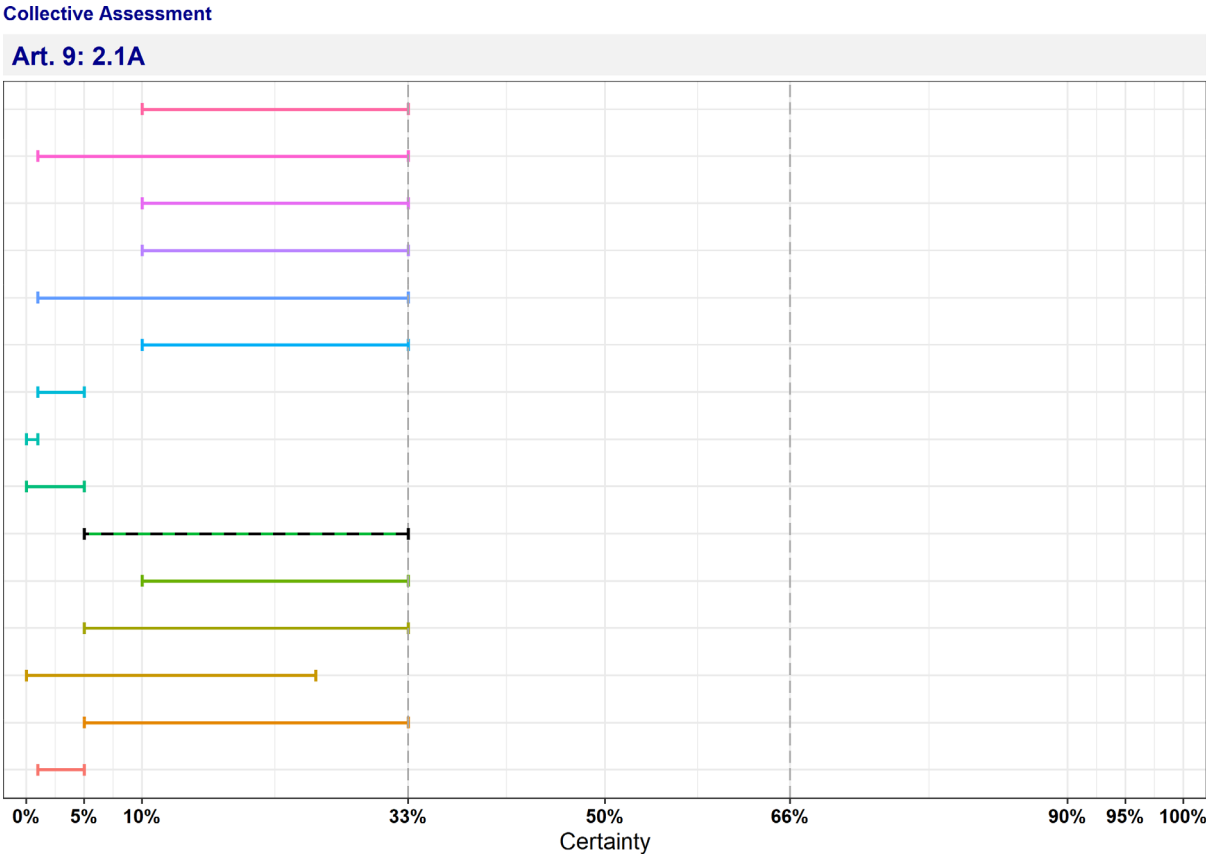

The median range is displayed as a dashed line.

**Figure A.10:** 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



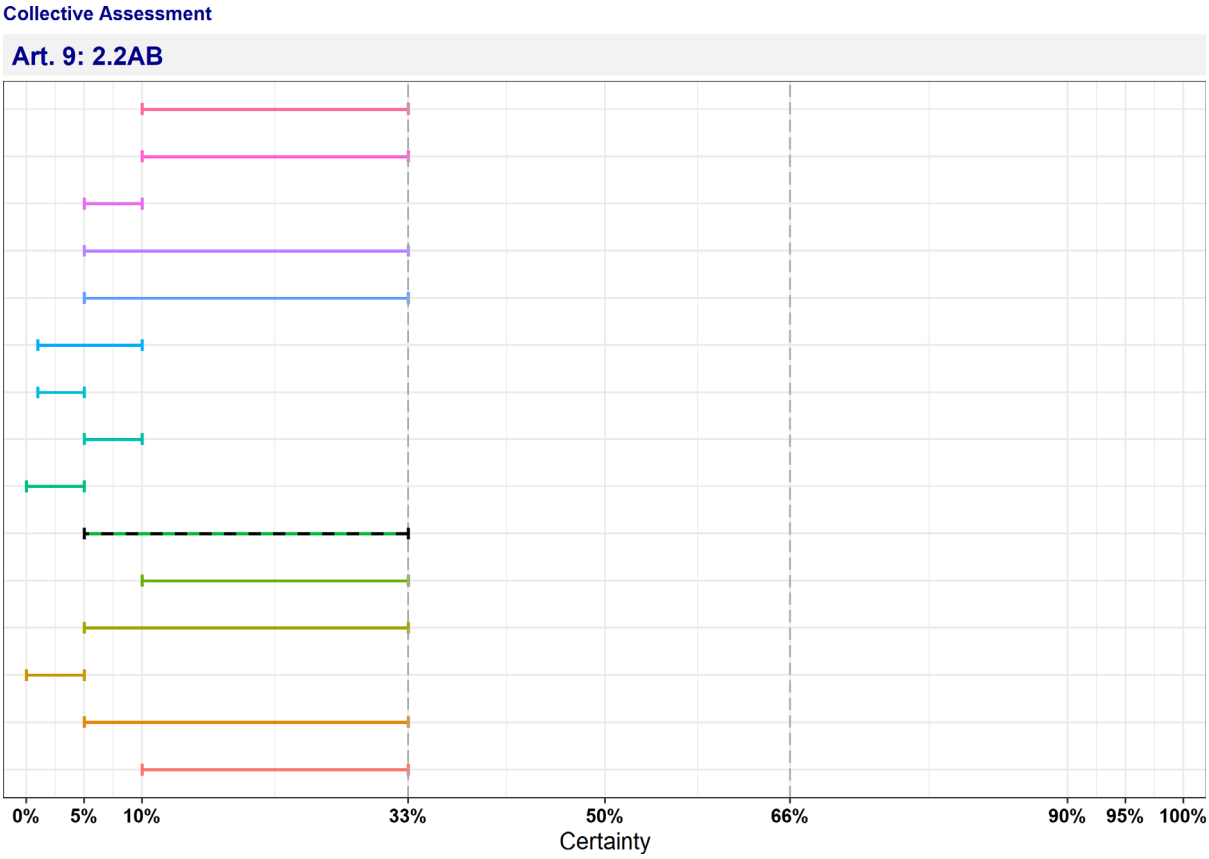

The median range is displayed as a dashed line.

**Figure A.11:** 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




The median range is displayed as a dashed line.

**Figure A.12:** Individual probability ranges reflecting non-fulfilment of criterion 2.1A (the disease is highly transmissible) after the collective judgement




The median range is displayed as a dashed line.

**Figure A.13:** Individual probability ranges reflecting non-fulfilment of criterion 2.2AB (there are possibilities of airborne or waterborne or vector-borne spread) after the collective judgement

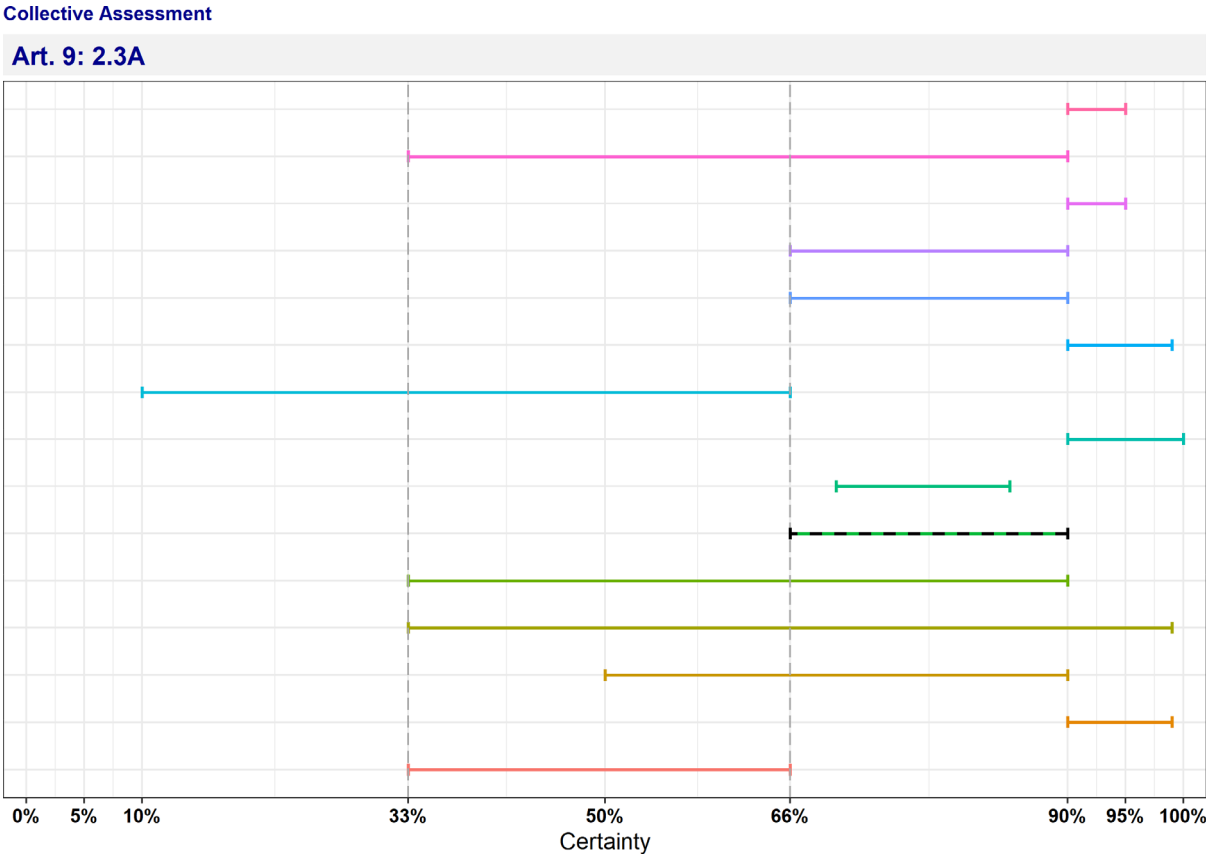



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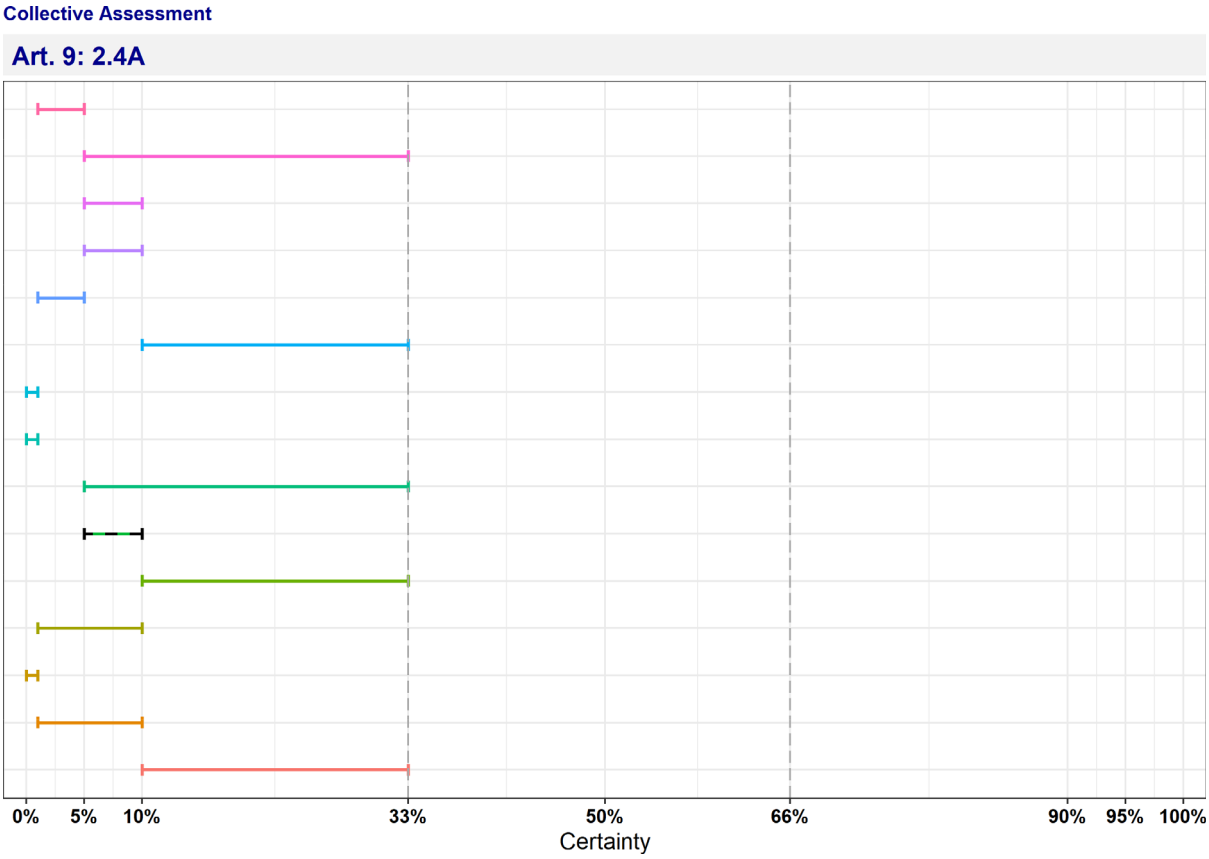
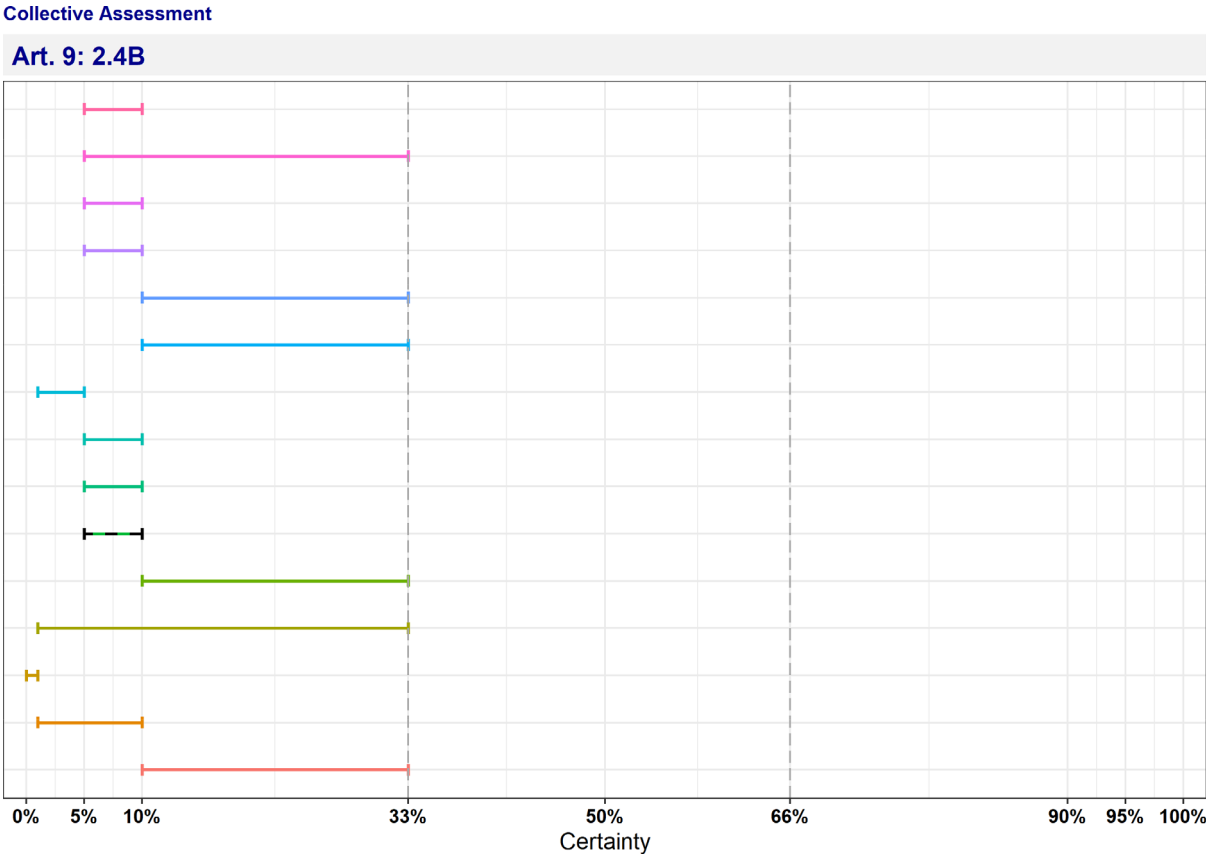
**Figure A.14:** Individual probability ranges reflecting fulfilment of criterion 2.3A (the disease affects multiple species of kept and wild animals or single species of kept animals of economic importance) after the collective judgement



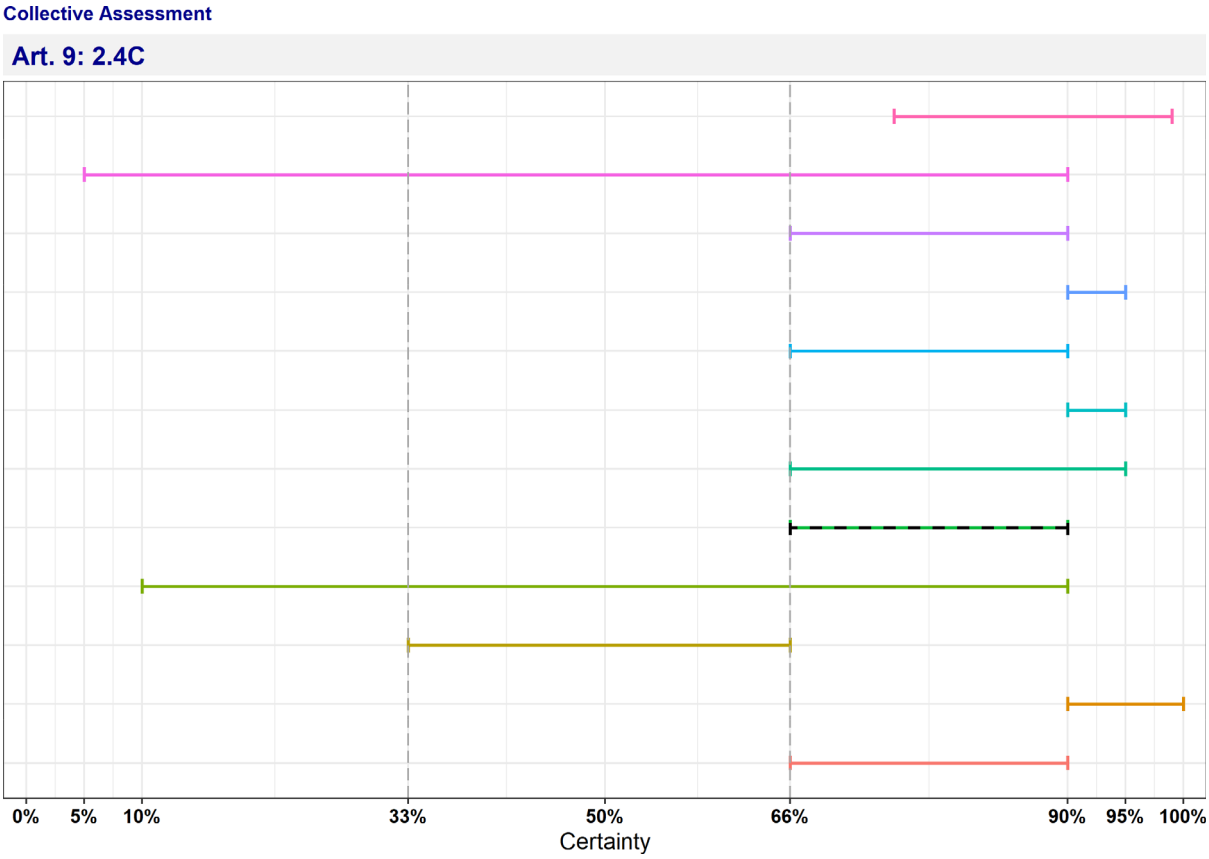

The median range is displayed as a dashed line.

**Figure A.15:** Individual probability ranges reflecting non-fulfilment of criterion 2.4A (the disease may result in high morbidity and significant mortality rates) after the collective judgement



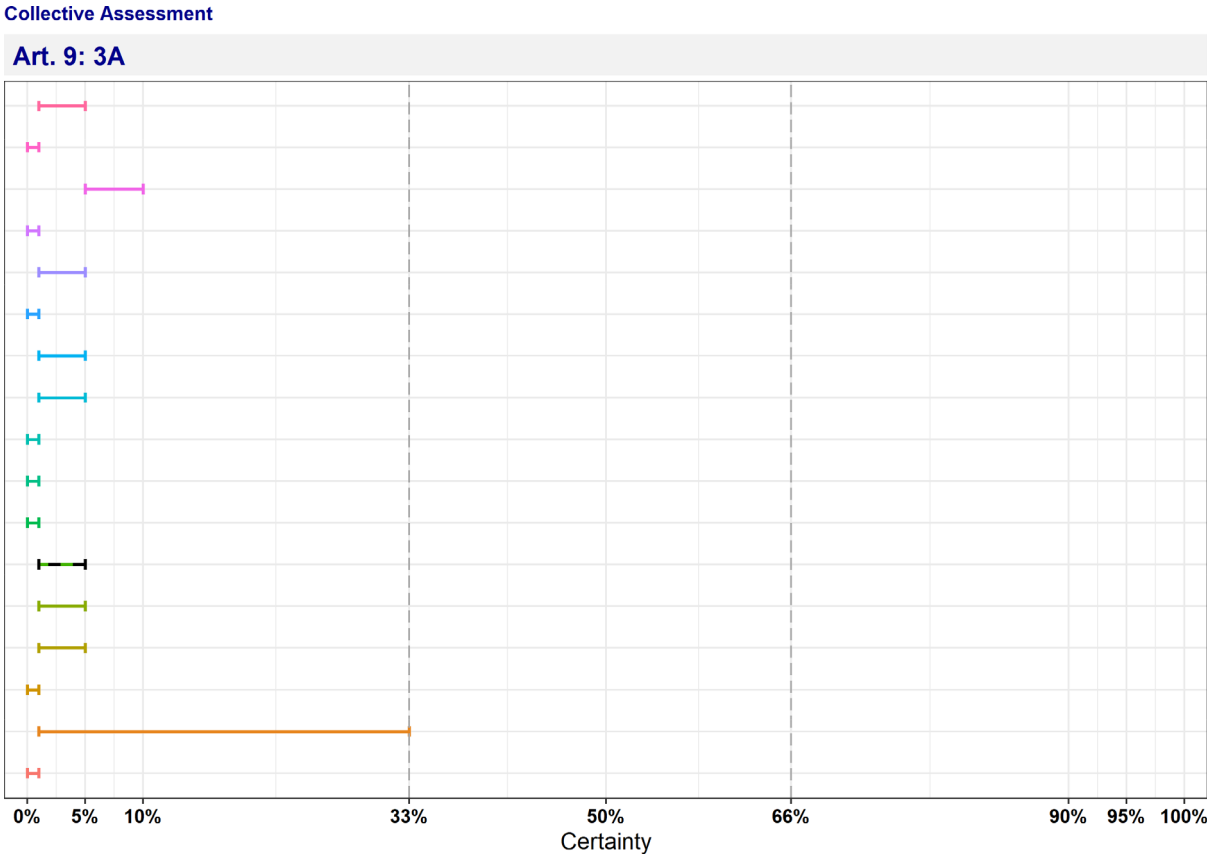

The median range is displayed as a dashed line.

**Figure A.16:** Individual probability ranges reflecting non-fulfilment of criterion 2.4B (the disease may result in high morbidity with in general low mortality) after the collective judgement



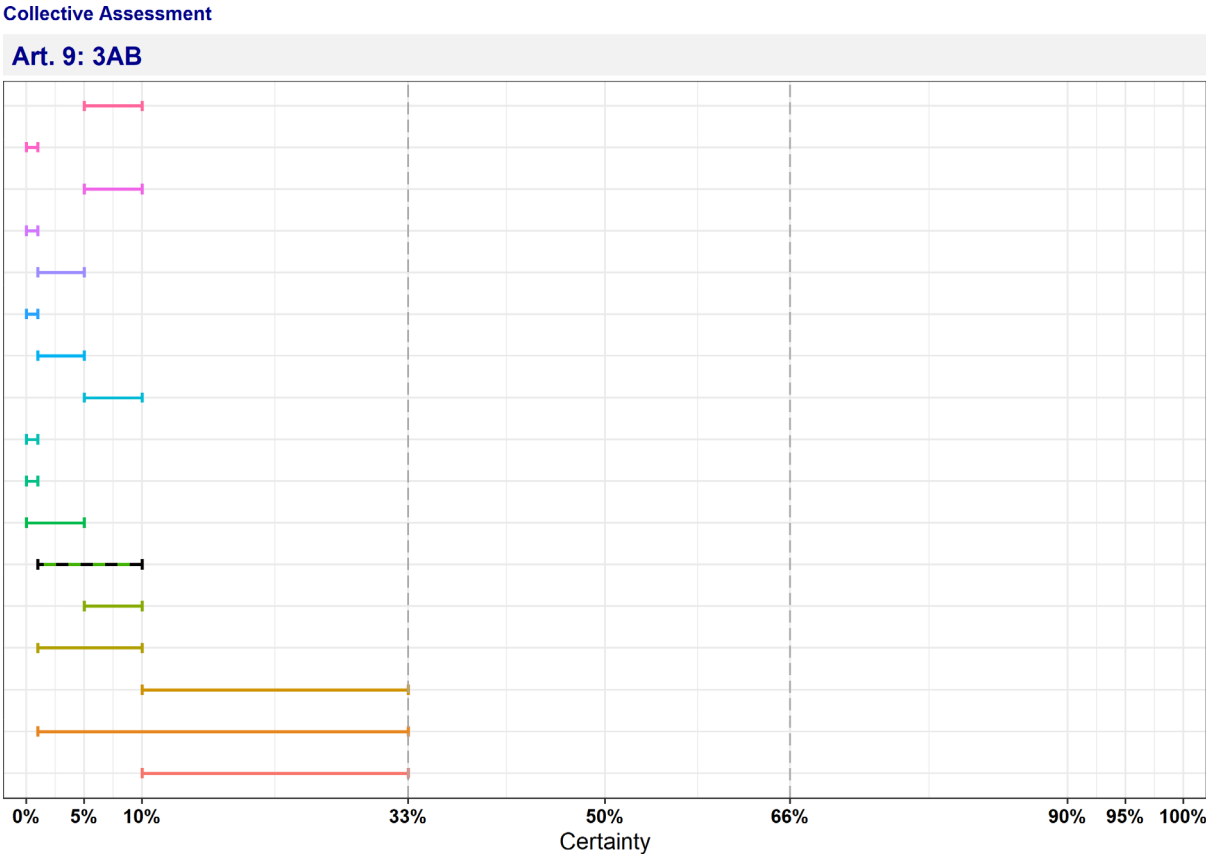

The median range is displayed as a dashed line.

**Figure A.17:** Individual probability ranges reflecting fulfilment of criterion 2.4C (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



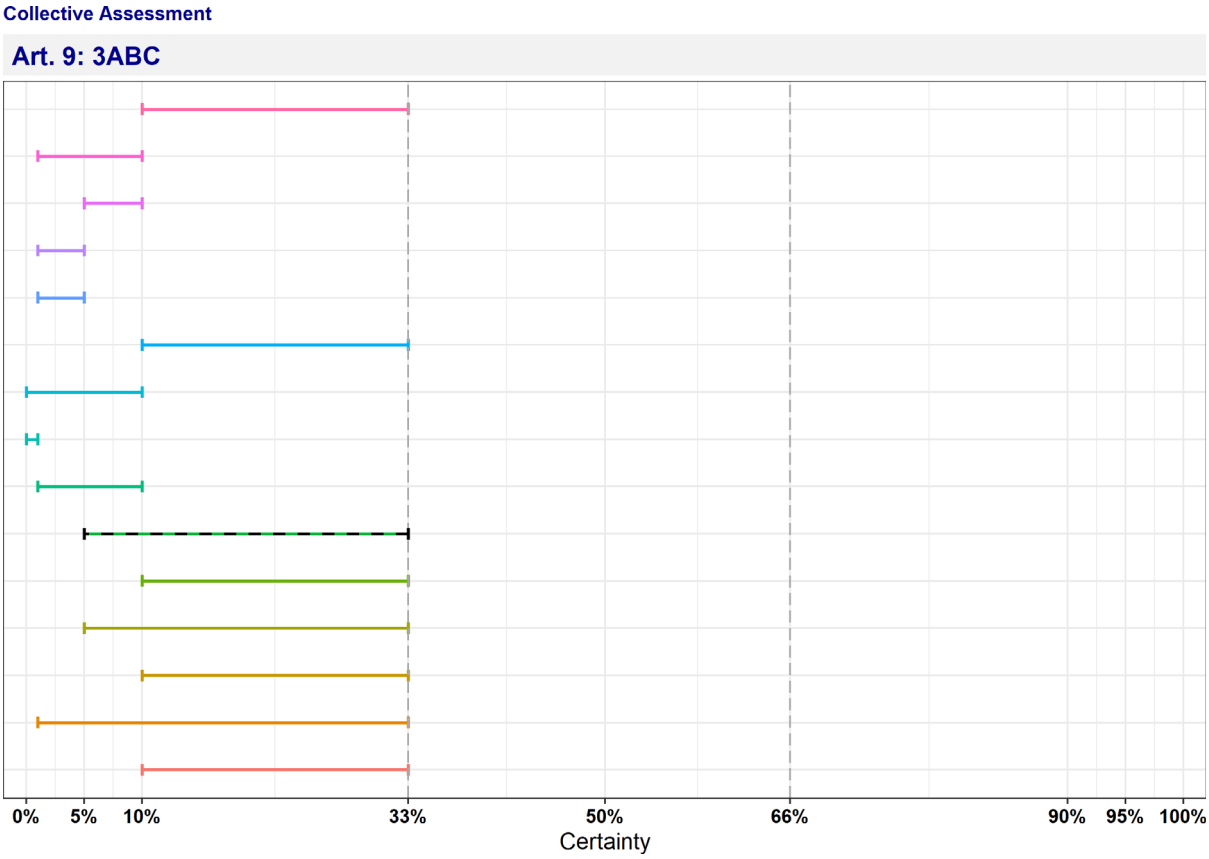

The median range is displayed as a dashed line.

**Figure A.18:** 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



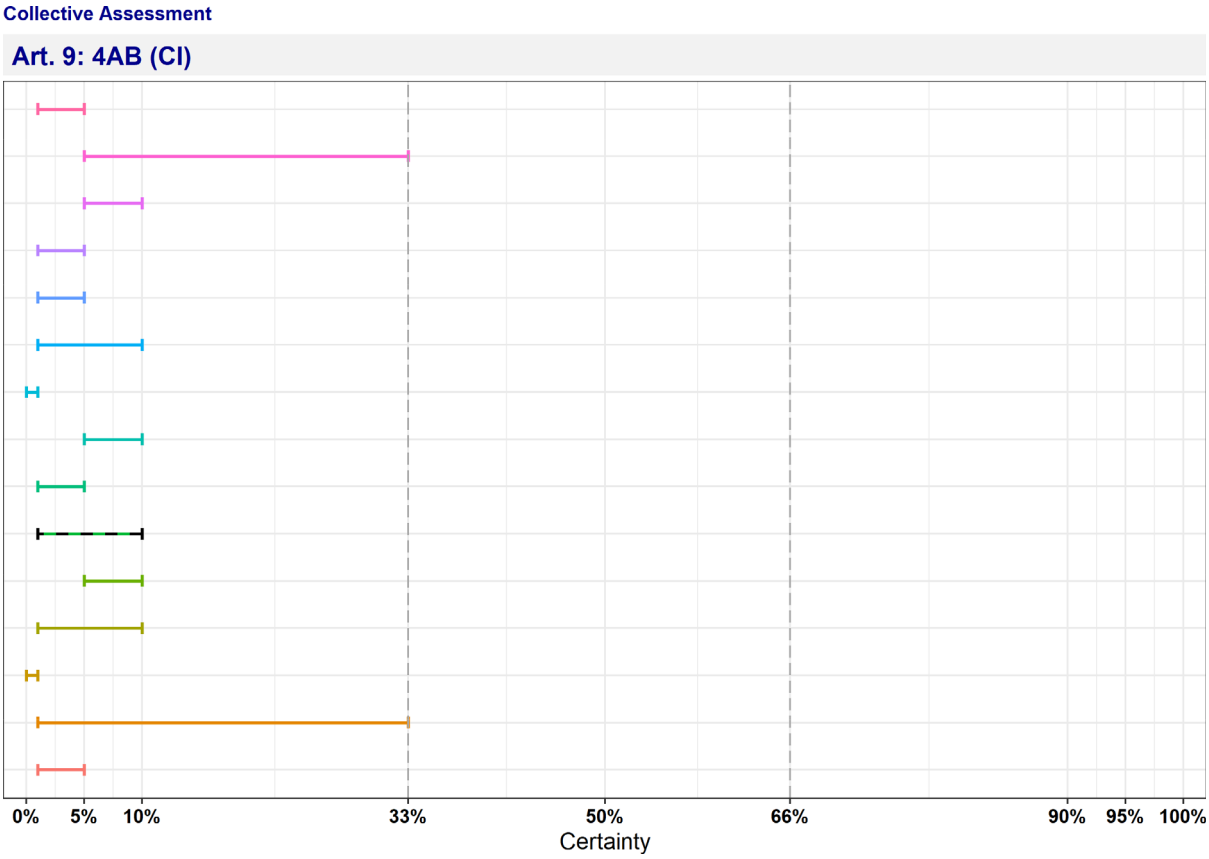

The median range is displayed as a dashed line.

**Figure A.19:** 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




The median range is displayed as a dashed line.

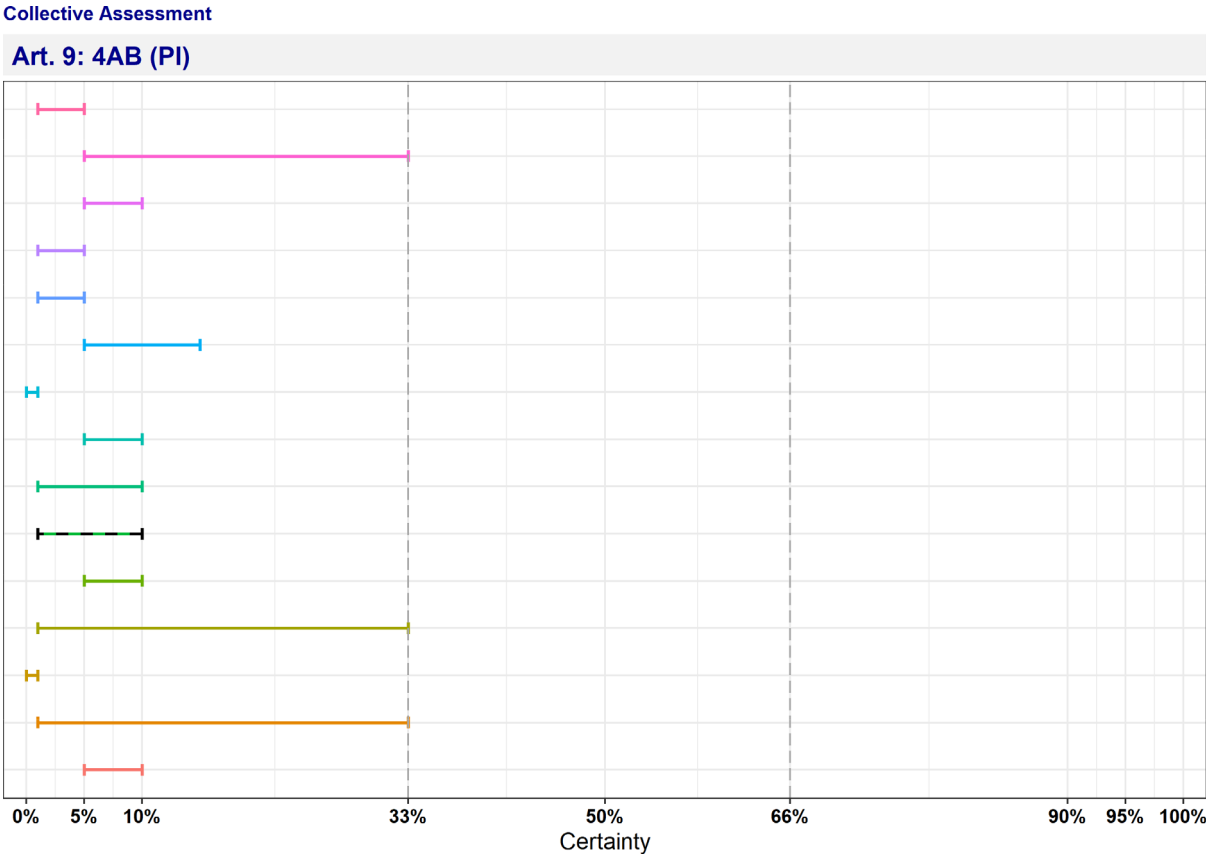
**Figure A.20:** Individual probability ranges reflecting non-fulfilment of criterion 3ABC (the disease has a zoonotic potential with significant consequences for public health or possible significant threats to food safety) after the collective judgement




CI: current impact

The median range is displayed as a dashed line.

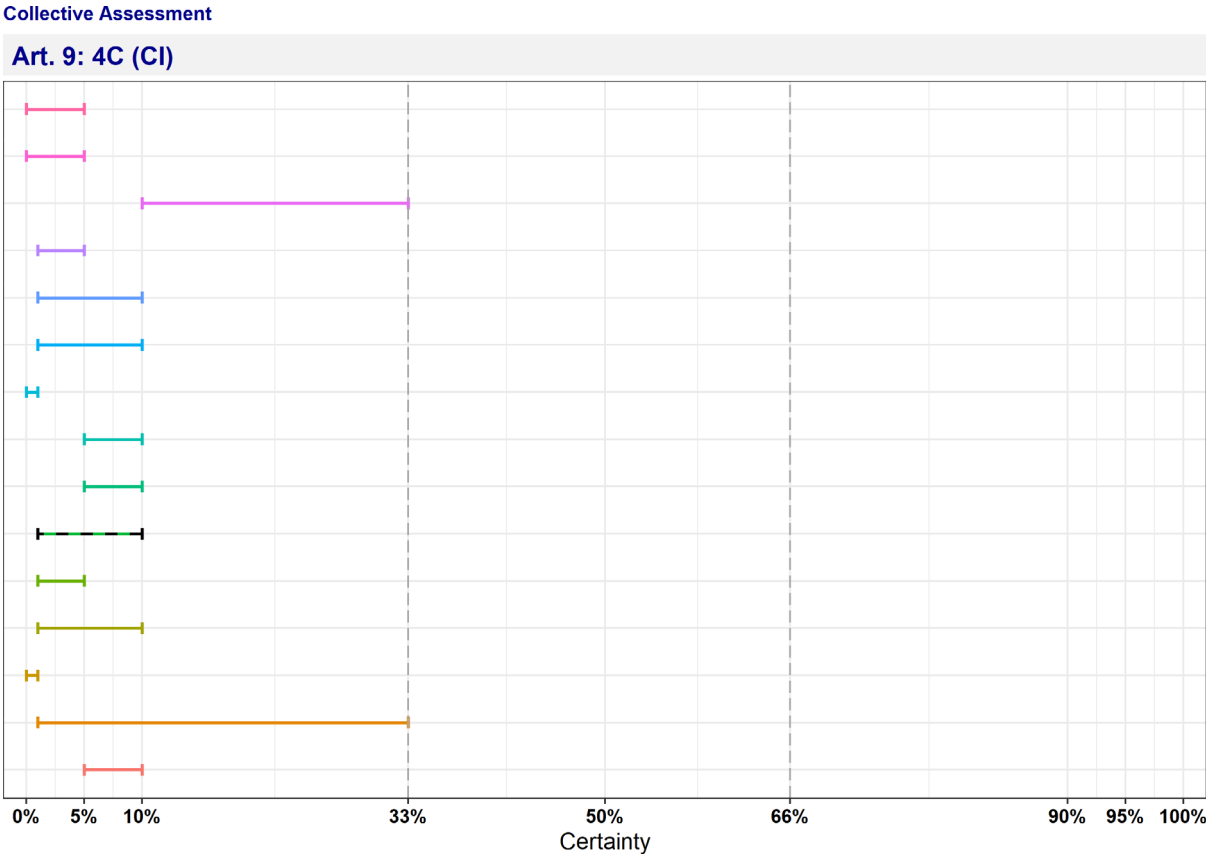
**Figure A.21:** Individual probability ranges reflecting non-fulfilment of criterion 4AB (current impact) (the disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals) after the collective judgement




PI: potential impact

The median range is displayed as a dashed line.

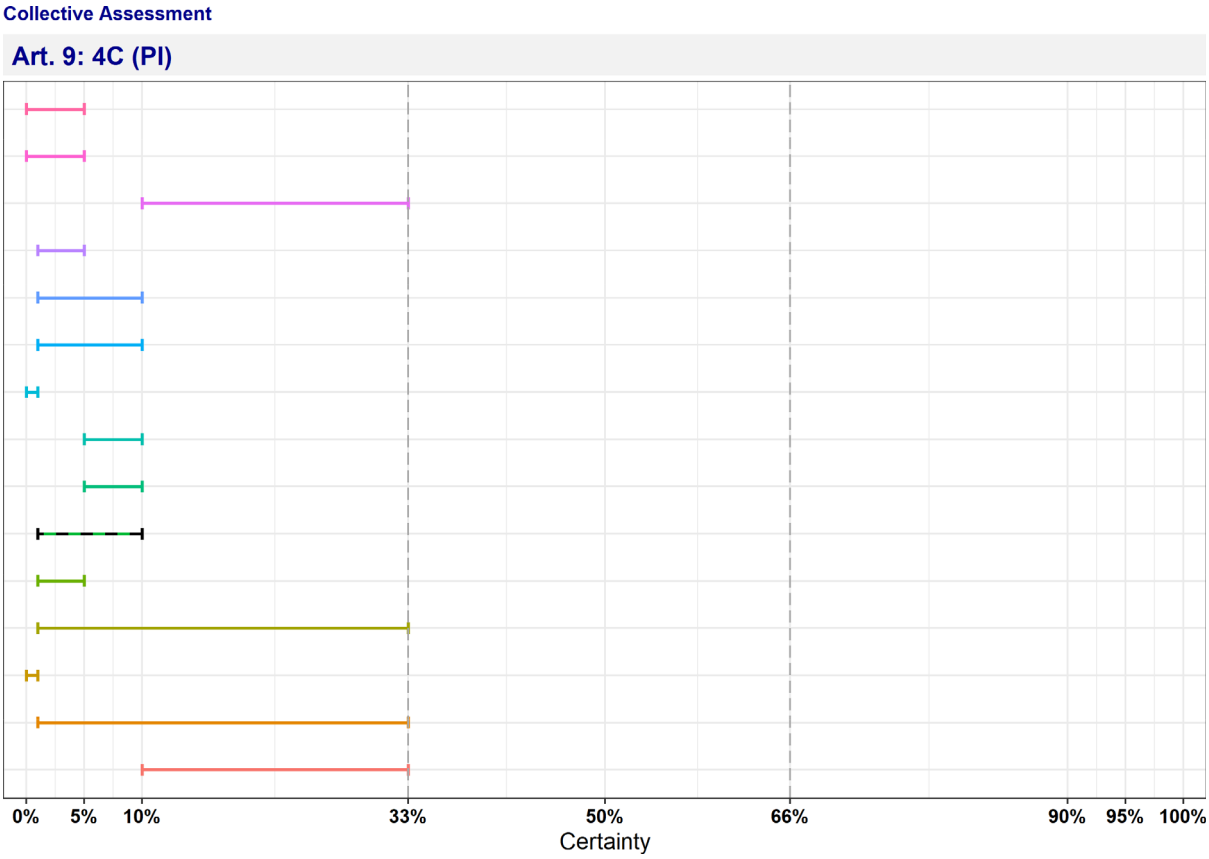
**Figure A.22:** Individual probability ranges reflecting non-fulfilment of criterion 4AB (potential impact) (the disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals) after the collective judgement




CI: current impact

The median range is displayed as a dashed line.

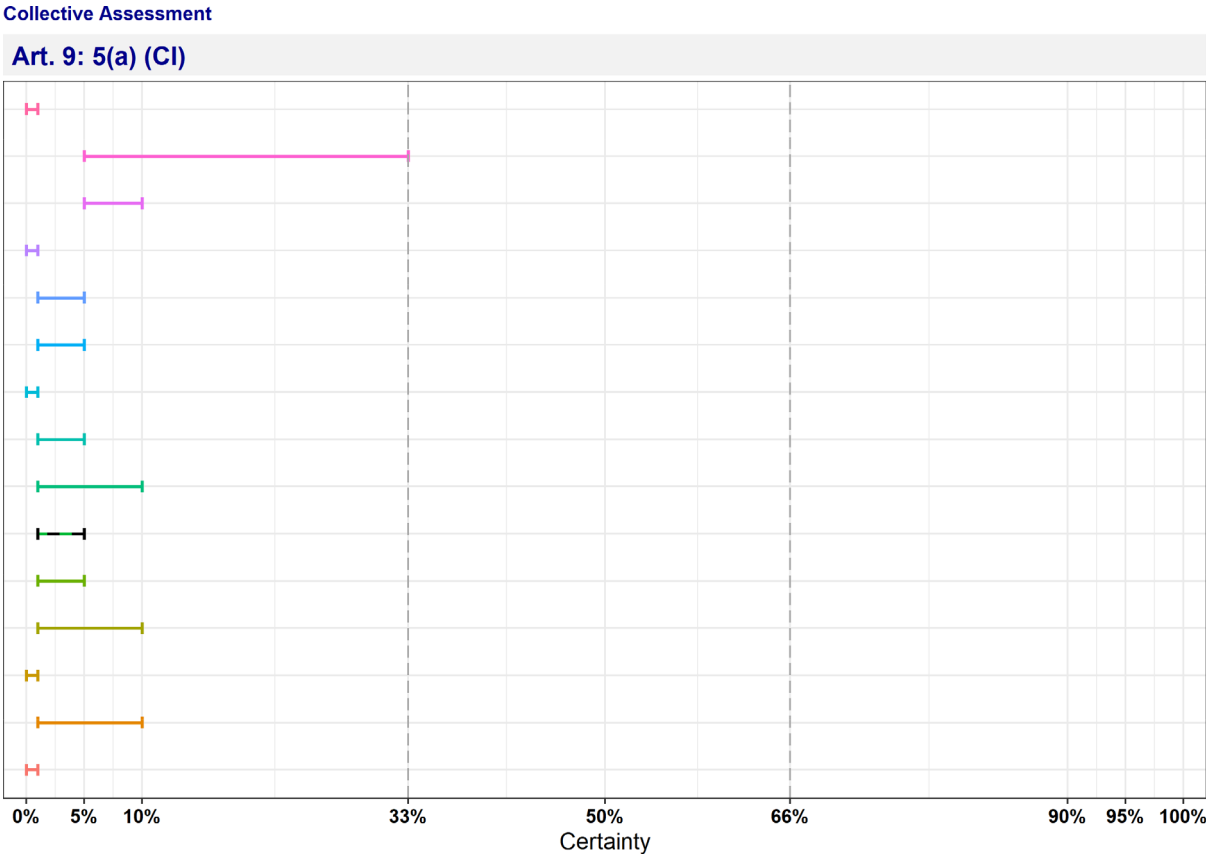
**Figure A.23:** Individual probability ranges reflecting non-fulfilment of criterion 4C (current impact) (the disease has a significant impact on the economy of the Union, mainly related to its direct impact on certain types of animal production systems) after the collective judgement




PI: potential impact

The median range is displayed as a dashed line.

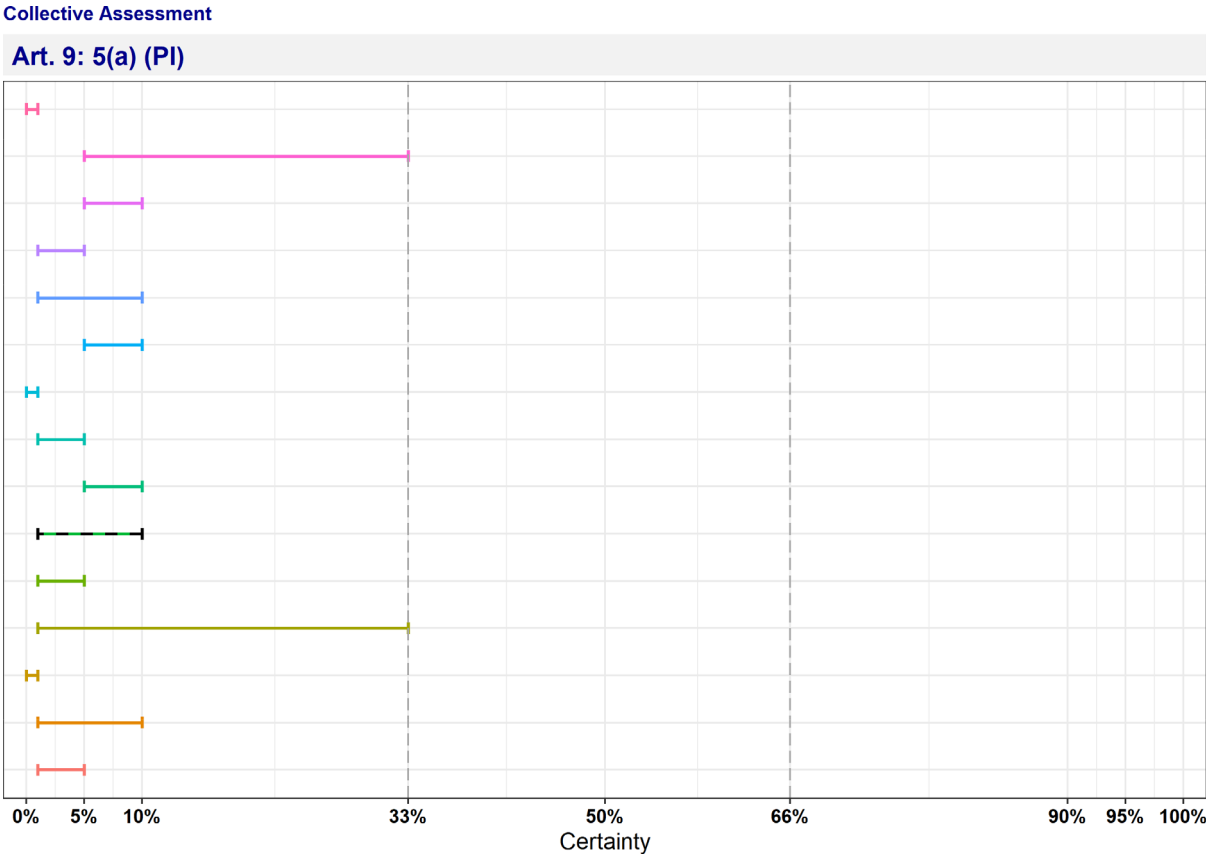
**Figure A.24:** Individual probability ranges reflecting non-fulfilment of criterion 4C (potential impact) (the disease has a significant impact on the economy of the Union, mainly related to its direct impact on certain types of animal production systems) after the collective judgement




CI: current impact

The median range is displayed as a dashed line.

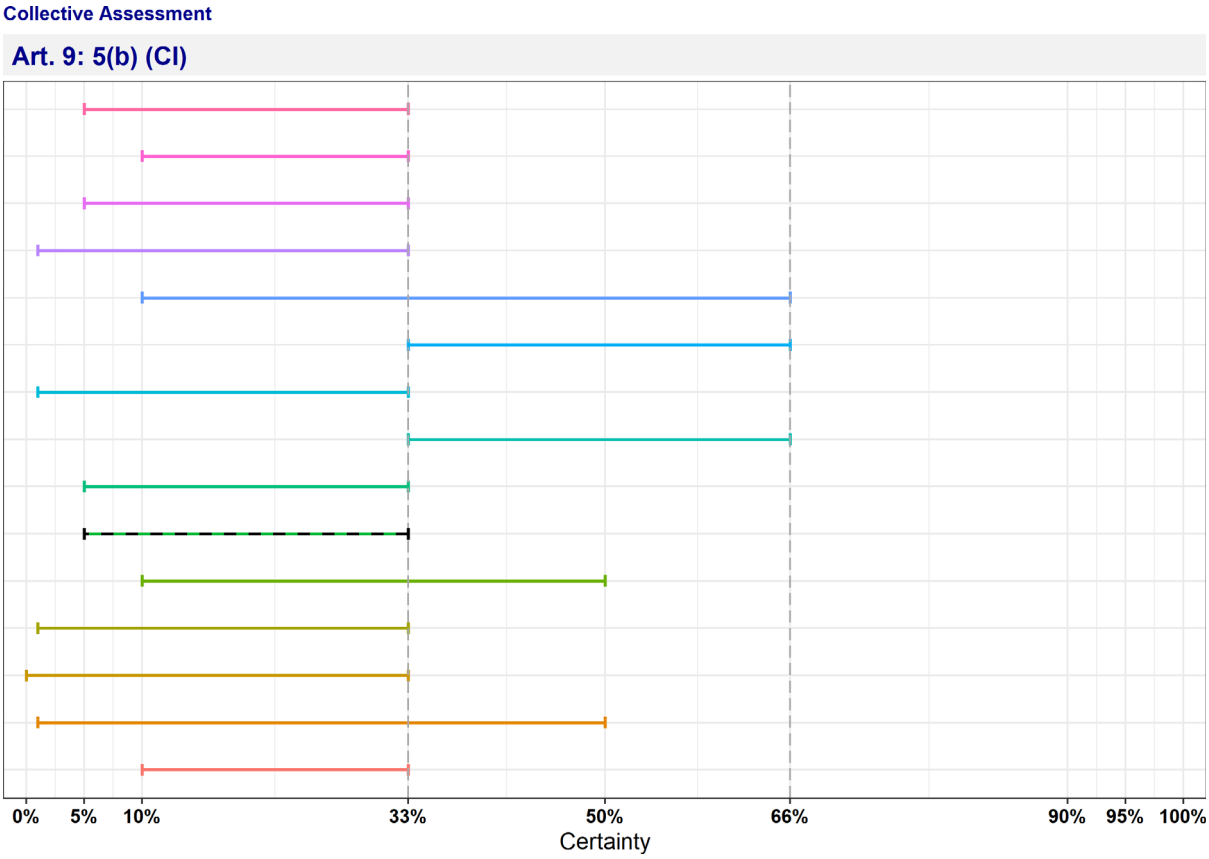
**Figure A.25:** Individual probability ranges reflecting non-fulfilment of criterion 5(a) (current impact) (the disease has a significant impact on society, with in particular an impact on labour markets) after the collective judgement




PI: potential impact

The median range is displayed as a dashed line.

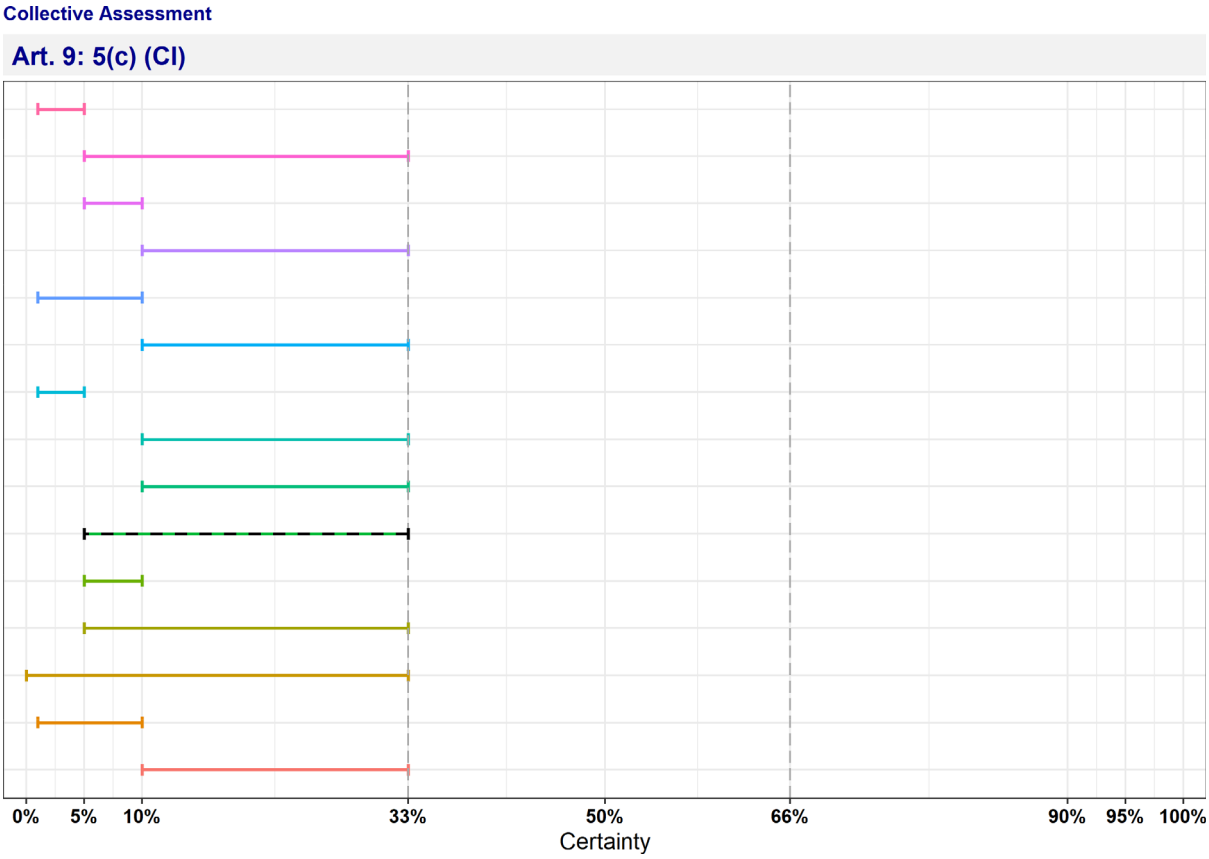
**Figure A.26:** Individual probability ranges reflecting non-fulfilment of criterion 5(a) (potential impact) (the disease has a significant impact on society, with in particular an impact on labour markets) after the collective judgement




CI: current impact

The median range is displayed as a dashed line.

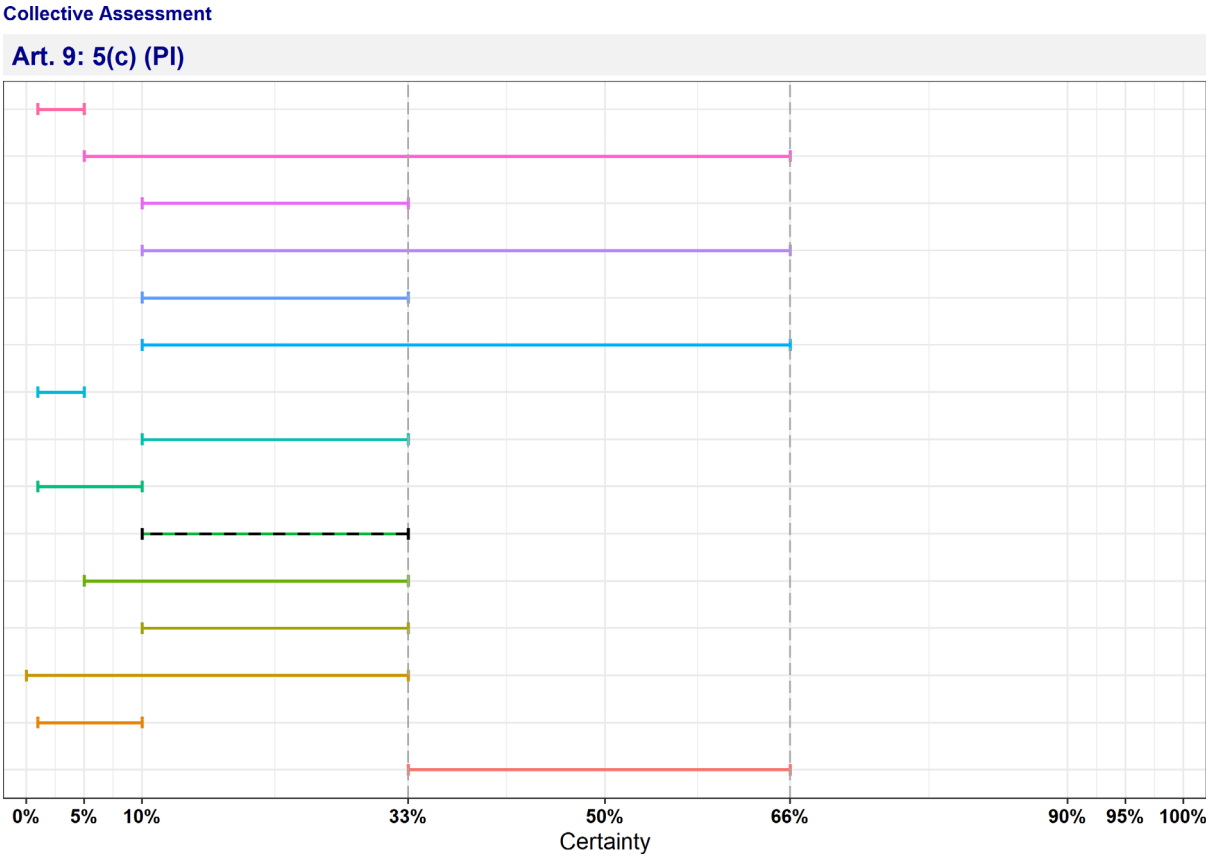
**Figure A.27:** Individual probability ranges reflecting non-fulfilment of criterion 5(b) (current impact) (the disease has a significant impact on animal welfare, by causing suffering of large numbers of animals) after the collective judgement




CI: current impact

The median range is displayed as a dashed line.

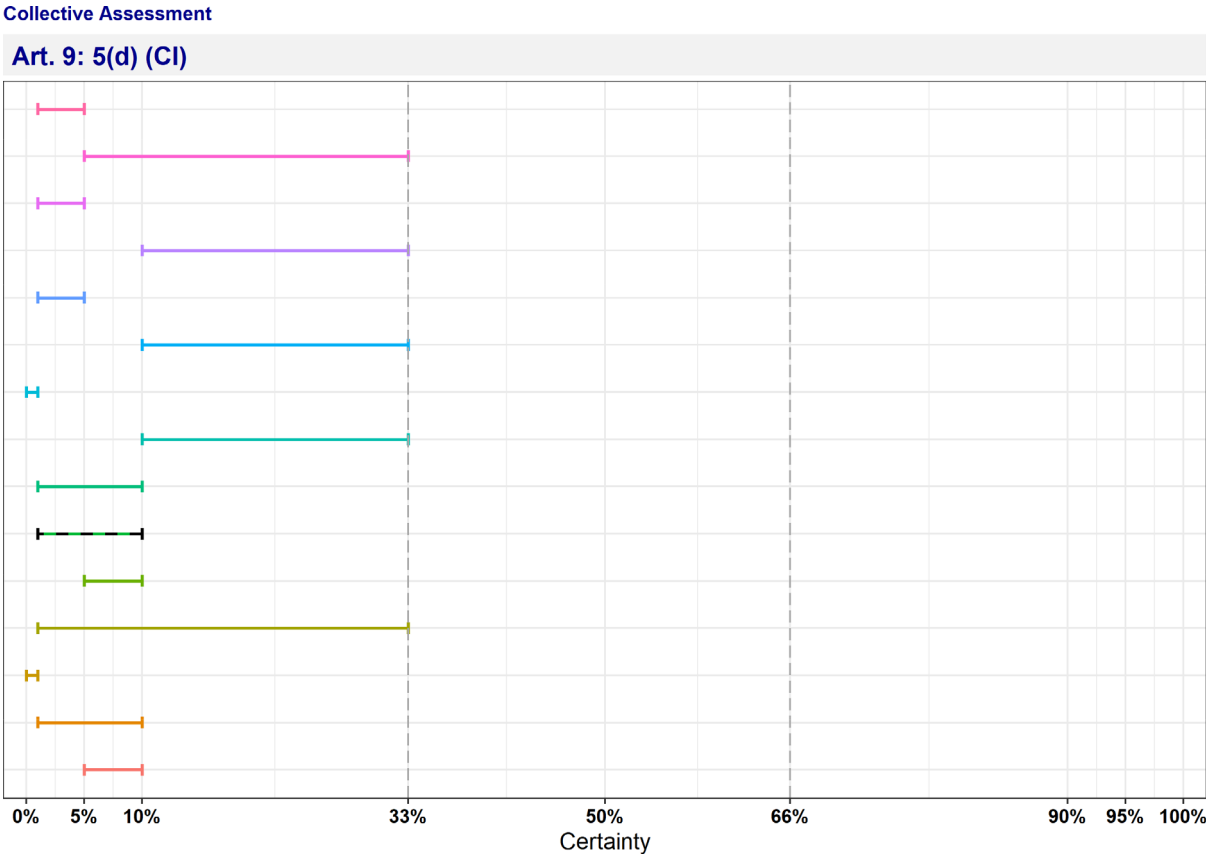
**Figure A.28:** Individual probability ranges reflecting non-fulfilment of criterion 5(c) (current impact) (the disease has a significant impact on the environment, due to the direct impact of the disease or due to the measures taken to control it) after the collective judgement




PI: potential impact

The median range is displayed as a dashed line.

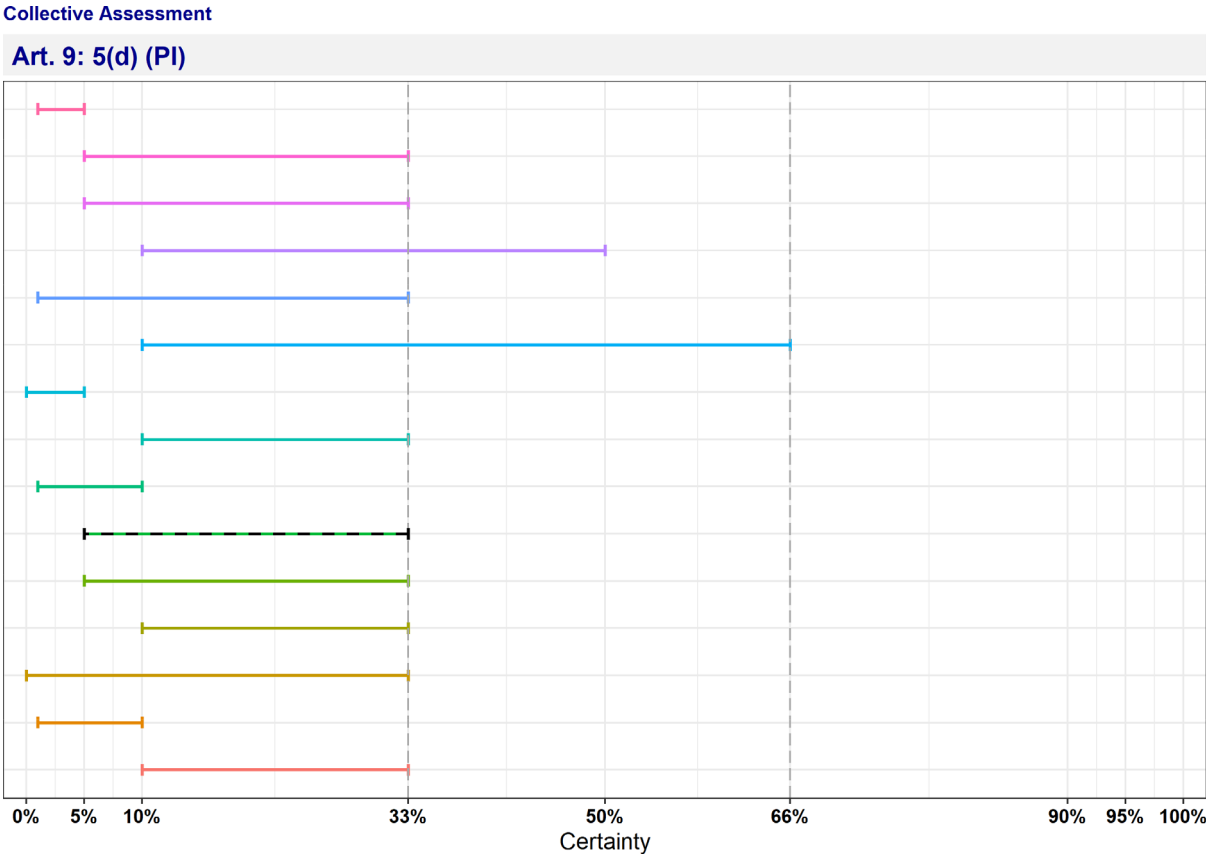
**Figure A.29:** Individual probability ranges reflecting non-fulfilment of criterion 5(c) (potential impact) (the disease has a significant impact on the environment, due to the direct impact of the disease or due to the measures taken to control it) after the collective judgement




CI: current impact

The median range is displayed as a dashed line.

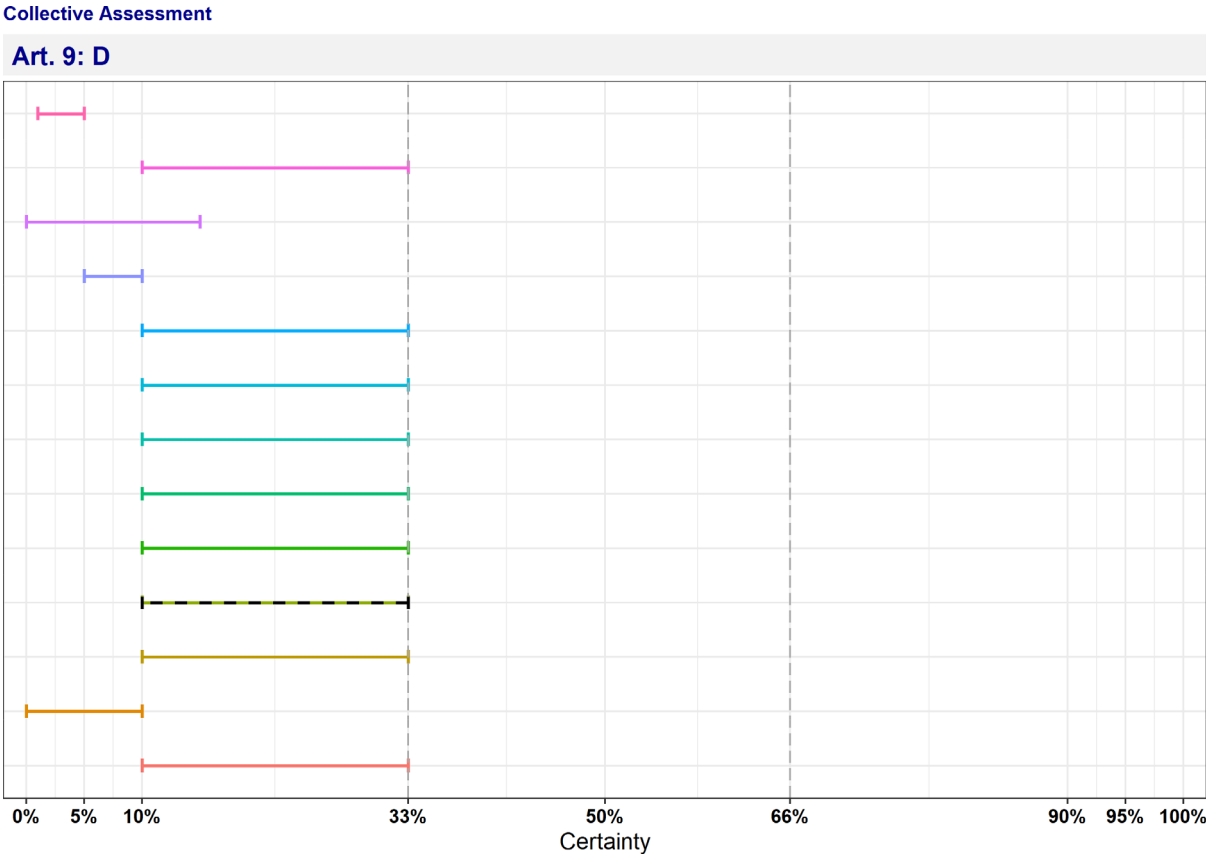
**Figure A.30:** Individual probability ranges reflecting non-fulfilment of criterion 5(d) (current impact) (the disease has a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds) after the collective judgement




PI: potential impact

The median range is displayed as a dashed line.

**Figure A.31:** 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

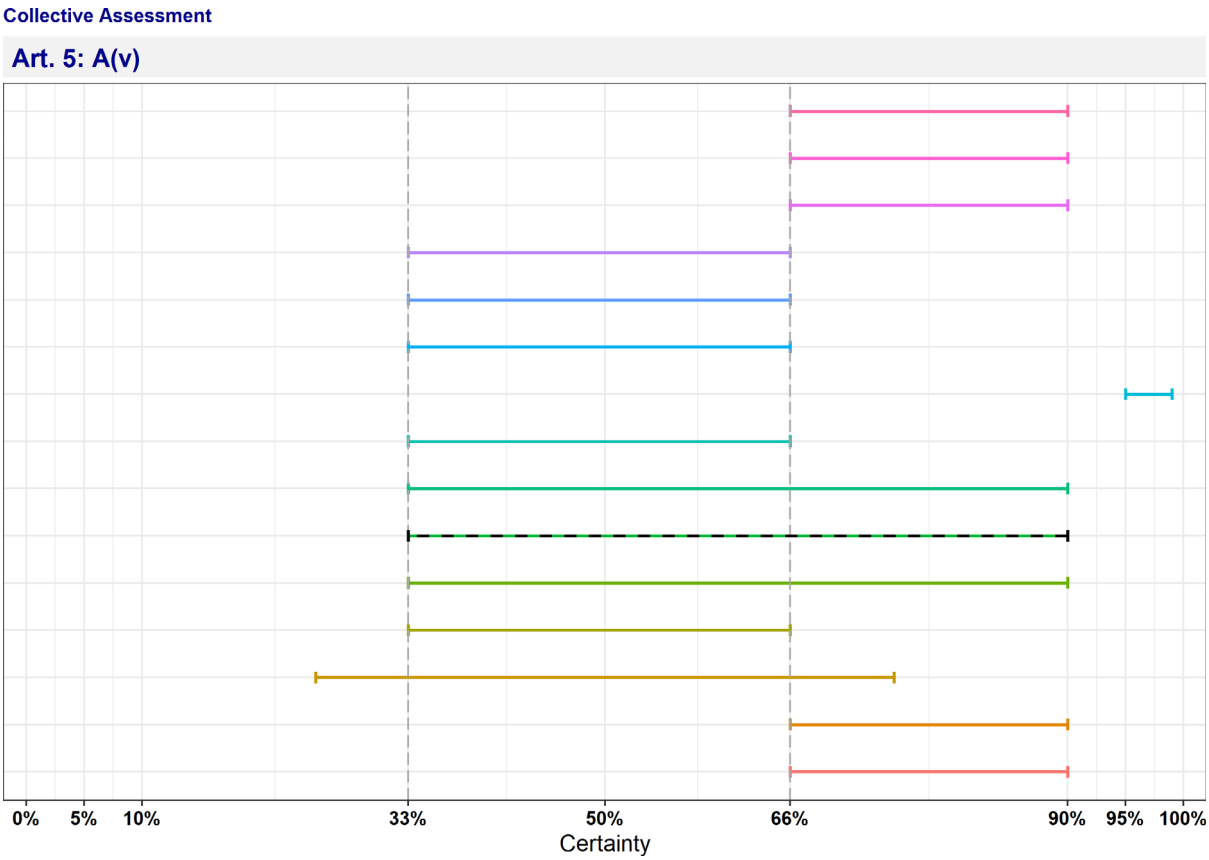



The median range is displayed as a dashed line.

**Figure A.32:** Individual probability ranges reflecting non-fulfilment of 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

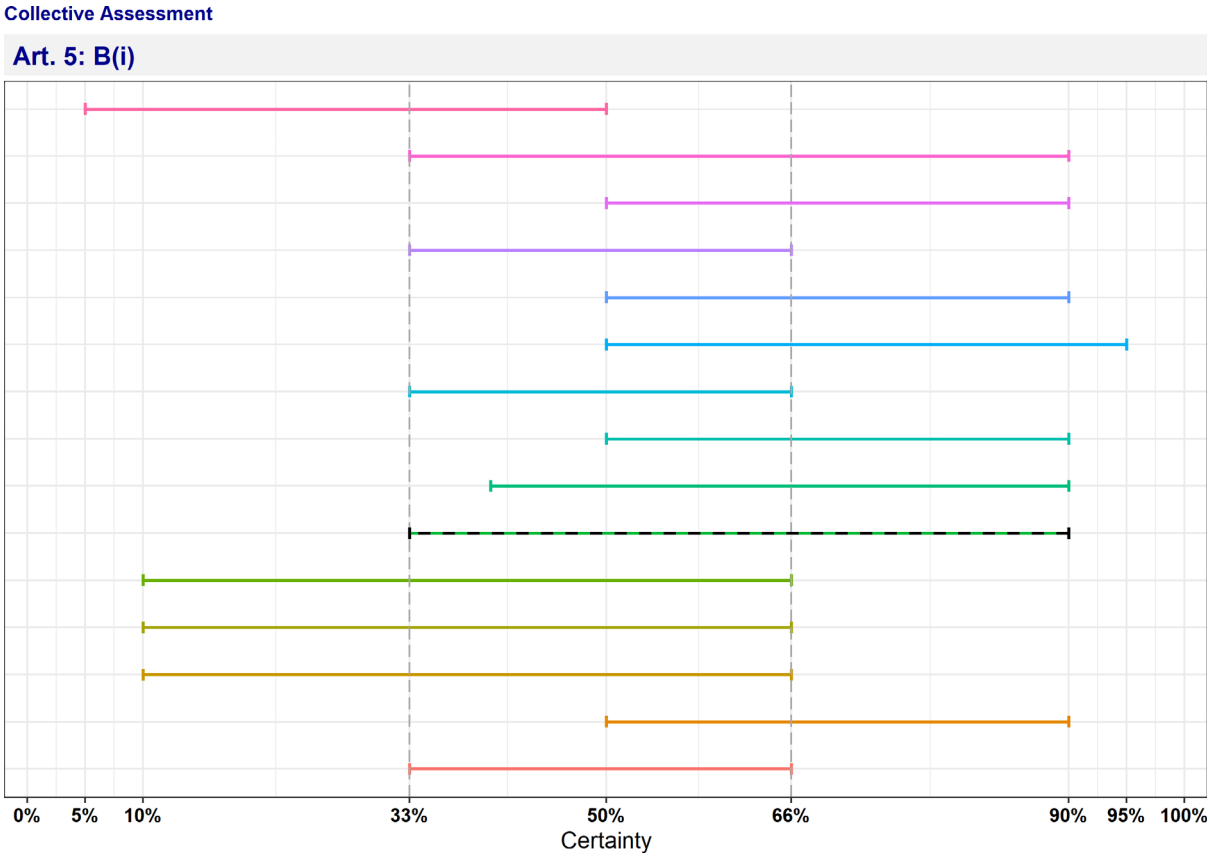
# Annex B – Criteria with uncertain outcome

## B.1. Article 5 criteria




The median range is displayed as a dashed line.

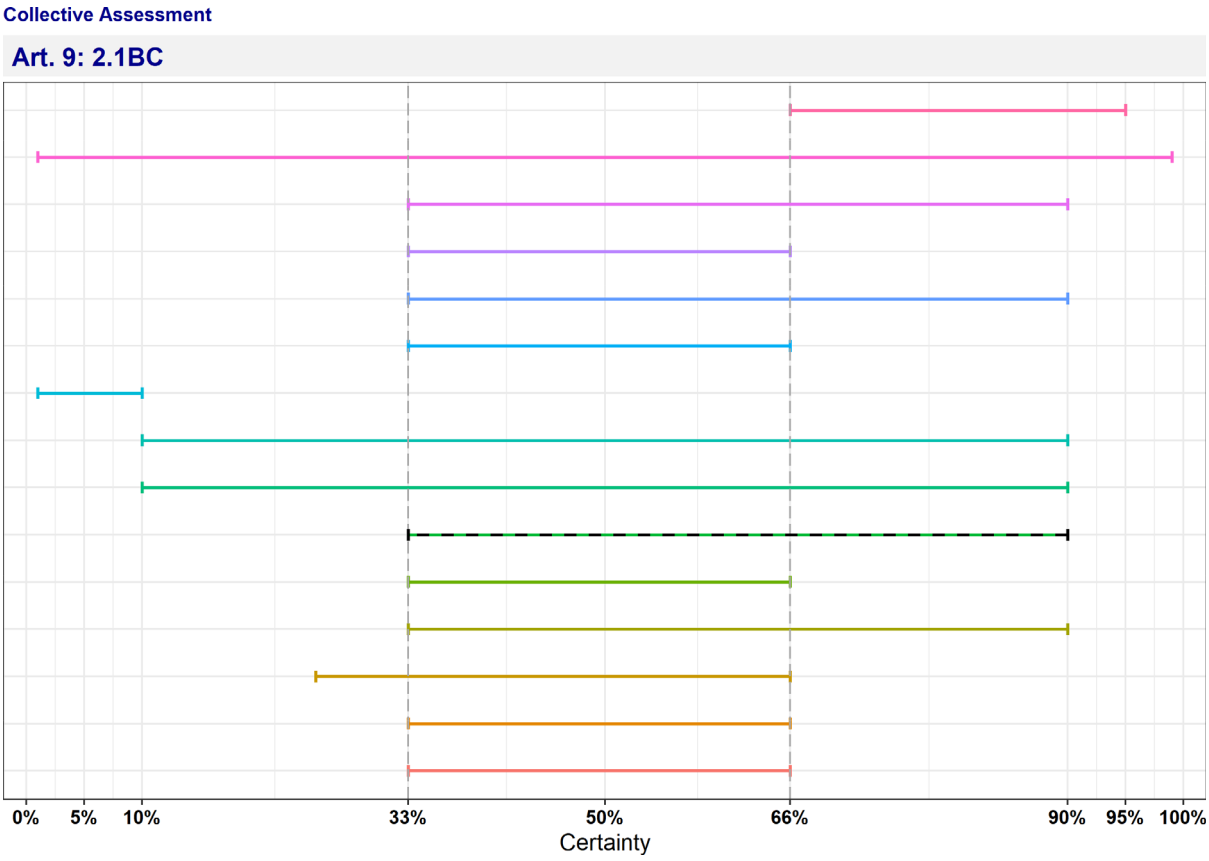
**Figure B.1:** Individual probability ranges reflecting uncertain outcome on criterion A(v) (risk-mitigating measures and, where relevant, surveillance of the disease are effective and proportionate to the risks posed by the disease in the Union) after the collective judgement




The median range is displayed as a dashed line.

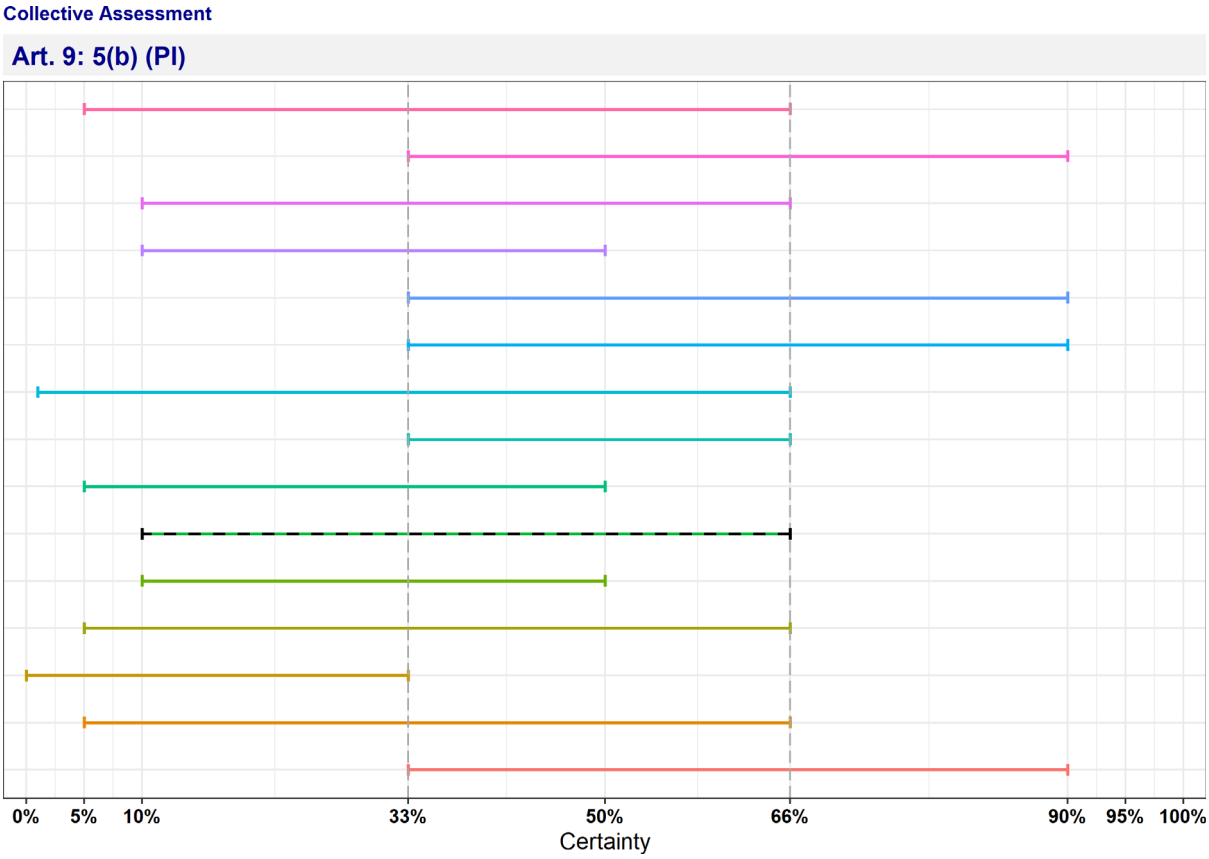
**Figure B.2:** Individual probability ranges reflecting uncertain outcome on criterion B(i) (the disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic character) after the collective judgement

## B.2. Article 9 criteria




The median range is displayed as a dashed line.

**Figure B.3:** Individual probability ranges reflecting uncertain outcome on criterion 2.1BC (the disease is moderately to highly transmissible) after the collective judgement




PI: potential impact

The median range is displayed as a dashed line.

**Figure B.4:** Individual probability ranges reflecting uncertain outcome on 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