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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 *Pseudomonas aeruginosa* in dogs and cats

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### Abstract

*Pseudomonas aeruginosa* (*P. aeruginosa*) 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 *P. aeruginosa* can be considered eligible to be listed for Union intervention according to Article 5 of the AHL (33–90% 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, 3 and 4 (Categories A, B, C and D; 0–5%, 1–5%, 5–33% and 5–33% probability of meeting the criteria, respectively) and the AHAW Panel was uncertain whether it meets the criteria in Section 5 (Category E, 33–90% probability of meeting the criteria). The animal species to be listed for AMR *P. aeruginosa* according to Article 8 criteria are mainly dogs and cats.

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**Keywords:** antimicrobial resistance, *Pseudomonas aeruginosa*, Animal Health Law, listing, categorisation, impact

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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<sup>1</sup> 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, *Pseudomonas aeruginosa* (*P. aeruginosa*) was identified among the most relevant AMR bacteria in the EU for dogs and cats due to its difficulty to treat and the severity of infections caused.

This scientific opinion presents the results of the assessment on AMR *P. aeruginosa* 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 *P. aeruginosa* 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 *P. aeruginosa* in dogs and cats according to the criteria of the AHL articles as follows:

- Article 7: AMR *P. aeruginosa* infection profile and impacts;
- Article 5: eligibility of AMR *P. aeruginosa* infection to be listed;
- Article 9: categorisation of AMR *P. aeruginosa* 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 *P. aeruginosa* infection.

## 2. Data and methodologies

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

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

The following assessment was performed by the EFSA Panel on Animal Health and Welfare (AHAW) based on the information collected and compiled in form of a fact sheet as in Section 3.1 of the present document. The outcome is the median of the probability ranges provided by the experts, which are accompanied by verbal interpretations only when they fall within the ranges as spelled out in Table 1.

<sup>1</sup> 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.

**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 *Pseudomonas aeruginosa* according to Article 7 criteria of the AHL

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

This fact sheet concerns the opportunistic pathogen *P. aeruginosa*. It is a Gram-negative bacterium from the genus *Pseudomonas*. Species within this genus can inhabit a wide variety of environments and include environmental organisms, plant pathogens as well as *P. aeruginosa*, a known opportunistic human and animal pathogen. *P. aeruginosa* has by the World Health Organization (WHO) been deemed a Priority 1 organism, for which there is an urgent need for new antimicrobials. This is due to high levels of antimicrobial resistance. When disease occurs in dogs, *P. aeruginosa* most commonly causes otitis, but due to its opportunistic nature can also cause a wide variety of other types of infections. *P. aeruginosa* can also cause infections in cats although this is less common.

Antimicrobial resistance in *P. aeruginosa* can be attributed to a variety of different mechanisms and is often combinatorial whereby different mechanisms can contribute to resistance to a single antimicrobial (Langendonk et al., 2021). The outer membrane of *P. aeruginosa* is less permeable to antibiotics than other Gram-negative bacteria such as *Escherichia coli* (about 100 times less permeable) (Lister et al., 2009). This low permeability results in intrinsic resistance to many antimicrobials. The outer membrane contains a variety of porins that affect movement in and out of the cell and efflux pumps that can actively pump antimicrobials out. Acquired resistance can occur through the acquisition of new genetic material, such as plasmids, and due to the development of mutations within existing genes which result in altered function. Furthermore, additional resistance can develop through lifestyle/expression changes such as biofilm formation or tolerance (Langendonk et al., 2021).

The fact sheet will discuss antimicrobial resistance in *P. aeruginosa* in companion animals, with the majority of studies in dogs and to a lesser extent in cats. This has been recently reviewed by EFSA (EFSA AHAW Panel, 2021a). As *P. aeruginosa* is found in a wide number of environments, there are also many studies on environmental reservoirs, including in birds. These studies will be discussed in the wider context. The information will focus on multi- and pan-resistance in *P. aeruginosa*. Where appropriate, key resistances, which include carbapenem resistance (as a WHO priority), polymyxin resistance (as a last-resort antibiotic in humans) and fluoroquinolone resistance, an important first-line treatment for many *P. aeruginosa* infections, will be highlighted.

In some cases, information will refer to *P. aeruginosa* (colonisation/prevalence or infection) only and not further elaborated in terms of resistance. This is because the information available on this does not specify antimicrobial resistance; however, the study is still considered important.

Some studies may report sequence type (ST) of *P. aeruginosa*. While ST is not always regarded as the best tool to resolve population structures and pathogenicity in *P. aeruginosa*, this will be reported when studies have linked these with antimicrobial resistance.

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

#### *Susceptible animal species*

*P. aeruginosa*, like in humans, is an opportunistic pathogen of many animal species. In this context, it can cause a range of infections including those in the ears, eyes, urogenital tract, wounds, respiratory system and skin. These infections often occur when normal barriers are breached, and therefore, it is not commonly the primary cause of disease in healthy individuals. However, once infection occurs, effective treatment can be challenging.

In dogs, *P. aeruginosa* can cause ulcerative keratitis (Hewitt et al., 2020), otitis, pyoderma, urinary tract infections, skin and wound infections and respiratory tract infections. The most common *P. aeruginosa*-associated infection in dogs is otitis. *P. aeruginosa* infections can be associated with immunosuppression in companion animals. Pneumonia in a dog post-kidney transplant has been reported (Park et al., 2013) along with cancer treatment-associated infections (Curran et al., 2021). Some dog breeds are more prone to particular infections, with one example being eye infections in the St. Bernard: *P. aeruginosa* was the most common Gram-negative pathogen in that niche and breed, and the most common multidrug-resistant (MDR) pathogen with 100% of isolates displaying resistance to more than seven different antimicrobials (Nadăș et al., 2021).

*P. aeruginosa* is also a pathogen in cats; however, this is to a lesser extent than in dogs (Haenni et al., 2015; de Jong et al., 2020). In cats, respiratory tract infections have been reported (Mohan et al., 2008; Sharma et al., 2019) along with ulcerative keratitis and wound infections (Lin and Petersen-Jones, 2008).

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

There is little information available on the susceptibility of wildlife species to *P. aeruginosa*. *P. aeruginosa* has been detected in migratory birds including swallows (*Yanornis martini*) (Zhang et al., 2017) and the white-faced whistling duck (*Dendrocygna viduata*) (Martins et al., 2018). In these studies, no signs of disease were reported; however, the isolates were found to carry metallo- $\beta$ -lactamase genes (*bla*-VIM and SPM-1, respectively). *P. aeruginosa* has been identified in Siberian (*Leucogeranus leucogeranus*) and Whooping cranes (*Grus americana*), particularly linked with keratitis (Miller et al., 1994). A *P. aeruginosa* isolate has also been cultured from a sea turtle (*Eretmochelys imbricata*), but there was no clear link to disease (Oliveira et al., 2017).

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

Mainly dogs (*Canis lupus familiaris*) and to a lesser extent cats (*Felis catus*) are naturally susceptible domestic species. *P. aeruginosa* can cause otitis media, pneumonia, septicaemia, enteritis and sudden death in chinchillas (*Chinchilla chinchilla*). A study in healthy chinchillas identified *P. aeruginosa* in 42% of 67 animals tested (Hirakawa et al., 2010). Antimicrobial resistance was detected within this panel with 59% resistant to gentamicin, 27% resistant to ceftazidime, 23% resistant to ciprofloxacin and 23% resistant to imipenem (Hirakawa et al., 2010). Rabbits (von Degerfeld et al., 2020), sugar gliders (*Petaurus breviceps*) (Varriale et al., 2019) and snakes (Goldstein et al., 1981) have also been identified with *P. aeruginosa*. In rabbits, it can cause pyometra; however, sugar gliders and snakes are thought to be carriers of *P. aeruginosa*. It can cause mastitis in sheep (Wright et al., 2015). *P. aeruginosa* has also been identified in clinically healthy companion birds (Varriale et al., 2020).

#### 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)

There are many species used as experimental *P. aeruginosa* infection models including mice (Kukavica-Ibrulj et al., 2014), rats (Kukavica-Ibrulj et al., 2008), pigs (Chevaleyre et al., 2016; Ten Have et al., 2019), ferrets (Keiser et al., 2015), chinchillas (Cotter et al., 1996) and zebrafish (Pont and Blanc-Potard, 2021).

#### *Reservoir animal species*

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

*P. aeruginosa* has been identified in the faeces of a number of different species of animals. A study by Ruiz-Roldán et al. (2020) reported *Pseudomonas* spp. in 6.5% of 703 faecal samples. *P. aeruginosa* was

identified in multiple different samples from wild boar (Ruiz-Roldán et al., 2020). Wild snakes have also been found to carry *P. aeruginosa* in the faeces of some healthy animals (13%) (Colinon et al., 2010).

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

Farm animals such as sheep have been identified as a source of *P. aeruginosa*, as these have been cultured from the faeces from healthy animals (Ruiz-Roldán et al., 2020). *P. aeruginosa* was cultured from the faeces of a high number (72/83) of captive snakes; however, prevalence was much lower in wild snakes (Colinon et al., 2010). MDR *P. aeruginosa* has also been identified in the faeces of dogs in shelters (Verma et al., 2021).

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

#### *Morbidity*

##### Parameter 1 – Prevalence/incidence

As an environmental, opportunistic pathogen, *P. aeruginosa* prevalence and incidence are difficult to determine. The bacterium can cause a wide variety of different infections and is often associated with altered underlying health. Most studies focus on the link with infection rather than studying incidence.

As *P. aeruginosa* is not a clear commensal in dogs or cats, longitudinal studies on carriage have not been performed. Few cross-sectional studies on carriage are available; however, a limited number are available on dogs. A study on 228 dogs with no clinical signs of disease revealed that *P. aeruginosa* could be cultured from samples taken from 16.7% of dogs. Isolates were cultured from the ear (6.1%), eye (4.4%), genitalia and rectum (both 3.1%) (Park et al., 2020). Microbiome studies in healthy dogs and those with otitis reported that Pseudomonadaceae were present in both groups, but the relative abundance differed with a higher abundance detected in dogs with otitis (Borriello et al., 2020). However, other studies have found very little evidence of *Pseudomonas* spp. in healthy ears in dogs (Korbelik et al., 2019).

The prevalence varies significantly depending on infection type, and there is often little context or data available to estimate overall levels, particularly for cats. In dogs, Hattab et al. (2021) reported that overall *P. aeruginosa* caused 8% of infections in clinical cases submitted for routine veterinary diagnostics, accounting for 25.4% of otitis infections, 10% of skin infections and 1.6% of urinary tract infections. Urinary infections are significantly more prevalent in female dogs (Hall et al., 2013). *P. aeruginosa* is capable of causing respiratory tract infections in both cats and dogs; however, it is a minor pathogen in this niche (Moyaert et al., 2019a). Otitis is the most common *P. aeruginosa* infection in dogs. Studies on superficial canine infections, the most common being otitis, report a range in prevalence from 25% to 41% (Bourély et al., 2019; Dégi et al., 2021; Hattab et al., 2021). The variation in prevalence is likely due to a combination of differences in sampling and surveillance/identification of cases for study. Prevalence can also be associated with breed. The St. Bernard is more prone to eye infections, and *P. aeruginosa* (including MDR isolates) were the most prevalent Gram-negative in this setting (Nadăș et al., 2021).

Studies reporting antimicrobial resistance are shown in Table 2. There is considerable variation in both the prevalence of resistance to certain antibiotics and the extent of antimicrobial susceptibility testing performed. Some studies report only resistance to gentamicin and enrofloxacin as common agents used to treat cats and dogs with *P. aeruginosa* infection. Gentamicin resistance shows a very wide variation from 4% to 62% (Table 2). This may also be affected by the inclusion criteria of some studies, and there is often little information regarding prior exposure to an antibiotic. Although comparisons are limited due to the small number of isolates from cats, there is little evidence for differences in resistance between isolates from cats and dogs (Werckenthin et al., 2007). Aminoglycoside resistance has been associated with mutations in efflux pumps such as MexXY (Poonsuk and Chuanchuen, 2012).

Fluoroquinolones are also used in the treatment of companion animals with *P. aeruginosa* infections. Enrofloxacin is a first-line veterinary fluoroquinolone with pradofloxacin and marbofloxacin also used. Ciprofloxacin is an important human fluoroquinolone. Like for gentamicin, resistance to enrofloxacin shows considerable study-to-study variation from 4% to 68% (Table 2). Vingopoulou et al. (2018) described similar resistance rates for enrofloxacin, pradofloxacin and marbofloxacin. Veterinary isolates have also displayed high resistance to ciprofloxacin (63–83%), therefore confirming the importance of studying resistance to human-associated antibiotics in studies on veterinary isolates (Haenni et al., 2015; Dégi et al., 2021).

Polymyxins such as colistin are important in the control of human infections and often deemed an antimicrobial of last resort. However, polymyxin B is used in veterinary medicine. Limited studies report resistance to polymyxins. Two studies have reported high levels of resistance to polymyxin B (Scott et al., 2019; Dégi et al., 2021). One of these studies also included resistance to colistin at 54% (Scott et al., 2019). However, both of these studies were on isolates from veterinary hospitals, which therefore may represent a bias towards problematic, chronic infection cases. A study from Denmark on isolates from dogs reported low levels of colistin resistance (2.6%) (Pedersen et al., 2007).

Carbapenem-resistant *P. aeruginosa* has been highlighted as a major issue by the WHO. Carbapenems include meropenem, imipenem and doripenem, key antimicrobials in human medicine, although this antimicrobial class is not used for treating infections in animals. Few studies investigated resistance to carbapenems; however, high prevalence of resistance has been reported in several studies (Gentilini et al., 2018; Dégi et al., 2021; Nocera et al., 2021).

**Table 2:** Published studies on *P. aeruginosa* from dogs and cats in Europe over the last two decades

Animal	Country	No. of isolates	Resistance (%)	Notes	Infection	Year	Reference
Dogs	France (RESAPATH)	46	TIC 24%, TIM 35%, FEP 9%, ATM 7%, AMK 15%, GEN 57%, TOB 11%, FOF 48%, CIP 63%	Isolates from dogs significantly more resistant to GEN and TIM and CIP than isolates from other animals	Otitis	2008–2011	Haenni et al. (2015)
Dogs, cats	France (RESAPATH)	24, 5	Carbapenem-resistant isolates studied: IMP 66% (19/29), MEM 69% (20/29)	29/527 carbapenem-resistant isolates chosen for inclusion in the study	Otitis and pulmonary infection	2008–2014	Haenni et al. (2017)
Dogs	Greece	75	ENR 44%, MAR 32%, PRA 48%	Prior treatment with FQ significantly increased resistance to FQ	Otitis	2010–2014	Vingopoulou et al. (2018)
Dogs	France (RESAPATH)	2103	ENR 68%, GEN 18%	Trend to decline in FQ resistance over time	Otitis	2012–2016	Bourély et al. (2019)
Dogs	Romania	58 (from 142 assessed)	CAZ 47%, AZT 48%, AMK 55%, ATM 59%, GEN 62%, FEP 64%, MEM 74%, TZP 74%, IMP 78%, CIP 83%, TOB 91%, PMB 98%	18 MDR isolates	Skin infections, otitis, perianal abscesses	2019	Dégi et al. (2021)
Dogs	Italy	24	CAZ 0%, GEN 0%, ATM 0%, IMP 0%, ENR 4%, TZP 8%	Intermediate resistance to ENR (42%) and IMP (29%) reported	Skin (6), otitis (15), UTIs (3)	2019–2020	Hattab et al., (2021)



Animal	Country	No. of isolates	Resistance (%)	Notes	Infection	Year	Reference
Dogs, cats	Belgium, Czech Republic, France, Germany, Hungary, Italy, Netherlands, Poland, Spain, Switzerland and UK (COMPACT)	23, 23	MICs reported instead of %.  Dogs: FQ MIC <sub>50/90</sub> of 0.5–2 µg mL <sup>-1</sup> and NEO MIC <sub>50</sub> and MIC <sub>90</sub> of 8 and 32 µg mL <sup>-1</sup>  Cats: FQ MIC <sub>50/90</sub> of 0.25–1 µg mL <sup>-1</sup> and NEO MIC <sub>50</sub> and MIC <sub>90</sub> of 8 and 8 µg mL <sup>-1</sup>		Respiratory disease	2013–2014	Moyaert et al. (2019a,b)
Dogs, cats	Iberian Peninsula	825, 76	Dogs: ≥ 50% – AMC, FOX, AMP, LEX, CXM, CVN, CTX, CPD, SXT, FFC, CHL, FOF  Cats: ≥ 50% – AMC, FOX, AMP, LEX, CXM, CVN, CTX, CPD, SXT, FFC, CHL, FOF. Of 28 antibiotics tested.	<i>Pseudomonas</i> spp. Rather than <i>P. aeruginosa</i>	Otitis, wound infections, respiratory tract infections, pleuritis, dermatitis, abscesses, conjunctivitis	2016–2018	Li et al. (2020)
Dogs, cats	12 European countries (ComPath)	174, 12	GEN – 10% R and 18% I	Only GEN tested	Skin, wound and ear infections	2013–2014	de Jong et al. (2020)
Dogs, cats	Germany	36	MDR isolates in open wound treatment: 78% MDR isolates in follow treatment: 82% MDR isolates in bite wounds: 12%	Limited data reported	Open wounds	2011–2013	Nolff et al. (2016)
Dogs, cats	Spain	45, 19	Dogs: ≥ 50% – AMC, AMP, LEX, CEF, CXM, CTX, CVN, ENR, PRA, DOX, FOF, NIT, SXT  Cats: ≥ 50% – AMC, AMP, LEX, CEF, CXM, CTX, CVN, DOX, FOF, NIT, SXT	4% of isolates were MDR and 1 isolate from a cat was PDR	UTIs	2016–2018	Darwich et al. (2021)

Animal	Country	No. of isolates	Resistance (%)	Notes	Infection	Year	Reference
Dogs, cats	Italy	29, 1	10 antibiotics tested in total: $\geq 50\%$ resistance in AMP, AMC, IMI, ENR, ERY, TET, SXT	Increasing levels of R to PRA and MAR over the 4-year period	Otitis, pyoderma	2016–2019	Nocera et al. (2021)
Dogs, cats	Czech Republic, France, Germany, Hungary, Italy, Netherlands, Poland, Spain, Sweden and UK (ComPath)	160, 11	GEN – 19% R in dogs ENR – 18% R in cats MIC90 reported for a range of antibiotics. Similar for dogs and cats: PRA 2 $\mu\text{g}/\text{mL}$ , ORB 8 $\mu\text{g}/\text{mL}$ , MAR 2 $\mu\text{g}/\text{mL}$ , Ibafloxacin > 8 $\mu\text{g}/\text{mL}$ , ENR 8 $\mu\text{g}/\text{mL}$ , GEN 8 $\mu\text{g}/\text{mL}$ , CVN > 32 $\mu\text{g}/\text{mL}$ , LEX > 32 $\mu\text{g}/\text{mL}$		Pyoderma, wound infections, abscesses and otitis	2008–2010	Ludwig et al. (2016)
Dogs, cats	Germany (BfT-GermVet)	78, 5	PRA resistance determined by MIC90: Skin and ear – 4 $\mu\text{g}/\text{mL}$ , genital/urinary – 4 $\mu\text{g}/\text{mL}$	Only focus was PRA	Skin, ear and genital infections, UTIs	2004–2006	Schink et al. (2013)
Dogs, cats	Germany (BfT-GermVet)	99 in total	Dogs: GEN R-27%, I-29%, ENR R-24%, I-49%, GEN R-11%, I-39%, ENR R-11%, I-61%		Skin, ear and mouth infections, urinary and genital tract infections	2004–2006	Werckenthin et al. (2007)
Dogs, cats	Italy	5, 1	IPM MIC – 19 $\mu\text{g}/\text{mL}$ , MEM MIC – 2–8 $\mu\text{g}/\text{mL}$	Isolates carried <i>oprD</i> mutations and extended-spectrum $\beta$ -lactamases	Hospitalised pets	2014–2015	Gentilini et al. (2018)
Dogs, cats	UK	20, 1	PMB 92%, CST 54%, AMK 0%, CEF 92%, ENR 33%, GEN 4%, IPM 0%, MAR 21%, TIC 21%, TIM 4%	Isolates from a referral centre, therefore presumably difficult to treat	Otitis; skin, wound, genital and urinary infections	2012	Scott et al. (2019)

Animal	Country	No. of isolates	Resistance (%)	Notes	Infection	Year	Reference
Dogs	Denmark	39	AMP 100%, AMC 100%, CET 100%, CLI 100%, ERY 100%, CHL 89.7%, SPT 97.4%, TET 89.7%, SXT 92.3%, KAN 95.0%, ENR 35.9%, GEN 15.4%, CST 2.6%		Otitis externa	2000–2005	Pedersen et al. (2007)
Dogs	Croatia	109	FEP 31.7%, CAZ 0%, ENR 51.9%, CIP 8.7%, GEN 43.3%, TIM 10.6%	Increase in resistance to GEN and ENR since 2002	Otitis	2007–2009	Mekić et al. (2011)

AMC: amoxicillin–clavulanic acid; AMK: amikacin; AMX: amoxicillin; ATM: aztreonam; AZM: azithromycin; CAZ: ceftazidime; CEF: ceftiofur; CET: cefalotin; CHL: chloramphenicol; CIP: ciprofloxacin; CLI: clindamycin; CPD: cefpodoxime; CST: Colistin; CTX: cefotaxime; CVN: ceftovecin; CXM: cefuroxime (axetil or sodium); DOX: doxycycline; ENR: enrofloxacin; ERY: erythromycin; FEP: cefepime; FFC: florfenicol; FOF: fosfomycin; FOX: ceftiofur; FQ: fluoroquinolones; GEN: gentamicin; I: intermediate; IPM: imipenem; KAN: kanamycin; LEX: cephalosporin; MAR: marbofloxacin; MDR: multidrug-resistant; MEM: meropenem; MIC: minimum inhibitory concentration; NEO: neomycin; NIT: nitrofurantoin; ORB: orbafoxacin; PDR: pandrug-resistant; PMB: polymyxin B; PRA: pradofloxacin; R: resistant; SPT: spectinomycin; SXT: trimethoprim–sulfamethoxazole; TET: tetracycline; TIC: ticarcillin; TIM: ticarcillin–clavulanic acid; TOB: tobramycin; TZP: piperacillin–tazobactam, UTI: urinary tract infection.

Outside of the Union, AMR *P. aeruginosa* has also been detected in companion animals. A study on healthy and infected dogs in South Korea reported antimicrobial resistance in strains isolated from both healthy dogs and from infection (mostly otitis externa) compared to healthy controls (Park et al., 2020). Whilst infection isolates showed higher resistance than healthy controls, this difference was not significant. Worryingly, genes encoding carbapenemases such as VIM-2 (Hyun et al., 2018) and IMP-45 (Wang et al., 2014) have been detected in Asia (Ekapopphan et al., 2018). These carbapenemase genes such as *bla*-VIM-2 have also been identified in other animal niches such as cattle and fowl (Argudín et al., 2017). Resistance varies between countries, as a large study in dogs from Japan revealed no imipenem resistance, but 35% of isolates showed resistance to fosfomycin (Yukawa et al., 2017). Increases in resistance have also been reported in the USA and UK (Hall et al., 2013; Hewitt et al., 2020). In the UK, a significant increase in AMR *P. aeruginosa* isolates was detected over a 10-year period (1999–2009) (Hall et al., 2013). Although these countries are outside of the Union, it is important to consider recent global studies for full insight.

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

No studies are available to measure the case-morbidity rate for *P. aeruginosa*.

#### *Mortality*

#### Parameter 3 – Case-fatality rate

Although *P. aeruginosa* is known to cause fatal conditions such as sepsis and pneumonia, there is little literature that reports case-fatality rates. The occurrence of death associated with AMR *P. aeruginosa* has not been reported.

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

#### Parameter 1 – Report of zoonotic human cases (anywhere)

*P. aeruginosa* is a known human pathogen. It is described as opportunistic and infections are normally associated with an underlying health condition or breach in a normal protective barrier. It can cause infections in the respiratory, gastrointestinal and urinary tract, otitis, keratitis, wounds and burns



infections. It can also cause sepsis and in some cases meningitis. *P. aeruginosa* causes 10–15% of all nosocomial infections worldwide and mortality rates associated with human infections can vary from 18% to 61% (Shi et al., 2019).

There are very few studies on potential transmission between animals and humans, and a combination of the opportunistic nature of *P. aeruginosa* and a separation between human and animal healthcare may result in potential cases being missed. Despite this, there have been some reports. A study identified cross-contamination of the environment and owners from dogs with otitis (Morris et al., 2017).

The pet cat of a person with cystic fibrosis (CF) developed a respiratory infection caused by a transmissible strain, the Liverpool Epidemic Strain (LES) (Mohan et al., 2008). However, there is little evidence of any risk to humans with CF. A large study of 703 people with CF studied risk factors associated with dog and cat ownership. There was no significant difference in prevalence or age of acquisition of *P. aeruginosa* (Morrow et al., 2014). A possible case of transmission from a dog to a young child with CF has been reported; however, similarity was by antibiogram alone and, if there was transmission, no knowledge of directionality (pet-to-human vs. human-to-pet) was known (Michl et al., 2017).

The term transmissible strain has been used to describe some unusual strains of *P. aeruginosa* for which there is evidence of cross-infection between unrelated individuals (Fothergill et al., 2012). Historically, this has occurred in people with CF in either healthcare settings or holiday camps. The genetic or phenotypic cause of transmissibility has not been determined. The vast majority of *P. aeruginosa* infections are acquired from environmental sources rather than direct spread from another infected individual.

The *P. aeruginosa* population has been well characterised using a variety of molecular genomics methods. Clones with links to human infections have also been found in animal infections; however, this is not evidence of transmission in itself (Haenni et al., 2017; Scott et al., 2019). This would be expected when studying a wide variety of infections. High-risk clones such as ST233 and ST395 have been identified in isolates from dogs. ST233 has been identified in five of six continents and contains *bla*-IMP and *bla*-NDM carbapenemases (Del Barrio-Tofiño et al., 2020). An ST233 VIM-2-producing *P. aeruginosa* isolate was isolated from a dog and from the faecal sample of its owner who had recently had a long hospital stay in an intensive care unit. This case study further highlights the potential for transmission between pets and owner with particular respect to high-risk clones (Fernandes et al., 2018).

### 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

*P. aeruginosa* is a highly resistant bacterial species and has by the WHO been designated a Priority 1 organism for which there is an urgent need for new therapeutics. A simple search using Pubmed and the terms '*Pseudomonas aeruginosa* antibiotic resistance' yielded over 15,000 results and over 1,000 in 2020. Certain ST types have been deemed as high-risk clones according to a combination of the antimicrobial resistance and virulence profiles. The worldwide top 10 *P. aeruginosa* high-risk clones include ST235, ST111, ST233, ST244, ST357, ST308, ST175, ST277, ST654 and ST298. These include extensively drug-resistant (XDR) strains that are resistant to all antibiotics tested (Del Barrio-Tofiño et al., 2020).

Fluoroquinolone resistance has been reported and associated with mutations in DNA gyrase, topoisomerase and efflux pump overexpression (Vingopoulou et al., 2018). Enrofloxacin resistance has been demonstrated at high levels (Bourély et al., 2019) and this fluoroquinolone has been used as a veterinary antibiotic for the longest. Ciprofloxacin is an important human antimicrobial. Resistance to this has been widely reported in human infections and has also been identified in companion animal isolates (Haenni et al., 2015; Dégi et al., 2021).

The main carbapenems in use are meropenem, imipenem, doripenem and ertapenem. Resistance to carbapenems can be caused by a variety of mechanisms. Resistance can occur through changes in existing genetic or the acquisition of new genetic material. Intrinsic changes include changes in outer membrane permeability through alterations to porins, efflux pump activity and existing cephalosporinase activity (Meletis et al., 2012). Mutations in genes encoding porins such as *oprD* and efflux pumps such as *mexAB-oprM* are commonly identified. Acquisition of new genetic material is often the gain of transferable carbapenemases such as metallo- $\beta$ -lactamases (Meletis et al., 2012). These enzymes can be carried on mobile genetic elements such as plasmids and integrons. Carbapenem resistance can be multifactorial and is often associated with resistance to other antibiotics, and therefore, the therapeutics available for use are dramatically reduced. This is a major issue in human medicine; however, this has been reported in veterinary medicine, too (Haenni et al., 2017).

Polymyxin B and polymyxin E (colistin) are used in veterinary and human medicine. These polycationic compounds disrupt the cell membrane by binding lipid A of lipopolysaccharide (LPS);

however, systemic use is often considered a last resort due to toxic side effects. Polymyxins have historically been widely used in the veterinary setting, particularly in livestock such as for the treatment of Enterobacteriaceae and growth promotion in pigs. Resistance to polymyxins can be associated with chromosomal alterations, largely changes in LPS structure, or through the acquisition of new genetic material such as *mcr* genes. LPS modification leading to polymyxin resistance has been reported due to mutations in two component systems including *pmrAB* and *phoPQ* (Khondker and Rheinstädter, 2020). Polymyxin resistance genes such as *mcr-1* have also been identified on plasmids (Wang et al., 2018). Although polymyxin resistance has been identified in isolates from companion animals (Scott et al., 2019; Dégi et al., 2021), transferable plasmid-related *mcr* genes have not been reported to date. However, *mcr* genes were first isolated from animals and their presence in other Gram-negative bacteria in this niche has been widely reported including in the Union, particularly from porcine origin (Liu et al., 2016; Xavier et al., 2016; Yin et al., 2017; Wang et al., 2018, 2019; Borowiak et al., 2019; Carroll et al., 2019; Gelbíčová et al., 2019).

### 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

Infection of cats and dogs is normally from the environment and does not transmit between individuals. Animals with infections may result in high levels of the bacterium in the immediate environment (household, shelter, etc.); however, there is little data on persistence in this niche. *P. aeruginosa* can cause both acute and chronic infections, and therefore, the length of infection can vary from days/week to chronic infections that can potentially last years in animals and decades in humans. Duration of treatment for *P. aeruginosa* infections in dogs is typically 3–4 weeks but can be up to 12 weeks (Hillier et al., 2006).

A case study of a cat with severe, chronic rhinosinusitis with mucoid *P. aeruginosa* has been reported (Sharma et al., 2019). Mucoid *P. aeruginosa* is generally linked with chronic respiratory infections and in people with CF often signifies a stage at which cure is not possible. Therefore, the presence of these phenotypes in infections in cats may be associated with infections that are much harder to eliminate. In the case study, the 6-year-old cat had presented with sinus issues since kittenhood, but the duration of infection with *P. aeruginosa* is unclear.

##### Parameter 2 – Presence and duration of latent infection period

There are no data to estimate the duration of the latent infection period for *P. aeruginosa* infections.

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

There are limited studies on the presence and duration of *P. aeruginosa* in healthy dogs and no data available in cats. As stated previously, a study on 228 dogs with no clinical signs of disease revealed that *P. aeruginosa* could be cultured from samples taken from 16.7% of dogs. Isolates were cultured from the ear (6.1%), eye (4.4%), genitalia and rectum (both 3.1%) (Park et al., 2020). Microbiome studies in healthy dogs and those with otitis reported that Pseudomonadaceae were present in both groups, but the relative abundance differed (Borriello et al., 2020). However, other studies have found very little evidence of *Pseudomonas* spp. in healthy ears (Korbelik et al., 2019). In a study of bacteria in faecal samples from dogs in shelters, only a single isolate of *P. aeruginosa* was cultured (Verma et al., 2021).

#### Environment

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

As *P. aeruginosa* is an environmental organism, it readily survives in soil and water. It can survive between 4°C and 42°C; however, virulence and growth would be reduced at lower temperatures (LaBauve and Wargo, 2012). It can also utilise a wide range of carbon sources and this flexibility is attributed to its large genome, which supports metabolic diversity.

Survival in air has been reported; however, this is normally through aerosolisation from those with respiratory infection, and the bacterium can be identified in aerosolised droplets. Aerosols from

coughing have been shown to travel up to 4 m and stay in the air for around 45 min (Schelstraete et al., 2008; Knibbs et al., 2014). However, these studies are based on humans and no data exist for potential aerosolisation from animals. Environmental contamination around infected individuals has been identified although there appears to be strain-to-strain variation in survival on dry surfaces (Panagea et al., 2005). Sinks can be a significant source of *P. aeruginosa* contamination and good cleaning/hygiene measures around sinks and water sources is needed, particularly in the healthcare setting (Fusch et al., 2015).

### **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)

There is little published evidence of animal-to-animal transmission. The vast majority of *P. aeruginosa* infection cases would be infection from the environment and there are no reports of nosocomial transmission in veterinary clinics resulting in infection. However, transmission between susceptible individuals (people with CF) has been documented in humans in both healthcare and leisure settings (Fothergill et al., 2012); therefore, there may be potential for transmission between susceptible individuals in certain settings. For people with CF, *P. aeruginosa* causes lung infections and therefore can be aerosolised through coughing. This may contribute to transmission and potential transmission dynamics may be altered for different infection types such as otitis or pyoderma. *P. aeruginosa* has been previously listed as a concern for transmission in small animal clinics with challenges highlighted as lesser patient compliance and hygiene (Stull and Weese, 2015). The bacterium was repeatedly isolated from bedding and the veterinary clinical environment before and after infection control intervention at a dog shelter (Horsman et al., 2020). The presence of *P. aeruginosa* in the surrounding environment and the data regarding transmission of *P. aeruginosa* in certain settings (Fothergill et al., 2012) may mean that the bacterium could be transmitted horizontally between susceptible animals (those with a breach to normal defence barriers or underlying health issues) in certain settings, such as veterinary inpatient facilities or homes with multiple animals/animal shelters.

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

A potential direct route of transmission from an infected human to a cat has been reported (Mohan et al., 2008); however, this involved a *P. aeruginosa* strain that is known for its link with person-to-person transmission (Fothergill et al., 2012). Bacterial contamination of the environment surrounding an infected individual has also been reported; therefore showing that indirect transmission may be possible (Panagea et al., 2005). The majority of cases of *P. aeruginosa* infection would be independently acquired from the environment. There is no evidence of food-borne transmission.

#### *Speed of transmission*

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

Although there have been isolated case reports of transmission from humans to animals, there is little population level data on this topic. There have been no clear reports of transmission of AMR *P. aeruginosa* from an animal to a human resulting in infection (Pomba et al., 2017). However, cases resulting in animal infection have been reported (Mohan et al., 2008) and *P. aeruginosa* has been isolated from the faeces of the immunosuppressed owner (Fernandes et al., 2018). Therefore, despite little information regarding the incidence, there is potential for transmission between these two groups and this may be associated with the susceptibility of the individuals/animals involved and the specific *P. aeruginosa* strain.

##### Parameter 4 – Transmission rate ( $\beta$ ) (from R0 and infectious period) between animals and, when relevant, between animals and humans

There are no data on the rate of transmission.

### 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 bacterial species is globally endemic and can be found in a wide variety of niches from soil and water along with contaminating the clinical environment. Infections caused by *P. aeruginosa* are largely considered to be sporadic and based on underlying health or genetic factors. There are examples of transmission of *P. aeruginosa* in humans in specific settings; however, these have not been widely reported in cats and dogs.

A comparison of the epidemiological occurrence and resistance levels in different countries is not possible due to differences in surveillance and reporting practices. This is also true for antimicrobial resistance occurrence. In particular, there is a paucity of studies that include resistance to human antibiotics in isolates in dogs and cats. Collateral resistance and cross-resistance have been reported for *P. aeruginosa* whereby resistance to several antimicrobials can occur simultaneously, and therefore, resistance may be present in niches where that particular antimicrobial has not been used routinely (Barbosa et al., 2017). MDR *P. aeruginosa* could pose a health risk to humans and animals.

#### *Risk of introduction*

This section is not relevant due to the ubiquitous occurrence of this bacterial species; the risk of introduction is therefore not relevant to assess, as the pathogen is already present 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 are heavily reliant on bacterial culture. *P. aeruginosa* grows readily on a wide variety of media and under a wide variety of conditions. Although selective media are readily available, the majority of diagnostic laboratories detects *P. aeruginosa* on standard media. Colony morphology can show wide variation in both colour (e.g. cream, yellow, green, red and translucent) and form (e.g. smooth, wrinkly, mucoid and rough), and therefore, identification could be challenging to someone inexperienced. Following culture, matrix-assisted laser desorption ionisation–time-of-flight mass spectrometry (MALDI-TOF MS) has become a reference standard for species identification in many diagnostic laboratories. Specific PCR-based assays are available and often target porins such as the *oprL* gene or the 16S rRNA gene (followed by amplicon sequencing). The vast majority of these methods are reliant on an initial culture period that can take 24–48 h. Direct methods to extract DNA directly from clinical samples followed by qPCR have been developed; however, these are not widely used, particularly with regard to clinical isolates from cats and dogs. Other rapid testing combinations have also been recently described (Ulrich et al., 2020).

AMR phenotype is determined following culture through use of either disk diffusion assays or agar plates, or broth microdilution minimum inhibitory concentration assays. Published clinical breakpoints are available through the European Committee on Antimicrobial Susceptibility Testing (EUCAST) or the Clinical and Laboratory Standards Institute (CLSI), with breakpoints for some commonly used antibiotics in cats and dogs such as polymyxin B only available through CLSI. Alternatives such as E-test strips are also used to determine resistance. For some antibiotics such as colistin and polymyxin B, liquid culture in cationic adjusted nutrient broth must be used to determine resistance due to limited diffusion through in agar. Amplification of specific resistance genes is not routinely used in the context of determining *P. aeruginosa* resistance as linkage between phenotype and genotype is problematic. This is due to multiple resistance mechanisms and their relative gene expression that can simultaneously contribute to increments in resistance. However, the presence of some genes has clear relevance including *mcr-1* and *mcr-2* for polymyxin resistance and genes encoding carbapenemases.

##### Parameter 2 – Existence of control tools

Currently, there are no licensed vaccines available for use against *P. aeruginosa*. However, there has been an increase in research in this area over recent years (Tümmler, 2019; Sainz-Mejías et al., 2020). Control is performed through the use of antimicrobials and this can be systemic or local. The choice is



dependent on the site of infection. Disinfectants can also be used as part of hygiene and contamination control measures.

Antibiotics are widely available and in general effective in cats and dogs (Hillier et al., 2006). Treatments are well tolerated and there are no data on treatment failure. However, the lack of data on treatment failure may be due to a lack of published studies specifically on this topic. Alternatively, the lack of data may suggest that treatment failure is not an issue, therefore highlighting a potential disparity between reported *in vitro* resistance and clinical resistance of infections in dogs and cats.

*P. aeruginosa* in dogs and cats are treated with fluoroquinolones including enrofloxacin, marbofloxacin and pradofloxacin or aminoglycosides such as gentamicin. Polymyxin B is also used topically in ear preparations for *P. aeruginosa*-associated otitis externa (Pye, 2018). Resistance to these antimicrobials, particularly enrofloxacin and gentamicin, are reported in Table 2. For otitis, ear hygiene can also aid in treatment success. Preparations that include Tris-EDTA have been shown to resolve infection and reduce MICs to some antibiotics including against biofilms (Pye, 2018).

### 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 *P. aeruginosa* are present in all MSs; however, the extent to which they are reported/studied varies based on internal surveillance studies. Infections of this type could be identified in any country of the world due to the ubiquitous occurrence of this bacterial species. Although *P. aeruginosa* is intrinsically resistant to many antibiotics, further antimicrobial resistance varies a lot between MSs (EFSA AHAW Panel, 2021a). Nevertheless, these reports can be affected by sample/isolate inclusion or study focus and wider data collection. Many manuscripts only report resistance to a narrow range of antimicrobials, thereby making detailed comparisons between MSs difficult.

*The loss of production due to the disease*

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

There is little evidence of animal neonatal deaths associated with *P. aeruginosa* although it does have the potential to cause fatal disease. Increasing antimicrobial resistance and associated treatment challenges may have the potential to affect the breeding industry if not well controlled in the future. This is most applicable to dogs, as in cats, infections are much less common.

#### 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

There are few reports on routes of transmission between animals and humans. The case report of infection from a human to a cat was associated with a chronic respiratory infection in the human and led to a respiratory infection in the cat (Mohan et al., 2008). There was reported very close contact between the two, and possible routes of transmission include via droplet spread or aerosolisation. Transmission could also occur indirectly via the contaminated shared environment of animals and humans.

Parameter 2 – Incidence of zoonotic cases

There are no data on the incidence of zoonotic cases of *P. aeruginosa* infection.

*Transmissibility between humans*

The most common route of *P. aeruginosa* infection is contamination from the environment associated with a breach in normal defences. In this way, the bacterium is described as an opportunistic pathogen. Transmissibility between humans has been identified in individuals with CF, particularly attending summer camps or shared clinics. A number of transmissible strains have been identified including the LES, DK2 from Denmark, the Prairie Epidemic Strain (PES), Australian Epidemic

Strain (AES 1–3), amongst others (Fothergill et al., 2012). The genetic factors underlying transmissibility are unclear and different transmissible strains do not cluster together in terms of genotype. These strains have been associated with increased morbidity and mortality in this patient population; however, there is variation between each strain (Fothergill et al., 2012).

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

As *P. aeruginosa* is an endemic, environmental bacterium, this section is not applicable.

### Parameter 4 – Sporadic, epidemic or pandemic potential

*P. aeruginosa* is an endemic bacterium. It generally causes sporadic cases in susceptible people although it is a significant cause of disease and a major healthcare-associated opportunistic pathogen.

#### *The severity of human forms of the disease*

*P. aeruginosa* can cause significant morbidity and mortality in human infections. As stated previously, infection is normally associated with an underlying condition or breach in an existing barrier. It can cause a range of infections including those in the ears, eyes, urogenital tract, wounds, respiratory system and skin. *P. aeruginosa* can also cause severe and life-threatening illnesses including sepsis and meningitis (Huang et al., 2002). It has also been reported as causing Shanghai Fever, a poorly understood condition of children (Chuang et al., 2014).

### Parameter 5 – Disability-adjusted life year (DALY)

DALY attributed to carbapenem-resistant *P. aeruginosa* in the EU has been extensively reviewed (Cassini et al., 2019). In 2015, the median number of infections was 61,892 and the median number of deaths attributed was 4,155. The median number of DALYs per 100,000 population was 27.2 and the median percentage of total DALYs was 16%. Italy and Greece had a substantially higher estimated burden of AMR bacteria than other EU and European Economic Area (EEA) countries (Cassini et al., 2019).

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

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

*P. aeruginosa* is a highly resistant Gram-negative pathogen. Treatment is through the use of antimicrobials in either single or dual combination. Breakpoints have been published by EUCAST (Matuschek et al., 2014) and antibiotics used against *P. aeruginosa* in humans are shown in Table 3. Antibiotic administration routes can be oral, topical, intravenous or inhaled, dependent on the infection type and antibiotic type.

For *Pseudomonas* otitis, first-line treatment is often topical using antibiotics such as neomycin, polymyxin B and gentamicin. Other treatment can include systemic antibiotics including tobramycin, amikacin, enrofloxacin (and other quinolones such as marbofloxacin or pradofloxacin).

**Table 3:** Antibiotics with activity against *P. aeruginosa* with breakpoints published by EUCAST, including their suggested use in veterinary medicine according to the European Medicines Agency (EMA, 2019)

Antibiotic class	Antibiotic	Usage in veterinary medicine
Penicillins	Piperacillin	Avoid
	Piperacillin–tazobactam	Avoid
	Ticarcillin	Avoid
	Ticarcillin–clavulanic acid	Avoid
Cephalosporins	Cefepime	Restrict
	Cefiderocol	Not stated
	Ceftazidime	Restrict
	Ceftazidime–avibactam	Avoid
	Cefoxitin	Caution
	Ceftolozane–tazobactam	Avoid

Antibiotic class	Antibiotic	Usage in veterinary medicine
Carbapenems	Doripenem	Avoid
	Imipenem	Avoid
	Imipenem–relebactam	Avoid
	Meropenem	Avoid
	Meropenem–vaborbactam	Avoid
Monobactams	Aztreonam	Avoid
Fluoroquinolones	Ciprofloxacin	Restrict
	Levofloxacin	Restrict
Aminoglycosides	Amikacin	Caution
	Tobramycin	Caution
Polymyxins	Colistin	Restrict

Fosfomycin and mupirocin should also be avoided, but no *P. aeruginosa*-specific breakpoint is currently available through EUCAST.

*P. aeruginosa* is an important human pathogen that can lead to death. MDR and XDR *P. aeruginosa* has been widely reported. Therefore, treatment failure has been reported in humans. A study on ventilator-associated pneumonia caused by *P. aeruginosa* reported treatment failure in 112/314 (36%) of patients (Planquette et al., 2013). A mortality rate of 19% has been reported for patients with carbapenem-resistant *P. aeruginosa* bacteraemia (Buehrle et al., 2017). In people with CF with *P. aeruginosa* lung infection, early eradication therapy is possible but a treatment failure of 15–19% has been reported (Højby et al., 2005; Taccetti et al., 2005). Once established, *P. aeruginosa* cannot be eradicated from this niche.

There are little data on treatment failure in animals; however, a paper by Hawkins et al. (2010) on a novel therapeutic reported inclusion criteria for dogs with otitis of at least 3 months with at least three failed antibiotic treatments and therefore suggests treatment failure is an issue. Effective treatments can be challenging and reoccurrence of infection following the cessation of treatment has been reported (Barnard and Foster, 2018). A study on 20 dogs with pyoderma caused by *P. aeruginosa*, one dog (5%) displayed treatment failure. The remaining dogs were treated for between 3 and 12 weeks and showed resolution of infection (Barnard and Foster, 2018).

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

No vaccines are currently 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

*P. aeruginosa* can cause a wide variety of infections in dogs and cats, and the severity of disease will be based on the type of infection along with individual risk factors of the animal and the infecting bacterial strain. However, in dogs, *P. aeruginosa* most commonly causes infections that are not life-threatening, such as otitis and pyoderma. A recent study on the cause of deaths in dogs did not reveal *P. aeruginosa* as a cause (Cardillo et al., 2020).

Clinical signs of otitis can include head shaking, discharge from the ears and ulceration of the ear canal. If infection penetrates deeper, this can progress to neurological involvement including hearing loss and pain when opening the mouth or swallowing (Pye, 2018). Treatment requires washing of the affected area and antibiotic treatment for 4 weeks. Following this, diagnostics are repeated to confirm the presence of the pathogen or not (Pye, 2018).

Pyoderma is a pyogenic bacterial skin infection and is a common cause of infection in dogs. Although *P. aeruginosa* is not the main pathogen causing pyoderma in dogs, it has been associated with deep pyoderma and is often considered challenging to treat. Studies have linked *P. aeruginosa* pyoderma with necrotic and ulcerative skin lesions with green discharge and haemorrhagic bullae, cellulitis and abscessation (Done, 1974; Hillier et al., 2006). Additional symptoms such as lethargy, anorexia and exercise intolerance have also been reported (Hillier et al., 2006).

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

#### Biodiversity

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

There are no data on this aspect. One isolate of *P. aeruginosa* was found in a study on sea turtles; however, there was no evidence of disease and the isolate was highly susceptible to antibiotics (Oliveira et al., 2017).

##### Parameter 2 – Mortality in wild species

There are no data on mortality in wild species attributed to *P. aeruginosa*.

#### Environment

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

*P. aeruginosa* is an environmental bacterium and therefore can survive in the environment. The environment could therefore be a source of sporadic infection in any susceptible species.

### 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 that are certified or recommended by the OIE.

Diagnosis of *P. aeruginosa* is based on a combination of clinical signs to identify the disease and standard bacterial culture to identify the causative pathogen. If available, this can be followed up by the use of MALDI-TOF MS. Detection of resistance is based on the previously mentioned tools, namely MIC testing and disk diffusion. PCR for detection of resistance genes can be performed, but this is not a routine practice for *P. aeruginosa*.

##### Effectiveness

##### Parameter 2 – Sensitivity and specificity of diagnostic tests

There are no officially/internationally recognised diagnostic tests.

MALDI-TOF MS has been used to identify high-risk clones of *P. aeruginosa* with a sensitivity and specificity of 97.1% and 99.4%, respectively (Mulet et al., 2021). Culture using *Pseudomonas*-selective media has shown a high sensitivity (98–100%) but low specificity ranging between 40% and 72% (Weiser et al., 2014). This highlights that bacteria can be misclassified using culture alone, even if selective media are used. Other confirmation such as MALDI-TOF MS could be used to confirm species identification.

##### Feasibility

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

The type of sample is based upon the clinical disease presented. For otitis and skin infections, swabs would be used. For UTIs, a urine sample may be obtained. For other infections such as genital,



respiratory and wounds, swabs would again be the most common type of sample. Biopsies or tissue scrapes may also be applicable for some infections.

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

No vaccines are currently available against *P. aeruginosa*.

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

##### Availability

##### Parameter 1 – Types of drugs available on the market

As stated previously, *P. aeruginosa* in dogs and cats are treated with fluoroquinolones including enrofloxacin, marbofloxacin and pradofloxacin or aminoglycosides such as gentamicin. Polymyxin B is also used topically in ear preparations for *P. aeruginosa*-associated otitis externa (Pye, 2018).

##### Parameter 2 – Availability/production capacity (per year)

Antimicrobials that can be used against *P. aeruginosa* are available globally.

##### Effectiveness

##### Parameter 3 – Therapeutic effects in the field (effectiveness)

In dogs and cats, *P. aeruginosa* treatment appears to be generally effective although the bacterium has the ability to cause chronic infections due to a combination of biofilm formation ability and antimicrobial resistance. The rate of treatment failure in cats and dogs is not reported. Increasing antimicrobial resistance is likely to lead to increased treatment times and poorer outcomes. MDR bacteria carrying mobile resistance genes have been reported (Lin et al., 2012).

##### Feasibility

##### Parameter 4 – Way of administration

Systemic antimicrobials are usually administered orally. This enables owners to treat pets relatively easily and at home. Skin infections can be treated topically without the need for systemic antimicrobial therapy. Ear drops and washes are also available for some otitis infections. With increasing antimicrobial resistance, further antimicrobial options may require alternative routes of administration. This could include repeated injection or intravenous administration. However, this would likely be associated with a greater impact on animal welfare and higher treatment costs.

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

##### Availability

##### Parameter 1 – Available biosecurity measures

Decontamination using disinfectants is possible for *P. aeruginosa*, with hydrogen peroxide and sodium hypochlorite being particularly effective (Lineback et al., 2018). This is important in the surgical environment and for surgical equipment. These interventions help to prevent hospital-acquired infections. Disinfectants are available in wipes, sprays and concentrate format.

##### Effectiveness

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

Disinfection-based biosecurity measures are effective against *P. aeruginosa* in the healthcare setting. However, disinfectants should not be kept for long periods as there have been reports on *P. aeruginosa* contaminating such products and this would ameliorate the effectiveness of this intervention. Effective disinfectants include didecyldimethylammonium chloride, hydrogen peroxide and sodium hypochlorite (Beier et al., 2015; Lineback et al., 2018). Resistance to disinfectants in veterinary-associated isolates has been reported but is not routinely monitored. This included resistance to cetyl ammonium halides, chlorhexidine and benzyl ammonium chlorides, which are common formulations used in the veterinary setting (Beier et al., 2015).

### Feasibility

#### Parameter 3 – Feasibility of biosecurity measures

These biosecurity measures are feasible and relatively low cost. They should be part of routine decontamination in surgical and healthcare settings.

#### **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 diseased animals with infection with MDR *P. aeruginosa* would be possible. Such isolation could involve housing a patient in a dedicated isolation ward or using enhanced precautions in a general ward in a veterinary setting if the diseased animal needs to be admitted. Movement restrictions could prevent the contamination of the environment with MDR isolates.

### Effectiveness

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

There is no data available on this aspect.

### Feasibility

#### Parameter 3 – Feasibility of restriction of animal movement

Within a veterinary facility or hospital, the ability to separate and isolate animals may be limited based on structure and size. Most diseased animals would be sent home during treatment. Owners could be advised to not keep the diseased animal with susceptible animals during treatment. Treatment typically takes 1–3 months; however, otitis can become a chronic issue in some dogs. Movement restrictions could potentially prevent the contamination of the environment with MDR/XDR isolates.

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

### Availability

#### Parameter 1 – Available methods for killing animals

Veterinarians may recommend euthanasia of diseased animals affected by severe *P. aeruginosa* infections that have poor prognosis and cannot be treated effectively with veterinary antimicrobials. This would be an individual decision based on the health of the animal and ultimately the agreement of the owner.

### Effectiveness

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

Euthanasia would usually not be considered a method for controlling spread of disease in companion animals. The ubiquitous nature of the bacterium and the opportunistic nature of infection would make this intervention inappropriate. Euthanasia would be a method for limiting suffering in individual animals.

### Feasibility

#### Parameter 3 – Feasibility of killing animals

Euthanasia is feasible but is usually considered a last resort following a number of treatment failures. However, *P. aeruginosa* is ubiquitous and killing infected animals does not solve the occurrence of the agent.

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

Bodies of dead animals infected with *P. aeruginosa* do not pose any additional risks to the public or indeed animal health. Disposal options would be the same methods as other companion animal deaths, namely burial or incineration. Effectiveness and feasibility are the same as for other deaths of companion animals. This is routine in most veterinary practices.

### 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)

Treatment costs would impact companion animal owners and these costs may be increased when faced with AMR strains. Intensive treatment may involve the use of prolonged treatment periods (months) and the use of multiple antimicrobial agents. If front-line treatments fail, alternative treatments would currently be off-license and may require repeated administration via injection (Pye, 2018). Despite intensive treatment, treatment failure is possible and can result in specialist treatment, hospitalisation, additional outpatient visits, detailed diagnostics and further therapy (both direct and supportive). However, specific costs associated with this and potential increases are not available.

Newer antimicrobials are being developed, but these would be likely reserved for human use. Other alternative such as phage therapy have been trialled in dogs with *P. aeruginosa* otitis (Hawkins et al., 2010).

##### Parameter 2 – Cost of eradication (culling, compensation)

Due to the ubiquitous nature of the bacterium, eradication is not possible. Euthanasia of individuals would be possible if clinically indicated. The cost of this will likely vary between veterinary clinics.

##### Parameter 3 – Cost of surveillance and monitoring

There are no specific data to estimate cost of surveillance in the Union. Current monitoring tends to be passive and often country-specific. Surveillance systems include Resapath, Compath and BfT-GermVet. However, there are no data on the specific costs of monitoring *P. aeruginosa* in dogs and cats.

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

There are no official embargoes or bans associated with *P. aeruginosa* infection in dogs and cats; however, affected animals would not be able to participate in shows if showing signs of infections. This could lead to a limited amount of trade loss; however, there is no information on this. The value of keeping, breeding and trading cats and dogs in the EU is €1.3 billion (Schrijver et al., 2015).

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

As stated above, the value of keeping, breeding and trading cats and dogs in the EU is €1.3 billion (Schrijver et al., 2015). There is little information on how AMR *P. aeruginosa* may affect this, but it could have an impact on dog and cat shows, as animals with *P. aeruginosa* infection and showing clinical signs could not participate.

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

Disease prevention methods are currently limited and likely revolve around hygiene at potential routes of entry or breached barriers; however, evidence of the impact of these interventions, particularly in the companion animal context are lacking. Control measures are likely to be well tolerated; however, increased antimicrobial resistance may lead to higher veterinary costs and less choice of antimicrobials. In situations of treatment failure with potentially life-threatening consequences, the lack of range of approved veterinary antibiotics may prove more difficult for owners to tolerate. This could put pressure on the use of antimicrobials reserved for human use only.

#### 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

Increasing antimicrobial resistance has the potential to affect animal welfare due to prolonged treatment, greater side effects and poor outcomes associated with treatment failure. Resistance to antibiotics that can be administered orally would lead to greater intervention and treatments that may require repeated injections. This would have an impact on welfare.

## Parameter 2 – Wildlife depopulation as control measure

Wildlife depopulation is not a measure that would be used in the control of this disease.

### 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)

With increasing prevalence of AMR *P. aeruginosa*, more antibiotics may be used to treat infections. During treatment, antibiotics are not completely absorbed and metabolised by the body and therefore can be found in excreted urine and faeces. Antimicrobials do have the potential to contaminate water; however, specific contamination directly from use of antimicrobials in companion animals has not been reported. Certain antibiotics are known to persist in the environment. Fluoroquinolones can persist in the environment for around 100 days and have good water solubility (Janecko et al., 2016). Furthermore, the breakdown of enrofloxacin, an important veterinary antibiotic, leads to the production of compounds highly similar to ciprofloxacin, an important human antibiotic. Long-term presence in the environment could lead to altered ecosystems such as in soil or aquatic niches.

#### Biodiversity

#### Parameter 1 – Mortality in wild species

There are no reports of mortality in wild species due to specific *P. aeruginosa* control measures. However, fluoroquinolones have the potential to affect algal and bacterial species along with some vertebrates and invertebrates (Kümmerer, 2009).

## 3.2. Assessment of AMR *Pseudomonas aeruginosa* 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 4 and Figure 1, the results of the expert judgement on the Article 5 criteria of the AHL for AMR *P. aeruginosa* in dogs and cats are presented.

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

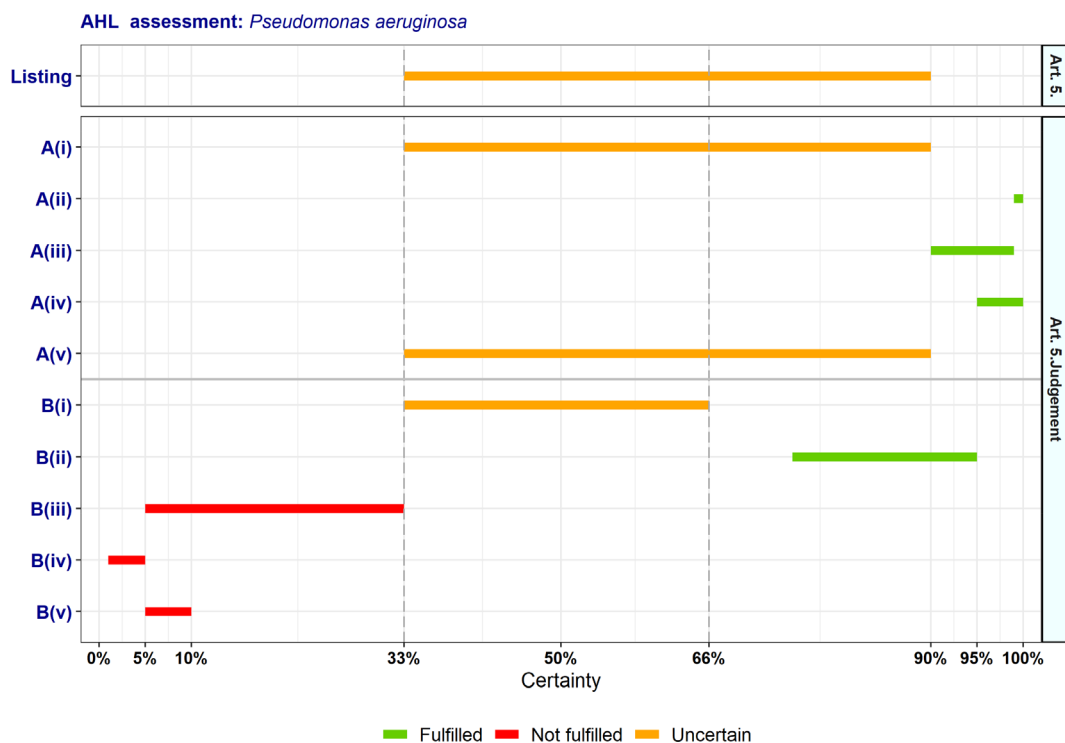
**Table 4:** Outcome of the expert judgement on Article 5 criteria

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	33–90	Uncertain	0	12
A(ii)	Animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union	99–100	Fulfilled	0	14
A(iii)	The disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character	90–99	Fulfilled	0	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	13
<b>At least one criterion to be met by the disease:</b>					
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	33–66	Uncertain	0	13

B(ii)	The disease agent has developed resistance to treatments which poses a significant danger to public and/or animal health in the Union	75–95	Fulfilled	0	13
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	13
B(iv)	The disease has the potential to generate a crisis or the disease agent could be used for the purpose of bioterrorism	1–5	Not fulfilled	0	14
B(v)	The disease has or could have a significant negative impact on the environment, including biodiversity, of the Union	5–10	Not fulfilled	0	13

na: not applicable.

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



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

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

### 3.2.1.1. Reasoning for uncertain outcome on Article 5 criteria

*Criterion A(i) (the disease is transmissible):*

- *P. aeruginosa* is an opportunistic pathogen.
- Transmission of *P. aeruginosa* is mainly indirect through the environment.
- Direct transmission (nosocomial infections) between susceptible individuals has only been described in humans.
- Direct transmission between animals may be feasible under certain conditions (e.g. veterinary inpatient facilities) and considering certain strains.

*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):*

- Antimicrobial treatment is only partly effective with increasing treatment time and antimicrobial resistance being common. Treatment is further complicated by intrinsic resistance of *P. aeruginosa* and its ability to produce biofilm.
- Diagnostic tools and biosecurity measures are available, but there is no information about their effectiveness.
- No vaccines are available.
- No structured or harmonised surveillance is in place.
- Risk-mitigating measures are not proportionate to the risk posed by AMR *P. aeruginosa*.

*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):*

- *P. aeruginosa* is an opportunistic pathogen, which occurs only sporadically in dogs and cats.
- *P. aeruginosa* is a frequent pathogen in dogs and among the most frequently reported among clinical cases submitted for routine diagnostics (Hattab et al., 2021).
- *P. aeruginosa* may lead to infections that are difficult to treat (e.g. otitis, UTIs, skin and wound infections).
- *P. aeruginosa* causes frequent and serious nosocomial infections in humans. It is designated a Priority 1 organism by the WHO for which there is an urgent need for new therapeutics. However, zoonotic transmission from animals to humans is questionable.

### 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 4, AMR *P. aeruginosa* complies with three criteria of the first set (A(ii)–A(iv)), but there is uncertainty (33–90% probability) on the assessment on compliance with both Criteria A(i) and A(v). Therefore, it is uncertain whether AMR *P. aeruginosa* 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 *Pseudomonas aeruginosa* according to criteria in Annex IV for the purpose of categorisation as in Article 9 of the AHL

In Tables 5–9 and related graphs (Figures 2–4), the results of the expert judgement on AMR *P. aeruginosa* 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 are reported in Sections B.1 and B.2 of Appendix B.

**Table 5:** 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	0–5	Not fulfilled	0	13
2.1	The disease is highly transmissible	5–10	Not fulfilled	0	14
2.2	There are possibilities of airborne or waterborne or vector-borne spread	5–10	Not fulfilled	0	13



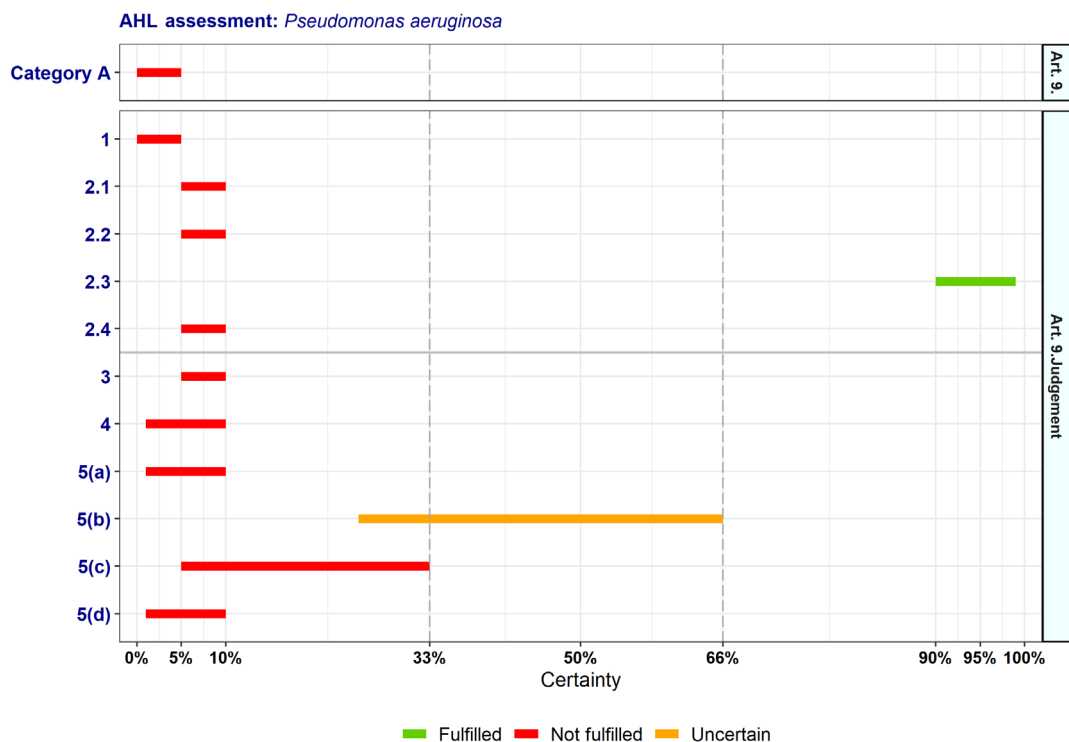
2.3	The disease affects multiple species of kept and wild animals or single species of kept animals of economic importance	90–99	Fulfilled	0	13
2.4	The disease may result in high morbidity and significant mortality rates	5–10	Not fulfilled	0	13

**At least one criterion to be met by the disease:**

In addition to the criteria set out above at point 1–2.4, the disease needs to fulfil at least one of the following criteria

3	The disease has a zoonotic potential with significant consequences for public health, including epidemic or pandemic potential, or possible significant threats to food safety	5–10	Not fulfilled	0	14
4	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	1–10	Not fulfilled	0	13
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	25–66	Uncertain	0	13
5(c)	The disease has a significant impact on the environment, due to the direct impact of the disease or due to the measures taken to control it	5–33	Not fulfilled	0	13
5(d)	The disease has a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	1–10	Not fulfilled	0	13

na: not applicable.



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

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

### 3.3.1. Detailed outcome on Category A criteria

#### 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):*

- Ear and skin infections (e.g. pyoderma) are frequent and may cause suffering to affected dogs and potentially cats.
- *P. aeruginosa* infection in dogs is quite common, but it is unclear whether this relates to large numbers of animals. All affected dogs in the EU may be considered a large number, but it is unclear to which extent AMR clones contribute to the burden of disease.
- In general, morbidity and mortality rates are low.
- Antimicrobial treatment is usually effective, but treatment time may be increased in case of antimicrobial resistance and treatment failure.

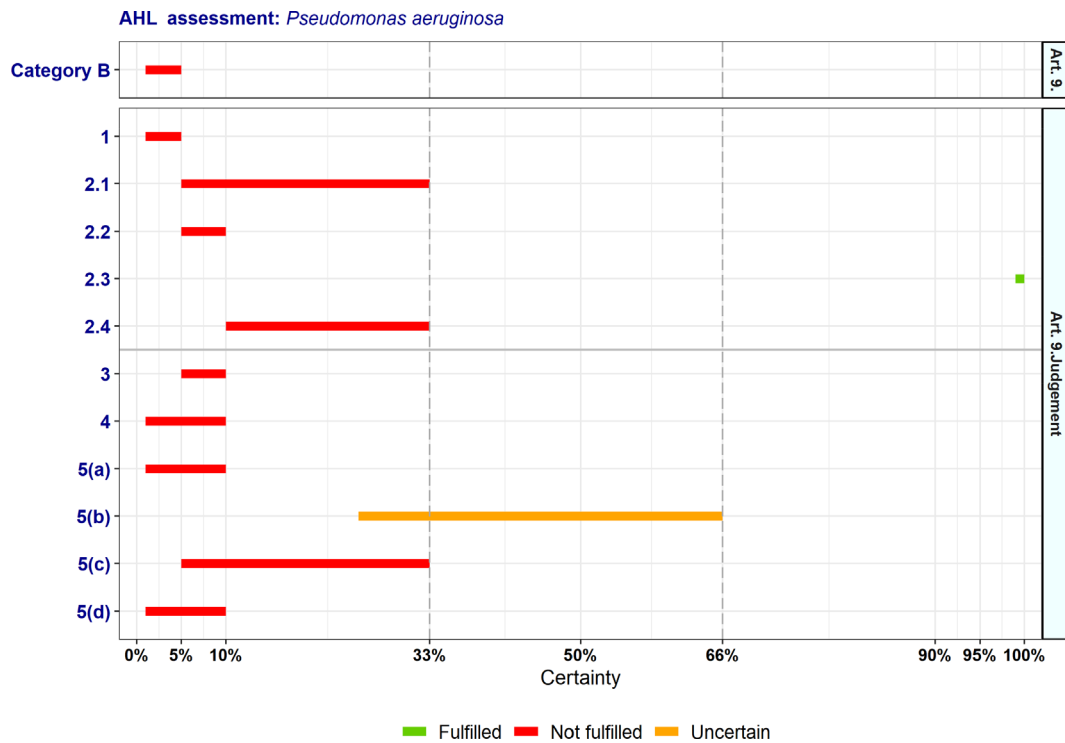
### 3.3.2. Detailed outcome on Category B criteria

**Table 6:** 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	1–5	Not fulfilled	0	13
2.1	The disease is moderately to highly transmissible	5–33	Not fulfilled	0	13
2.2	There are possibilities of airborne or waterborne or vector-borne spread	5–10	Not fulfilled	0	13
2.3	The disease affects single or multiple species	–	Fulfilled	0	13
2.4	The disease may result in high morbidity with in general low mortality	10–33	Not fulfilled	0	13
<b>At least one criterion to be met by the disease:</b>					
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	5–10	Not fulfilled	0	13
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	13
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	25–66	Uncertain	0	13
5(c)	The disease has a significant impact on the environment, due to the direct impact of the disease or due to the measures taken to control it	5–33	Not fulfilled	0	13
5(d)	The disease has a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	1–10	Not fulfilled	0	13

na: not applicable.





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

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

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

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

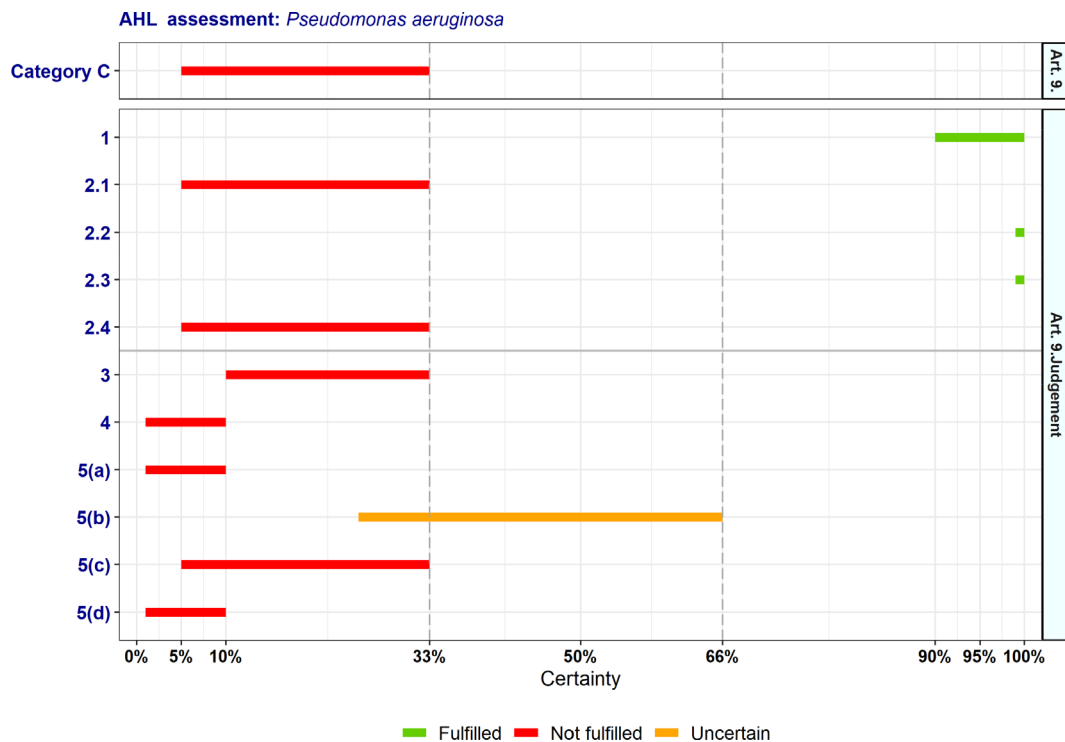
Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		Outcome			
		Median range (%)	Criterion fulfilment	Number of na	Number of experts
1	The disease is present in the whole or part of the Union territory with an endemic character	90–100	Fulfilled	0	13
2.1	The disease is moderately to highly transmissible	5–33	Not fulfilled	0	13
2.2	The disease is transmitted mainly by direct or indirect transmission	–	Fulfilled	0	13
2.3	The disease affects single or multiple species	–	Fulfilled	0	13
2.4	The disease usually does not result in high morbidity and has negligible or no mortality and often the most observed effect of the disease is production loss	5–33	Not fulfilled	0	13

**At least one criterion to be met by the disease:**

In addition to the criteria set out above at point 1–2.4, the disease needs to fulfil at least one of the following criteria

3	The disease has a zoonotic potential with significant consequences for public health or possible significant threats to food safety	10–33	Not fulfilled	0	13
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	13
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	25–66	Uncertain	0	13
5(c)	The disease has a significant impact on the environment, due to the direct impact of the disease or due to the measures taken to control it	5–33	Not fulfilled	0	13
5(d)	The disease has a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	1–10	Not fulfilled	0	13

na: not applicable.



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

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

**3.3.3.1. Reasoning for uncertain outcome on Category C criteria**

*Criterion 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 8:** Outcome of the expert judgement related to the criteria of Section 4 of Annex IV (Category D of Article 9)

Diseases in Category D <b>need to fulfil criteria of Section 1, 2, 3 or 5 of Annex IV</b> of the AHL <b>and the following:</b>		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	5–33	Not fulfilled	0	13

na: not applicable.

### 3.3.5. Detailed outcome on Category E criteria

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

Diseases in Category E <b>need to fulfil criteria of Section 1, 2 or 3 of Annex IV</b> of the AHL <b>and/or the following:</b>		Outcome	
		Median range (%)	Fulfilment
E	Surveillance of the disease is necessary for reasons related to animal health, animal welfare, human health, the economy, society or the environment  (If a disease fulfils the criteria as in Article 5, thus being eligible to be listed, consequently Category E would apply.)	33–90	Uncertain

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

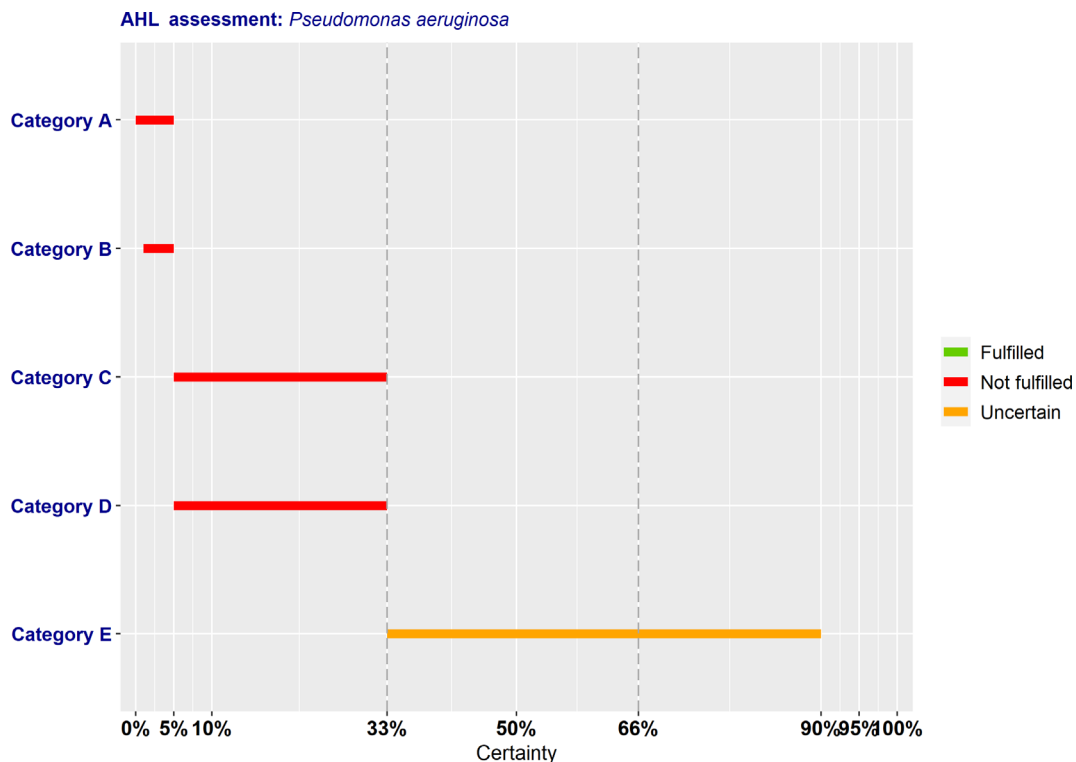
As from the legal text of the AHL, a disease is considered fitting in a certain category (A, B, C, D or E – corresponding to points (a) to (e) of Article 9(1) of the AHL) if it fulfils all criteria of the first set from 1 to 2.4 and at least one of the second set of criteria from 3 to 5(d), as shown in Tables 5–59. 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 *P. aeruginosa* as in Article 9, is presented in Table 10 and Figure 5.

**Table 10:** Outcome of the assessment on criteria in Annex IV of the AHL for the purpose of categorisation as in Article 9

Category	Article 9 criteria										
	1° set of criteria					2° set of criteria					
	1	2.1	2.2	2.3	2.4	3	4	5(a)	5(b)	5(c)	5(d)
	Geographical distribution	Transmissibility	Routes of transmission	Multiple species	Morbidity and mortality	Zoonotic potential	Impact on economy	Impact on society	Impact on animal welfare	Impact on environment	Impact on biodiversity
A	0–5	5–10	5–10	90–99	5–10	5–10	1–10	1–10	25–66	5–33	1–10
B	1–5	5–33	5–10	–	10–33	5–10	1–10	1–10	25–66	5–33	1–10
C	90–100	5–33	–	–	5–33	10–33	1–10	1–10	25–66	5–33	1–10
D	5–33										
E	33–90										

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



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

According to the assessment here performed, AMR *P. aeruginosa* 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)–(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 *P. aeruginosa* complies only with Criterion 2.3 (90–99% 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 *P. aeruginosa* does not comply with any apart from Criterion 5(b), for which the assessment was inconclusive (25–66% probability). Overall, it was assessed with 0–5% probability that AMR *P. aeruginosa* 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 *P. aeruginosa* complies only with Criterion 2.3, which is fulfilled by default. 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 *P. aeruginosa* does not comply with any apart from Criterion 5(b), for which the assessment was inconclusive (25–66% probability). Overall, it was assessed with 1–5% probability that AMR *P. aeruginosa* 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 *P. aeruginosa* complies with Criteria 1 (90–100% probability), 2.2 and 2.3 (both fulfilled by default). 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 *P. aeruginosa* does not comply with any apart from Criterion 5(b), for which the assessment was inconclusive (25–66% probability). Overall, it was assessed with 5–33% probability that AMR *P. aeruginosa* may be assigned to Category C according to criteria in Section 3 of Annex IV for the purpose of categorisation as in Article 9 of the AHL.
- 4) To be assigned to Category D, a disease needs to comply with criteria of Section 1, 2, 3 or 5 of Annex IV of the AHL and with the specific Criterion D of Section 4, with which AMR *P. aeruginosa* does not comply (5–33% 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 *Pseudomonas aeruginosa* 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 *P. aeruginosa* 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.<sup>2</sup>

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 *P. aeruginosa* according to the criteria of Article 8(3) of the AHL are as displayed in Table 11 (elaborated from information reported in Section 3.1.1.1 of the present document).

<sup>2</sup> 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 *P. aeruginosa* 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. However, most evidence reported in the fact sheet relates to dogs and cats.

**Table 11:** Animal species to be listed for AMR *P. aeruginosa* according to the criteria of Article 8

	Class/Order	Family	Genus/Species
Susceptible	Carnivora	Canidae	Domestic dog ( <i>Canis lupus familiaris</i> ) <sup>(a)</sup>
		Felidae	Domestic cat ( <i>Felis catus</i> ) <sup>(a)</sup>
		Mustelidae	Ferret ( <i>Mustela furo</i> )
	Artiodactyla	Bovidae	Sheep ( <i>Ovis aries</i> )
		Suidae	Pig ( <i>Sus domesticus</i> )
	Rodentia	Chinchillidae	Chinchilla ( <i>Chinchilla chinchilla</i> )
		Muridae	House mouse ( <i>Mus musculus</i> )
			Rat ( <i>Rattus</i> sp.)
	Lagomorpha	Leporidae	Rabbits
	Diprotodontia	Petauridae	Sugar glider ( <i>Petaurus breviceps</i> )
	Anseriformes	Anatidae	White-faced whistling duck ( <i>Dendrocygna viduata</i> )
	Gruiformes	Gruidae	Siberian crane ( <i>Leucogeranus leucogeranus</i> )
			Whooping crane ( <i>Grus americana</i> )
	Testudines	Cheloniidae	Hawksbill sea turtle ( <i>Eretmochelys imbricata</i> )
Squamata			
	Passeriformes	Hirundinidae	Swallows
	Cypriniformes	Cyprinidae	Zebrafish ( <i>Danio rerio</i> )
Reservoir	Carnivora	Canidae	Domestic dog ( <i>Canis lupus familiaris</i> )
	Artiodactyla	Suidae	Wild boar ( <i>Sus scrofa</i> )
	Squamata		
Vector	None		

(a): Most evidence reported in the fact sheet relates to these animal species.

## 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 (33–90% probability, from ‘as likely as not’ to ‘likely’) whether AMR *P. aeruginosa* 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 0–5% probability (from ‘almost impossible’ to ‘extremely unlikely’) that AMR *P. aeruginosa* 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 1–5% probability (‘extremely unlikely’) that AMR *P. aeruginosa* meets the criteria as in Section 2 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in point (b) of Article 9(1) of the AHL.



- The AHAW Panel considered with 5–33% probability (from 'very unlikely' to 'unlikely') that AMR *P. aeruginosa* 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 5–33% probability (from 'very unlikely' to 'unlikely') that AMR *P. aeruginosa* meets the criteria as in Section 4 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in point (d) of Article 9(1) of the AHL.
- The AHAW Panel was uncertain (33–90% probability, from 'as likely as not' to 'likely') whether AMR *P. aeruginosa* 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 *P. aeruginosa* according to Article 8(3) of the AHL are mainly dogs and cats, as reported in Table 11 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 *P. aeruginosa* is inconclusive on its eligibility to be listed for Union intervention, specific initiatives (e.g. monitoring or applied research) into various aspects of AMR *P. aeruginosa* 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

AES	Australian Epidemic Strain
AHAW	Animal Health and Welfare
AHL	Animal Health Law
AMC	Amoxicillin–clavulanic acid
AMK	Amikacin
AMR	Antimicrobial-resistant
AMX	Amoxicillin
ATM	Aztreonam
AZM	Azithromycin
CAZ	Ceftazidime
CEF	Ceftiofur
CET	Cefalotin
CF	Cystic fibrosis
CFSPH	Center for Food Security and Public Health
CHL	Chloramphenicol
CI	Current impact
CIP	Ciprofloxacin
CITES	Convention on International Trade in Endangered Species
CLI	Clindamycin
CLSI	Clinical and Laboratory Standards Institute
CPD	Cefpodoxime
CST	Colistin
CTX	Cefotaxime
CVN	Cefovecin
CXM	Cefuroxime
DALY	Disability-adjusted life year
DIVA	Differentiation of infected from vaccinated animals
DOX	Doxycycline
EEA	European Economic Area

ENR	Enrofloxacin
ERY	Erythromycin
EUCAST	European Committee on Antimicrobial Susceptibility Testing
FEP	Cefepime
FFC	Florfenicol
FOF	Fosfomycin
FOX	Cefoxitin
FQ	Fluoroquinolones
GEN	Gentamicin
I	Intermediate
IPM	Imipenem
IUCN	International Union for Conservation of Nature
KAN	Kanamycin
LES	Liverpool Epidemic Strain
LEX	Cephalexin
LPS	Lipopolysaccharide
MALDI-TOF MS	Matrix-assisted laser desorption ionisation–time-of-flight mass spectrometry
MAR	Marbofloxacin
MDR	Multidrug-resistant
MEM	Meropenem
MIC	Minimum inhibitory concentration
MS	Member State
NEO	Neomycin
NIT	Nitrofurantoin
OIE	Office International des Épizooties (World Organisation for Animal Health)
ORB	Orbafloxacin
PDR	Pandrug-resistant
PES	Prairie Epidemic Strain
PI	Potential impact
PMB	Polymyxin B
PRA	Pradofloxacin
R	Resistant
SPT	Spectinomycin
ST	Sequence type
SXT	Trimethoprim–sulfamethoxazole
TET	Tetracycline
TIC	Ticarcillin
TIM	Ticarcillin–clavulanic acid
TOB	Tobramycin
ToR	Term of Reference
TZP	Piperacillin–tazobactam
UTI	Urinary tract infection
WHO	World Health Organization
XDR	Extensively drug-resistant

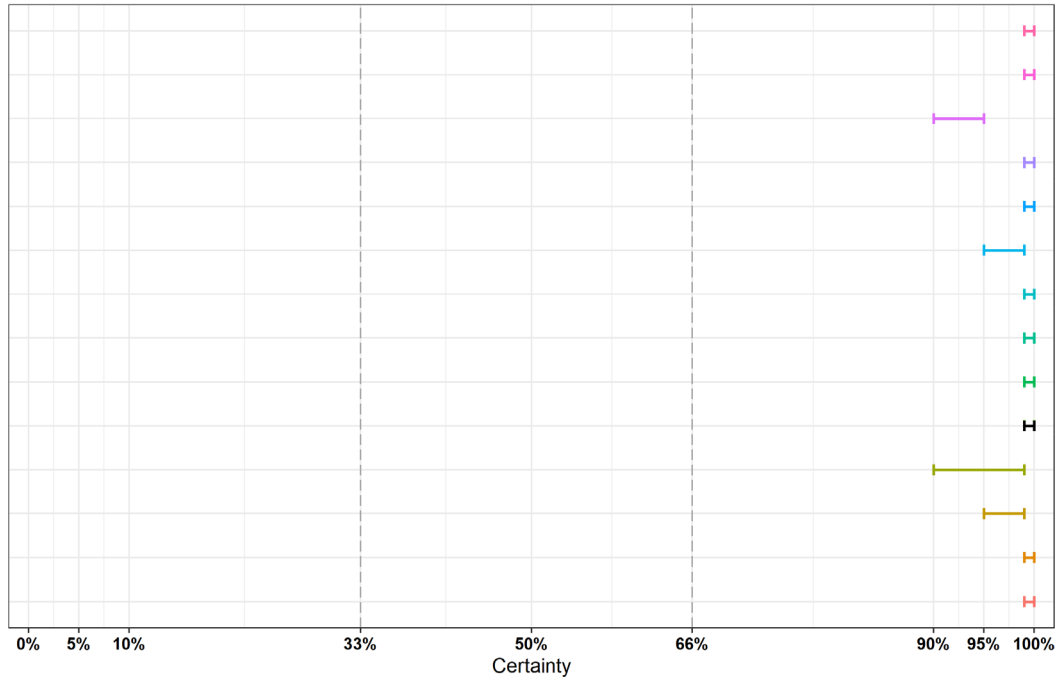


## Appendix A – Criteria with certain outcome

### A.1. Article 5 criteria

Collective Assessment

Art. 5: A(ii)

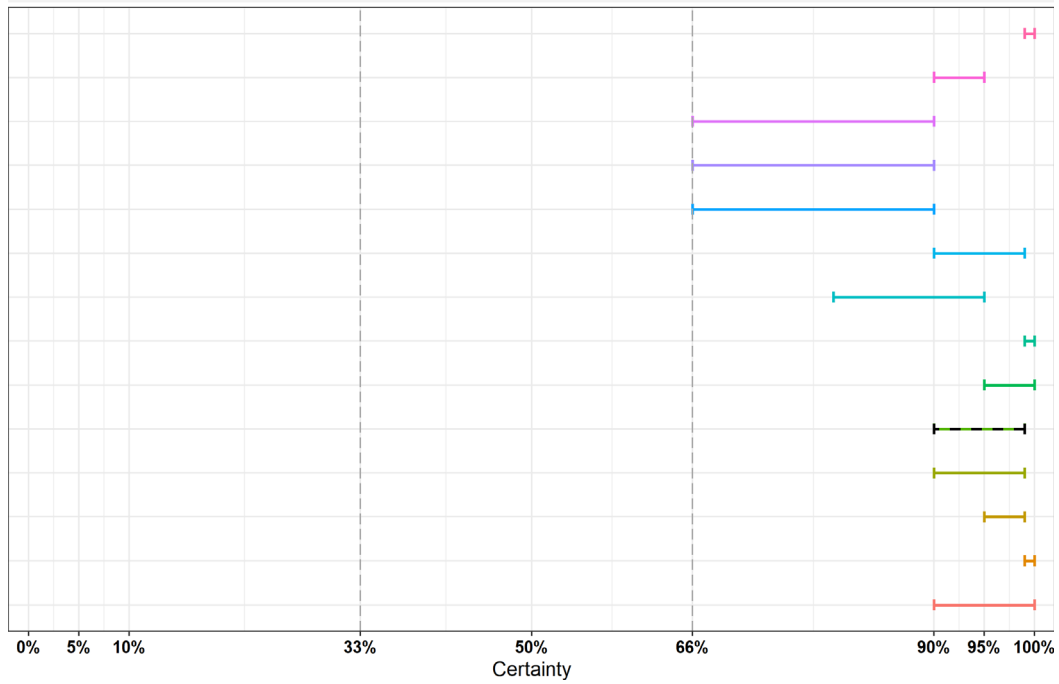


The median range is displayed as a dashed line.

**Figure A.1:** Individual probability ranges reflecting fulfilment of Criterion A(ii) (animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union) after the collective judgement

Collective Assessment

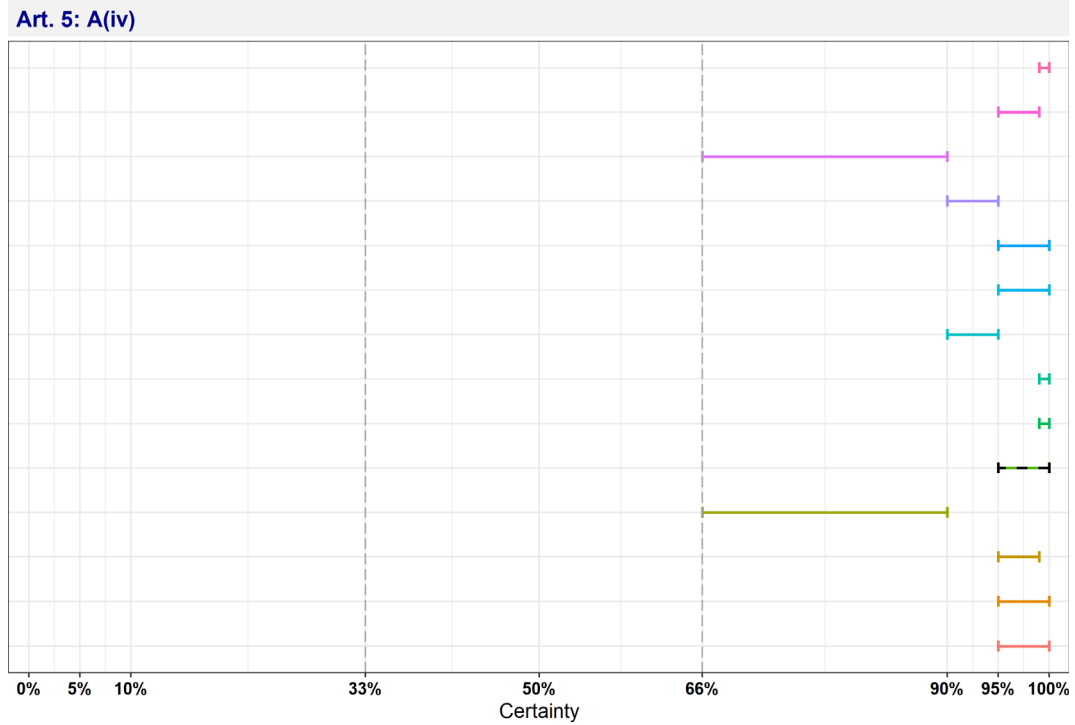
Art. 5: A(iii)



The median range is displayed as a dashed line.

**Figure A.2:** Individual probability ranges reflecting fulfilment of Criterion A(iii) (the disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character) after the collective judgement

Collective Assessment

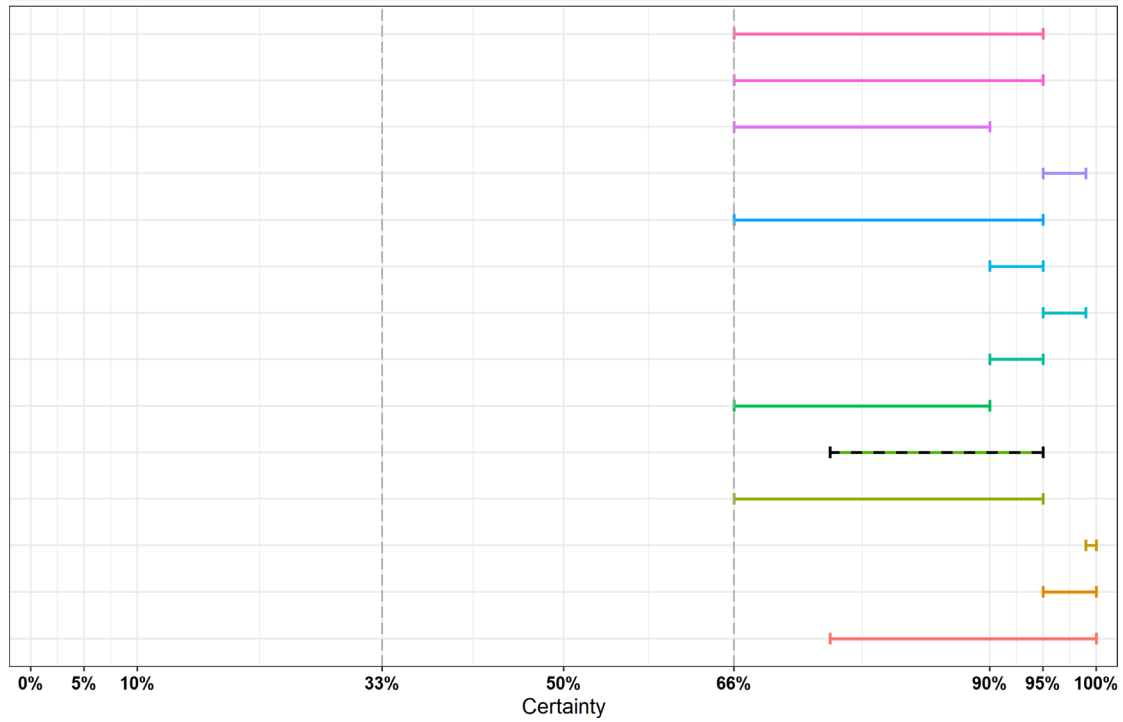


The median range is displayed as a dashed line.

**Figure A.3:** Individual probability ranges reflecting fulfilment of Criterion A(iv) (diagnostic tools are available for the disease) after the collective judgement

Collective Assessment

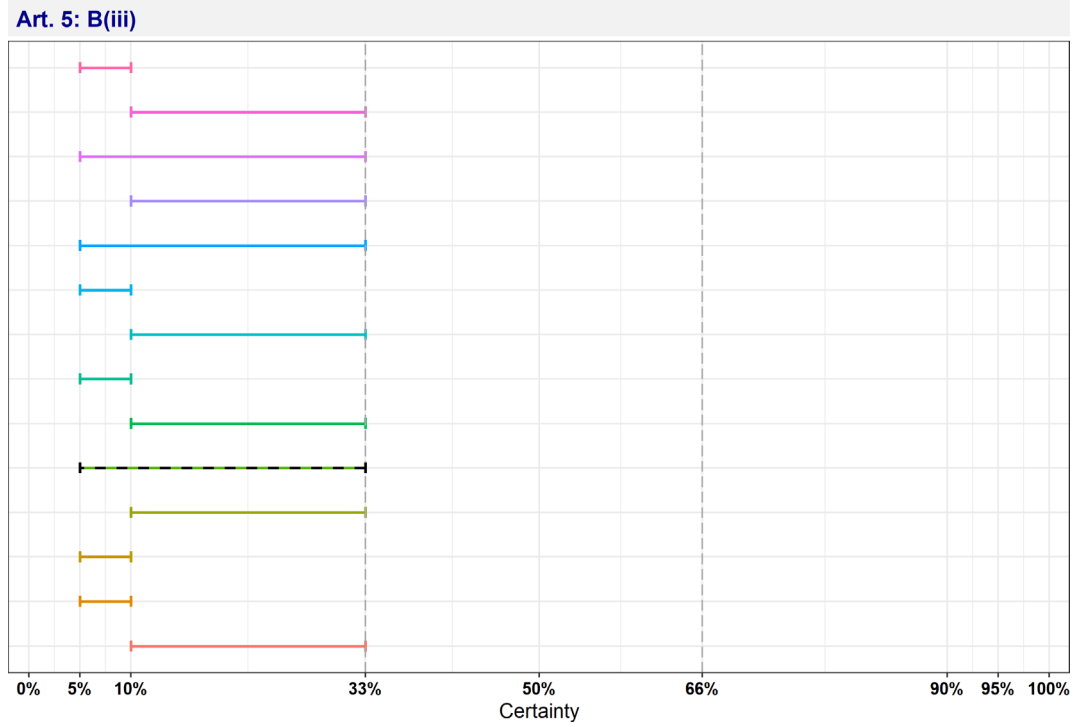
Art. 5: B(ii)



The median range is displayed as a dashed line.

**Figure A.4:** Individual probability ranges reflecting fulfilment of Criterion B(ii) (the disease agent has developed resistance to treatments which poses a significant danger to public and/or animal health in the Union) after the collective judgement

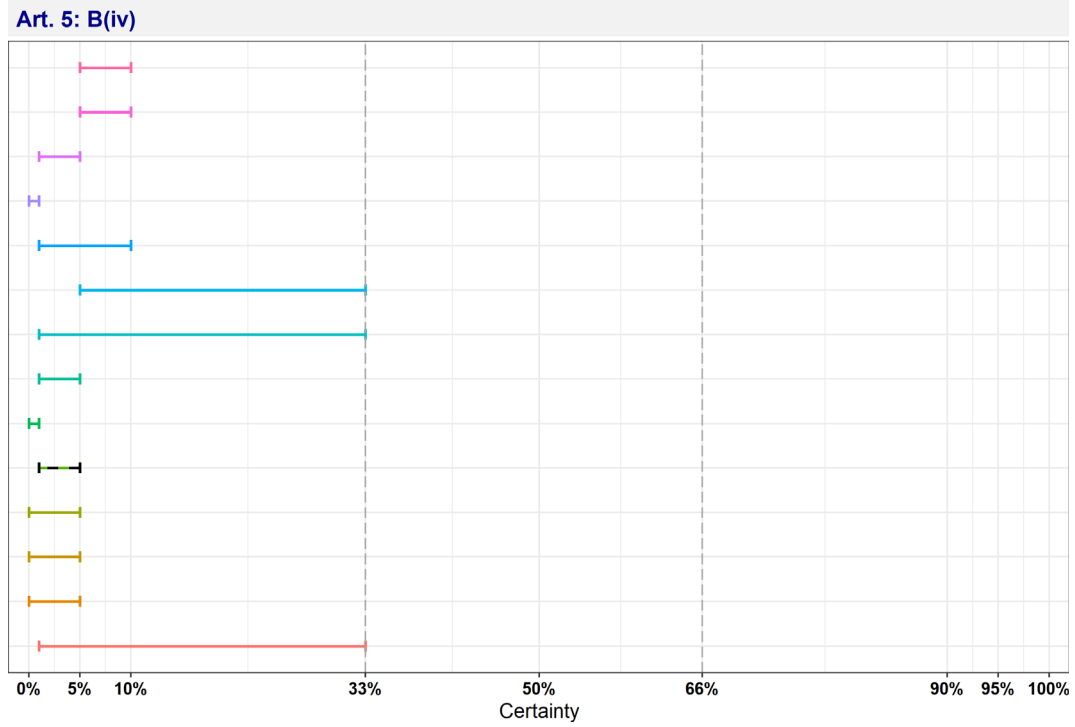
Collective Assessment



The median range is displayed as a dashed line.

**Figure A.5:** 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

Collective Assessment

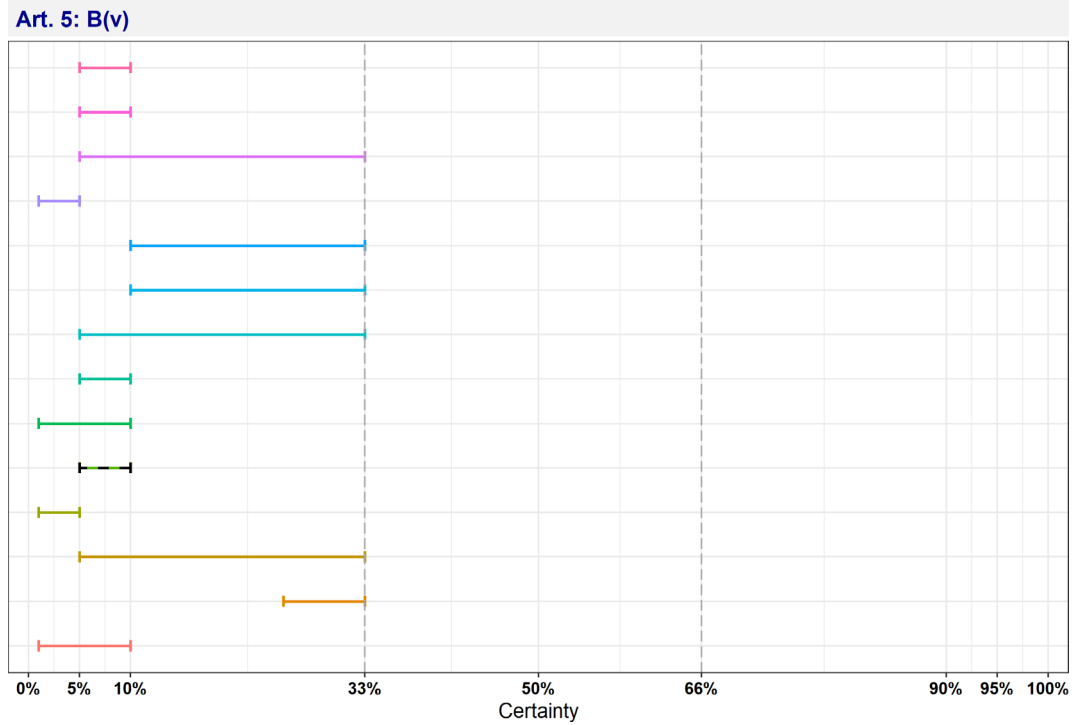


The median range is displayed as a dashed line.

**Figure A.6:** Individual probability ranges reflecting non-fulfilment of Criterion B(iv) (the disease has the potential to generate a crisis or the disease agent could be used for the purpose of bioterrorism) after the collective judgement



Collective Assessment

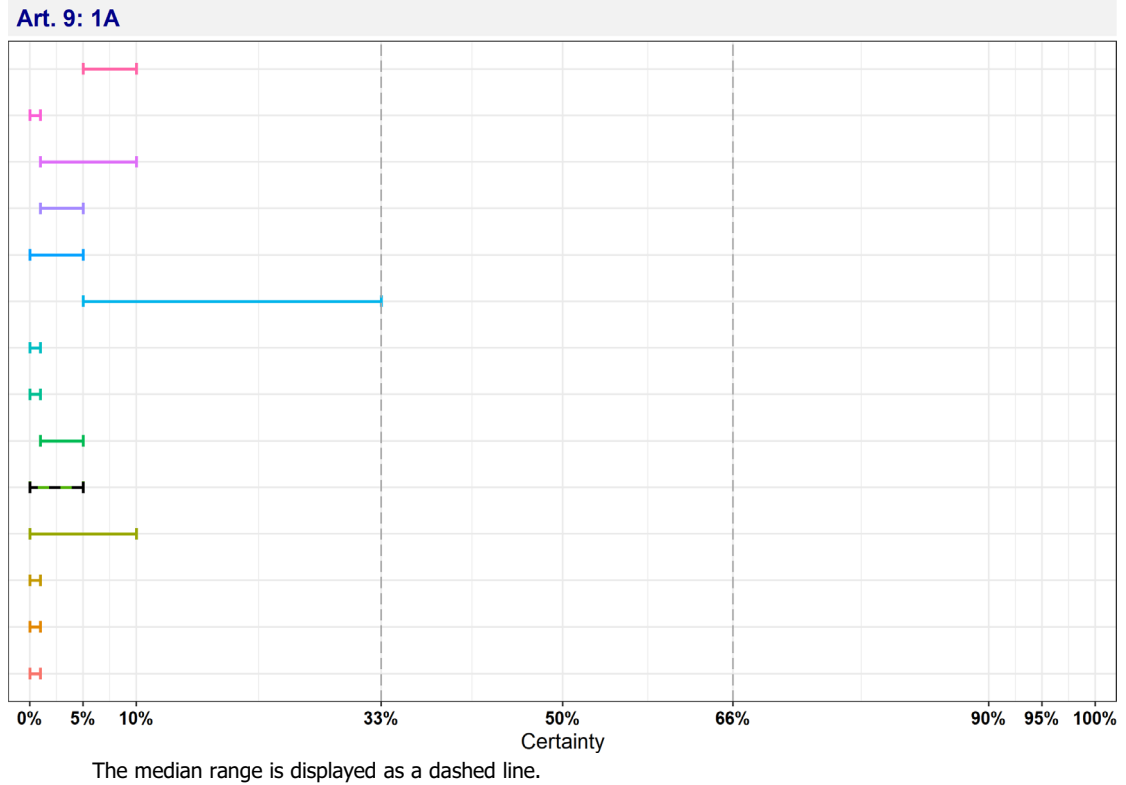


The median range is displayed as a dashed line.

**Figure A.7:** Individual probability ranges reflecting non-fulfilment of Criterion B(v) (the disease has or could have a significant negative impact on the environment, including biodiversity, of the Union) after the collective judgement

## A.2. Article 9 criteria

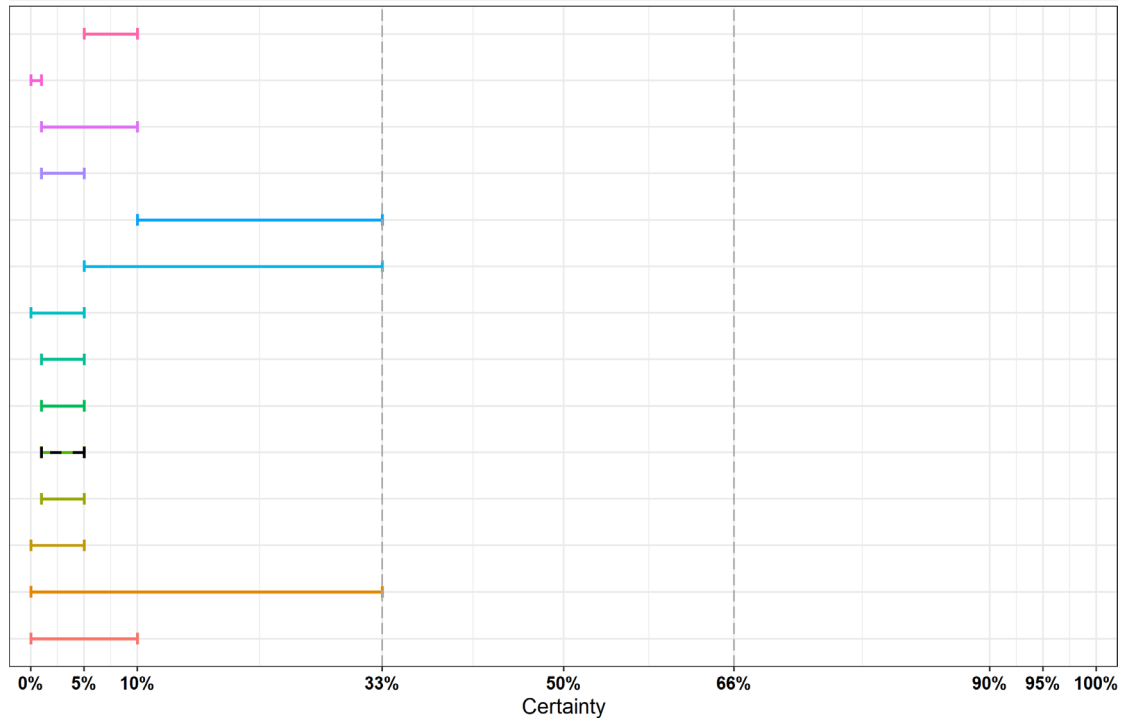
### Collective Assessment



**Figure A.8:** Individual probability ranges reflecting non-fulfilment of Criterion 1A (the disease is not present in the territory of the Union or present only in exceptional cases (irregular introductions) or present in only in a very limited part of the territory of the Union) after the collective judgement

Collective Assessment

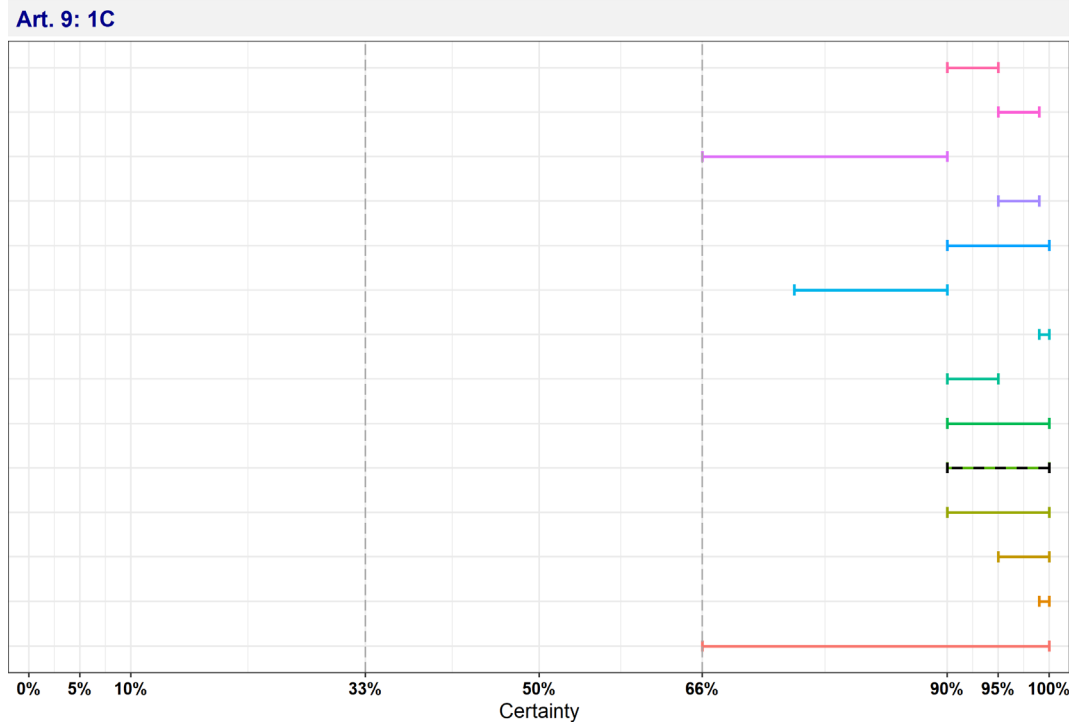
Art. 9: 1B



The median range is displayed as a dashed line.

**Figure A.9:** Individual probability ranges reflecting non-fulfilment of Criterion 1B (the disease is present in the whole or part of the Union territory with an endemic character and (at the same time) several Member States or zones of the Union are free of the disease) after the collective judgement

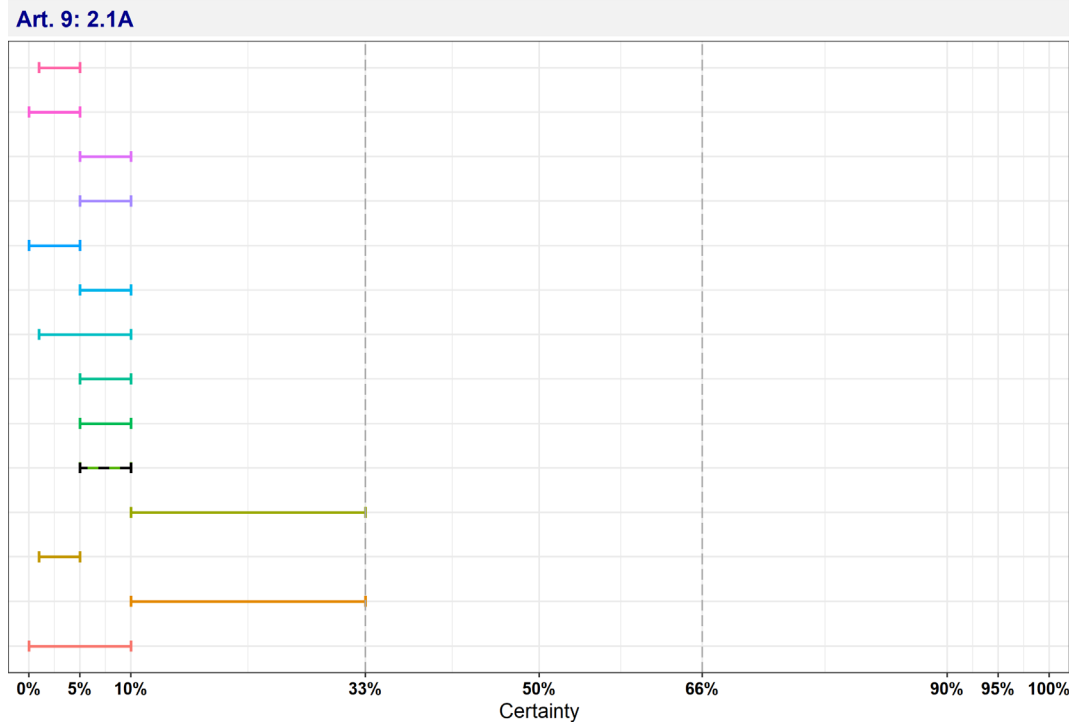
Collective Assessment



The median range is displayed as a dashed line.

**Figure A.10:** Individual probability ranges reflecting fulfilment of Criterion 1C (the disease is present in the whole or part of the Union territory with an endemic character) after the collective judgement

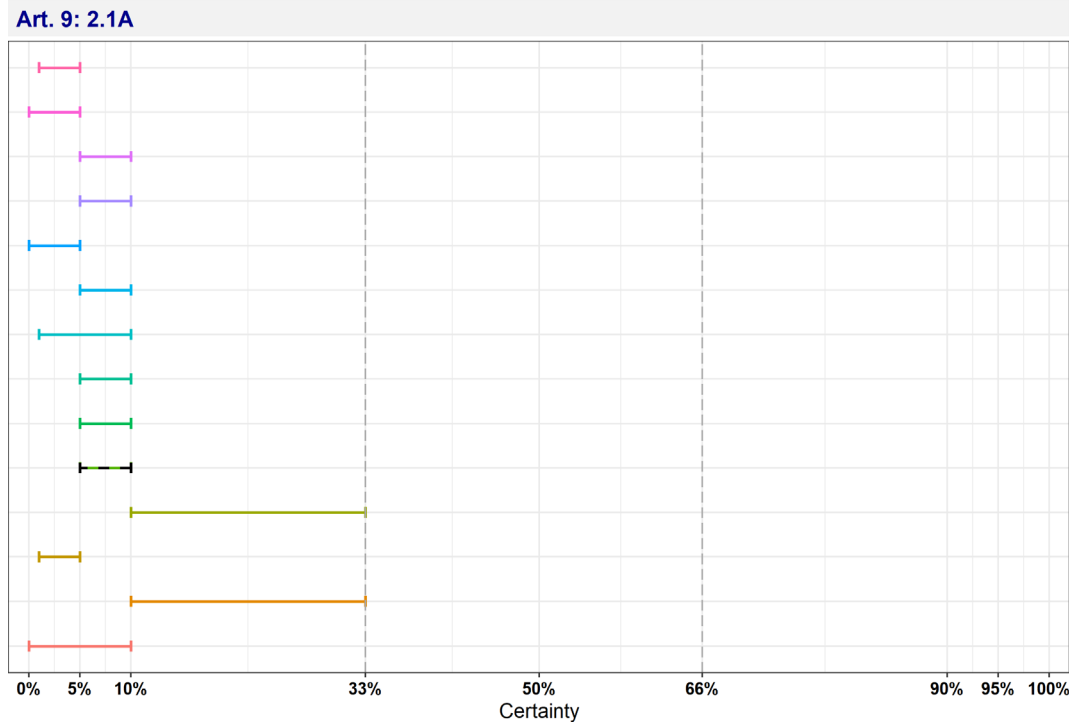
Collective Assessment



The median range is displayed as a dashed line.

**Figure A.11:** Individual probability ranges reflecting non-fulfilment of Criterion 2.1A (the disease is highly transmissible) after the collective judgement

Collective Assessment

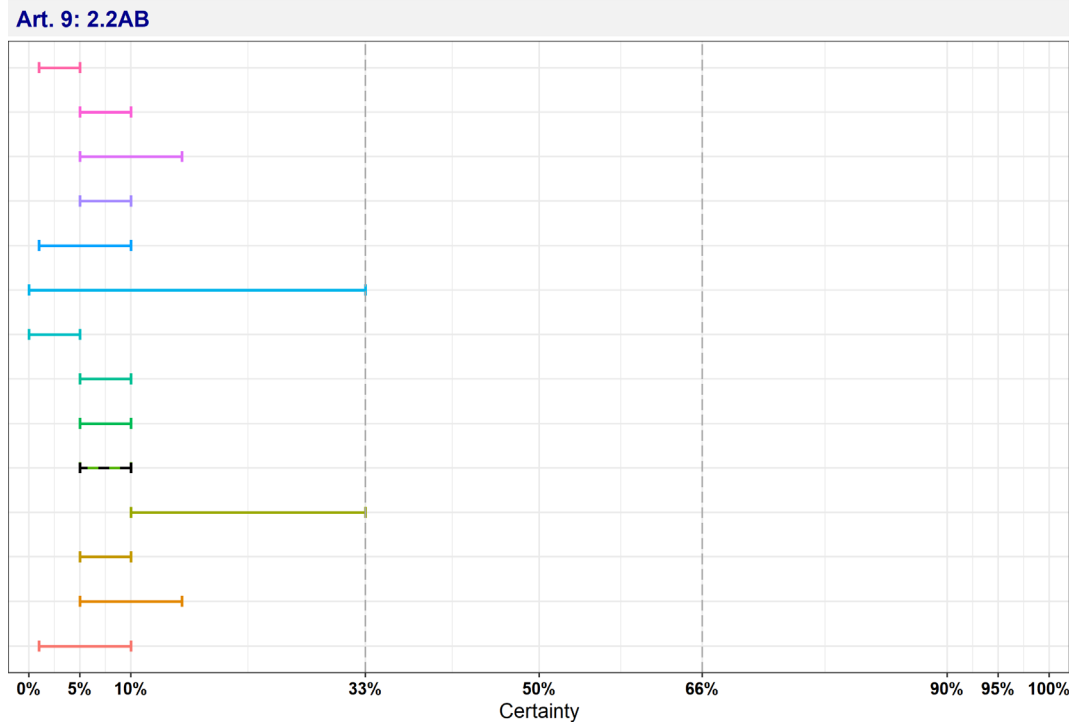


The median range is displayed as a dashed line.

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



Collective Assessment

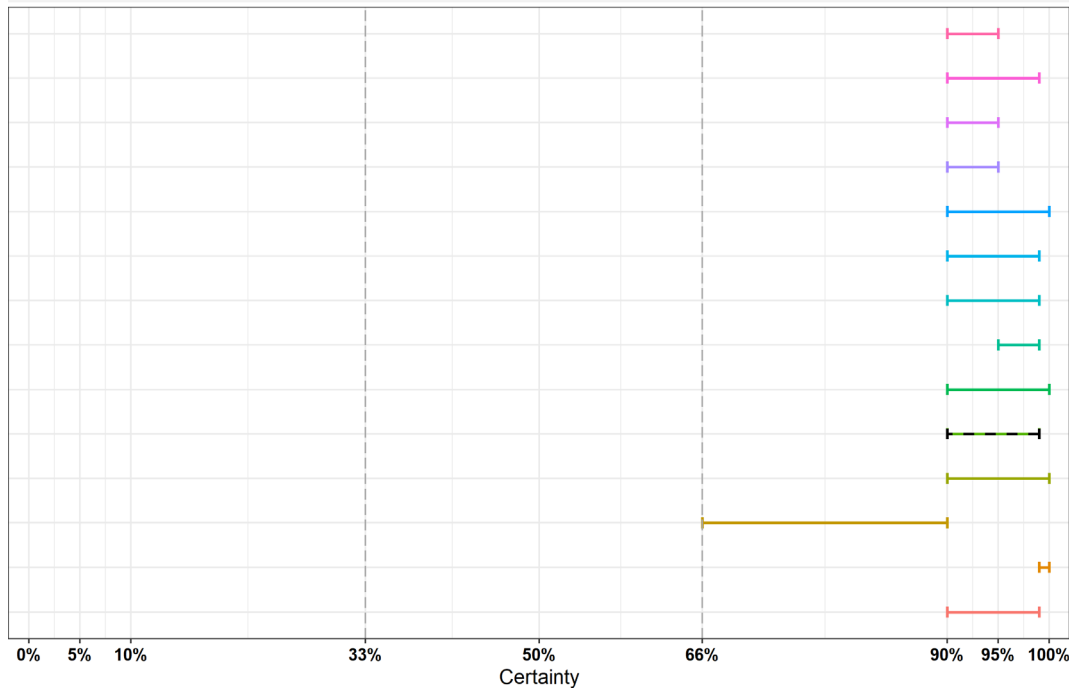


The median range is displayed as a dashed line.

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

Collective Assessment

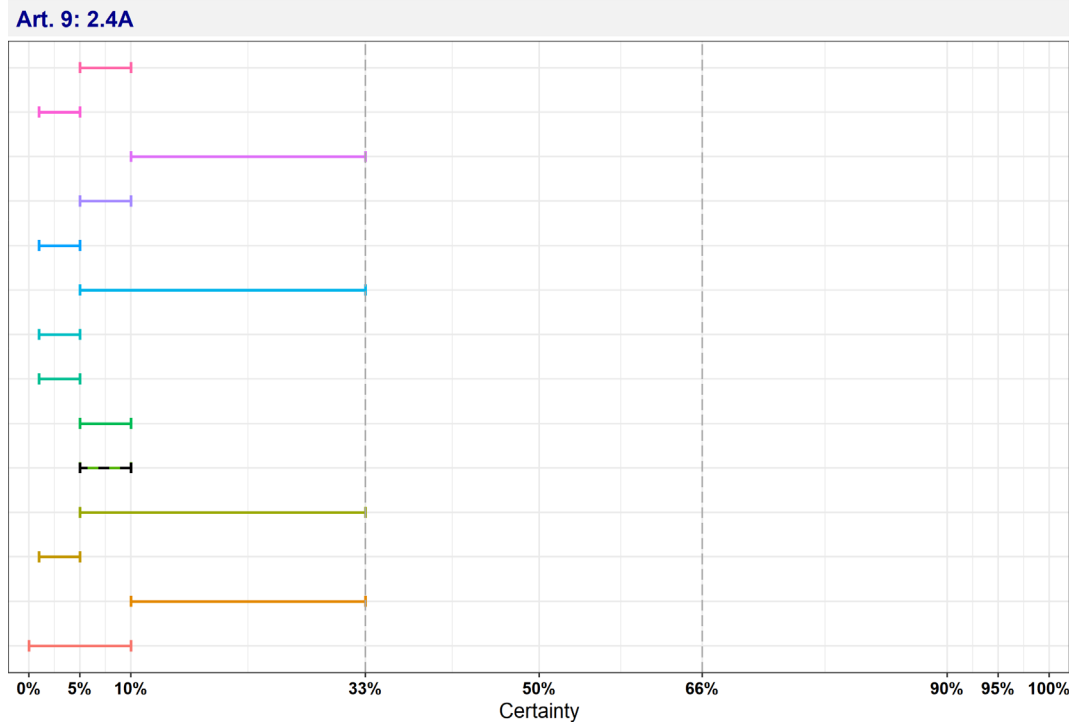
Art. 9: 2.3A



The median range is displayed as a dashed line.

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

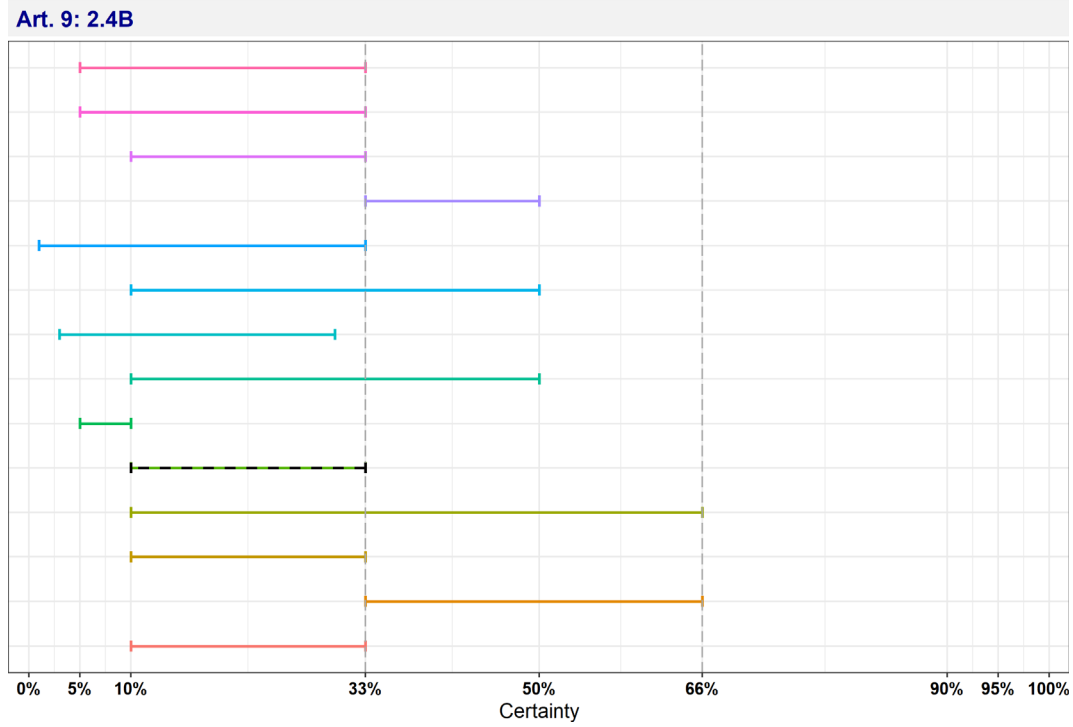
Collective Assessment



The median range is displayed as a dashed line.

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

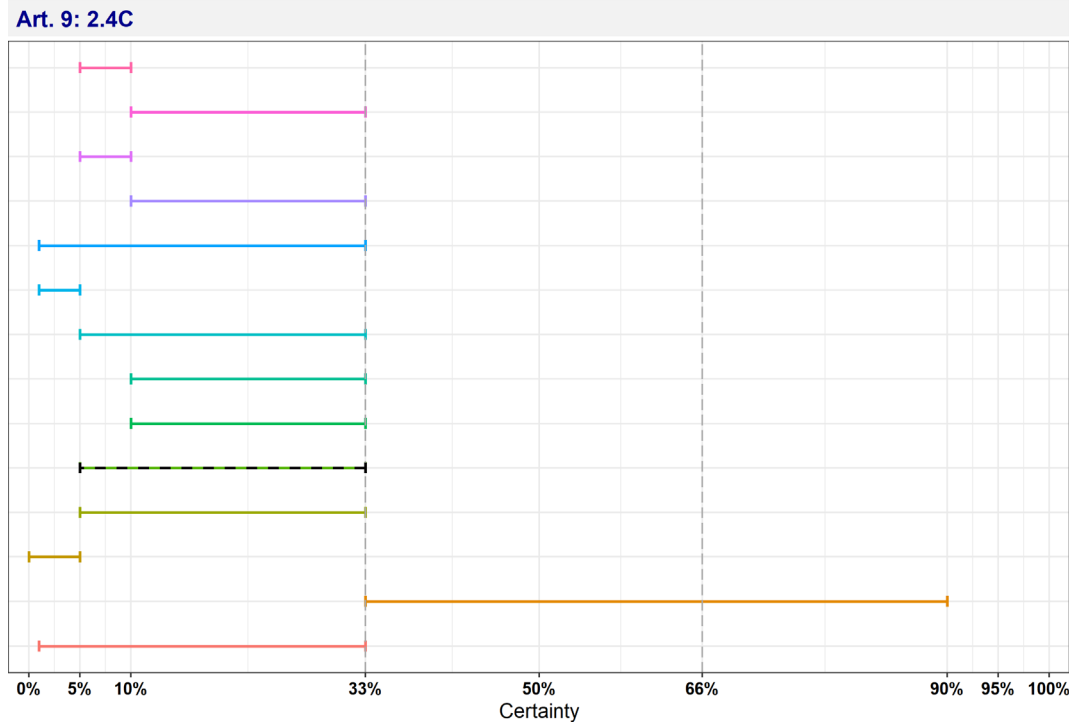
Collective Assessment



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

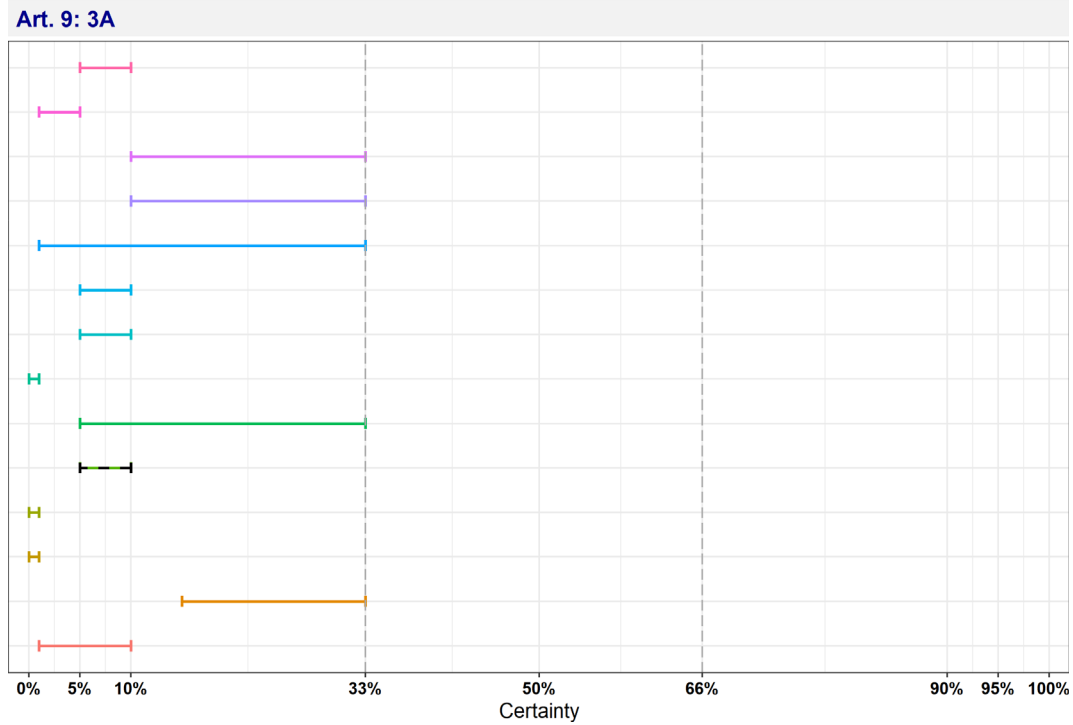
Collective Assessment



The median range is displayed as a dashed line.

**Figure A.17:** Individual probability ranges reflecting non-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

Collective Assessment

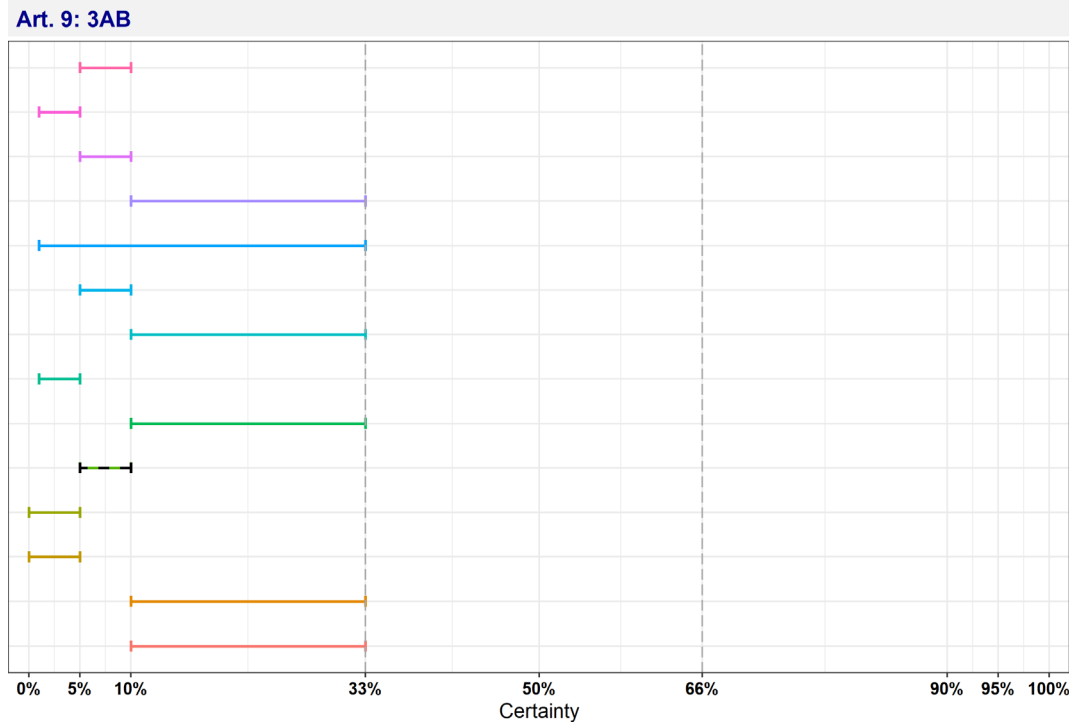


The median range is displayed as a dashed line.

**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



Collective Assessment

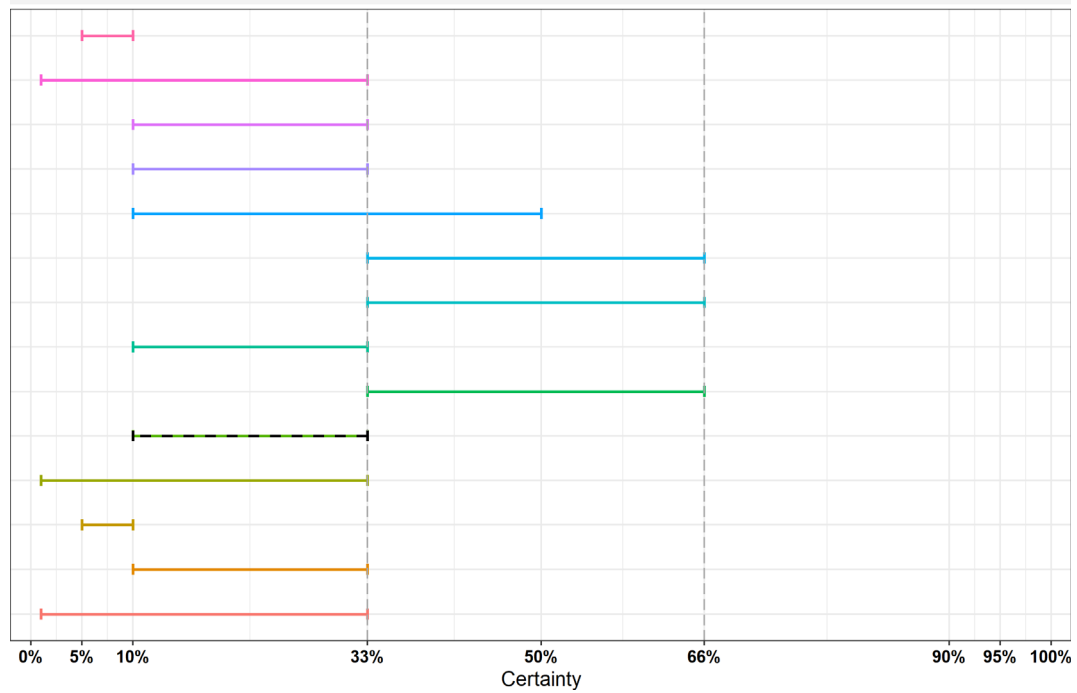


The median range is displayed as a dashed line.

**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

Collective Assessment

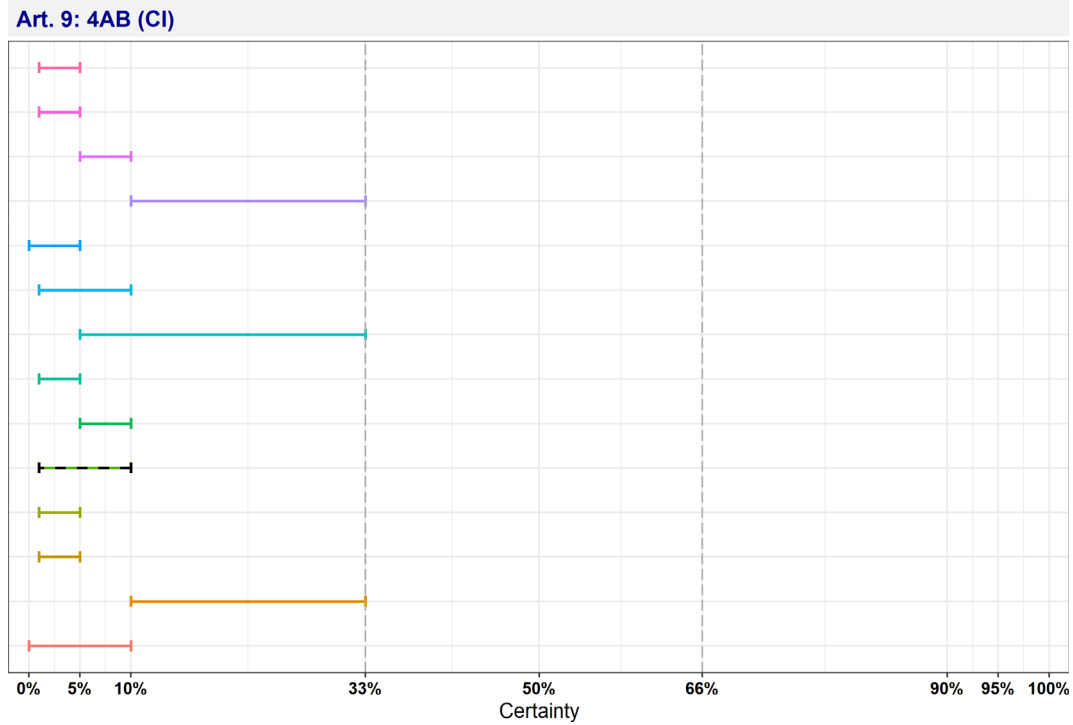
Art. 9: 3ABC



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

Collective Assessment

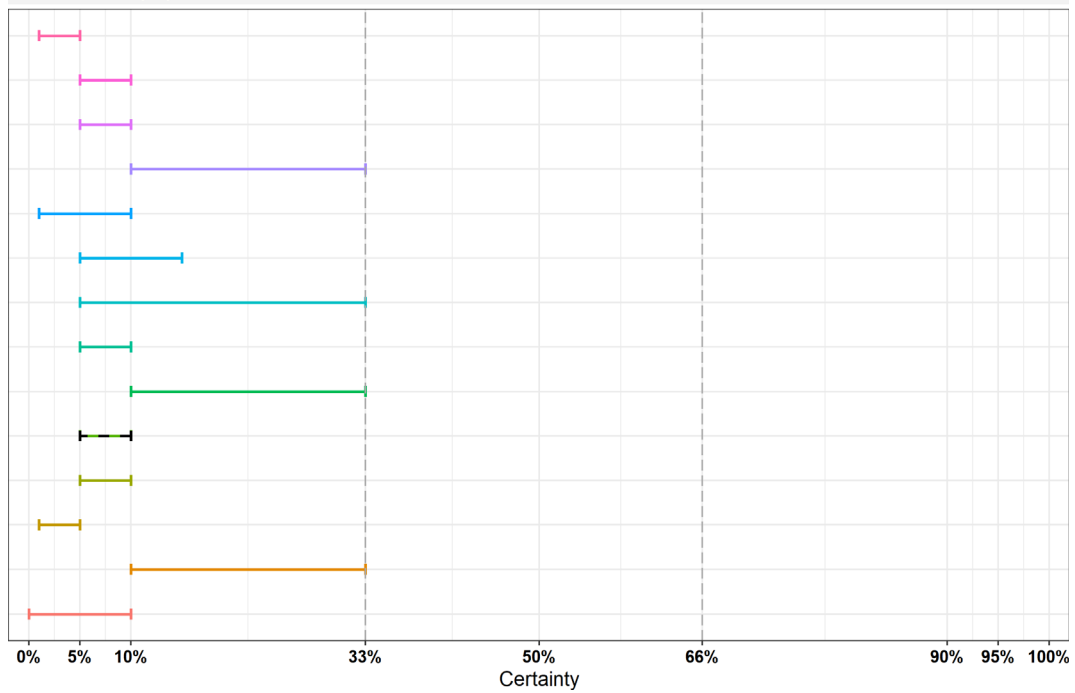


CI: current impact.  
 The median range is displayed as a dashed line.

**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

Collective Assessment

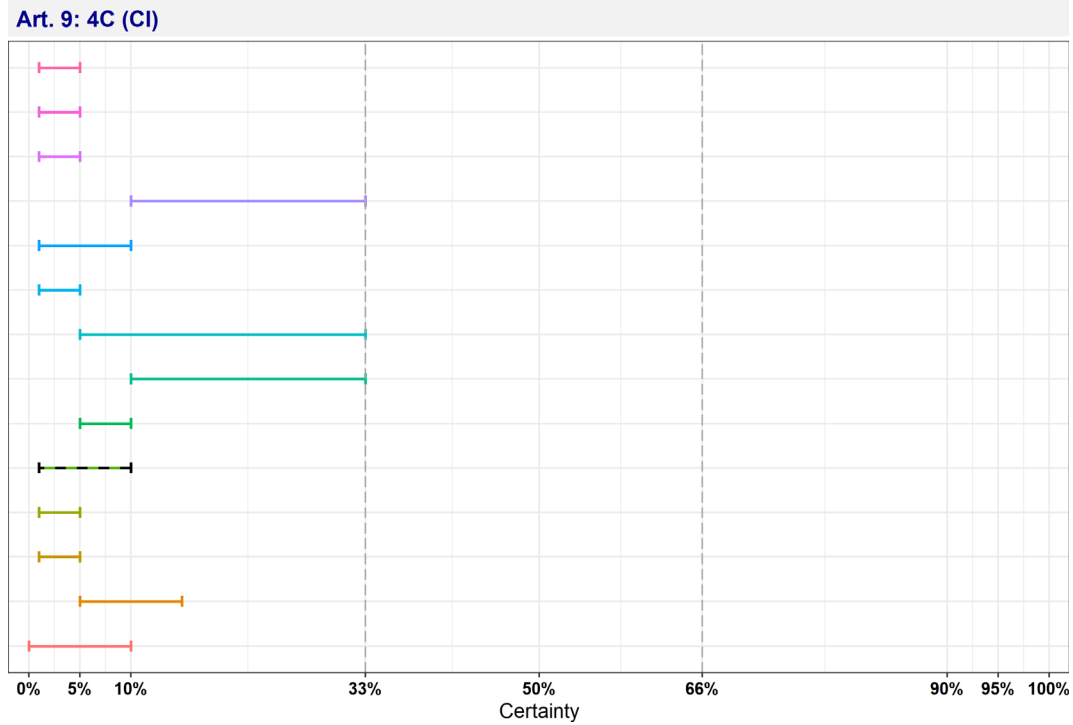
Art. 9: 4AB (PI)



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

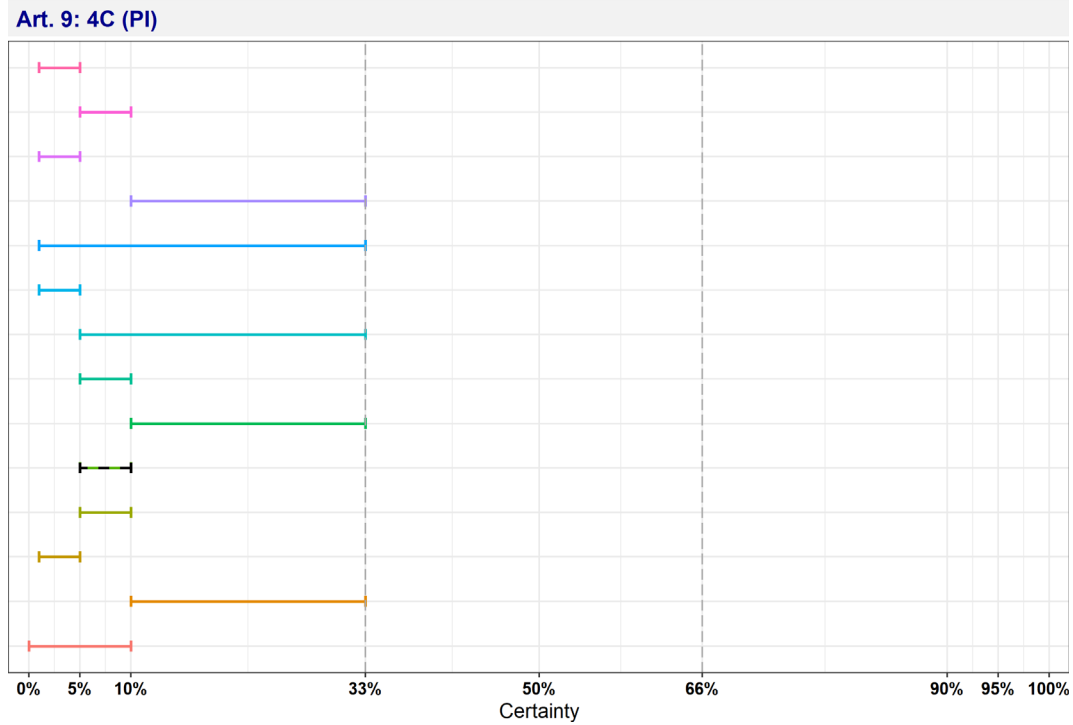
Collective Assessment



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

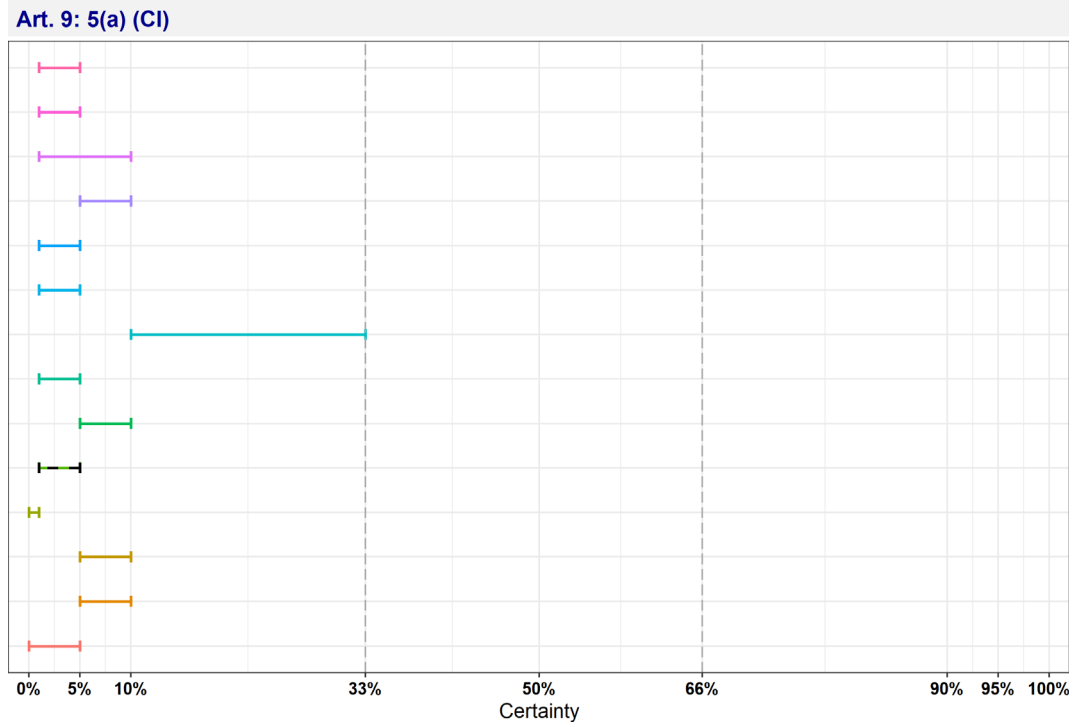
Collective Assessment



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

Collective Assessment

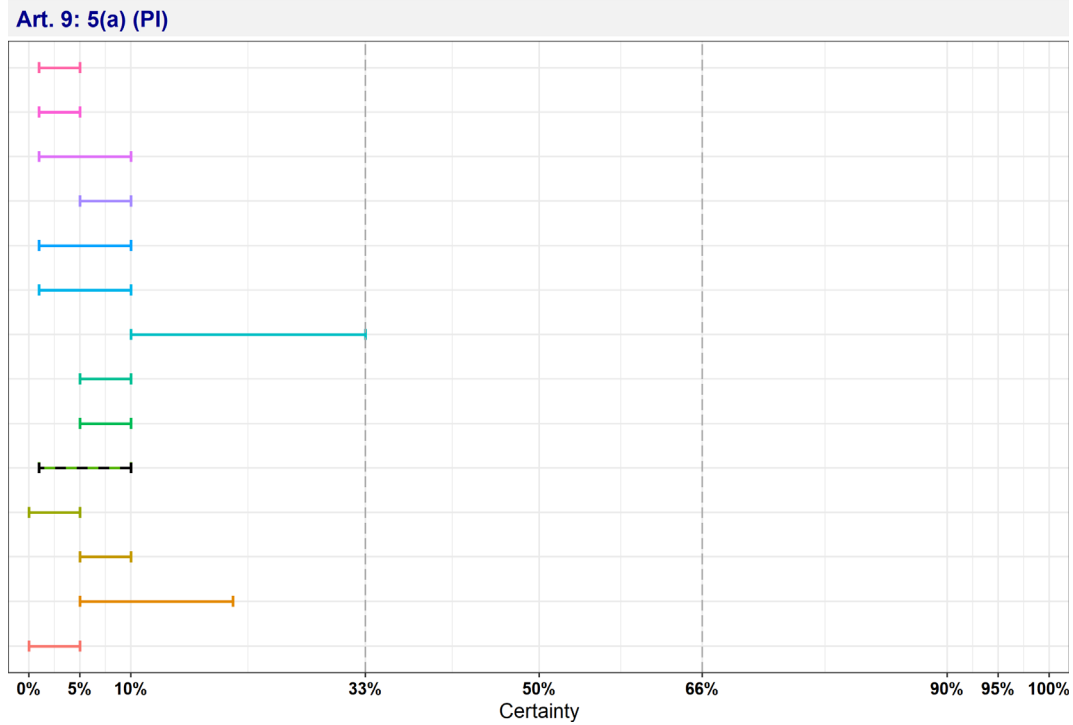


CI: current impact.  
 The median range is displayed as a dashed line.

**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



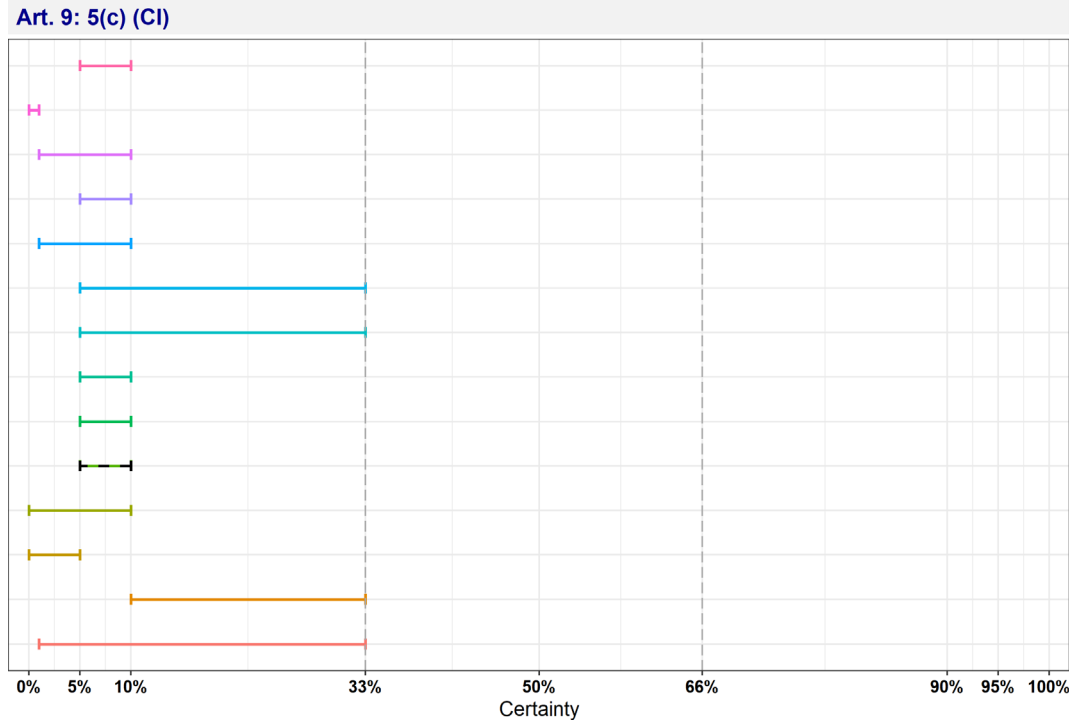
Collective Assessment



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

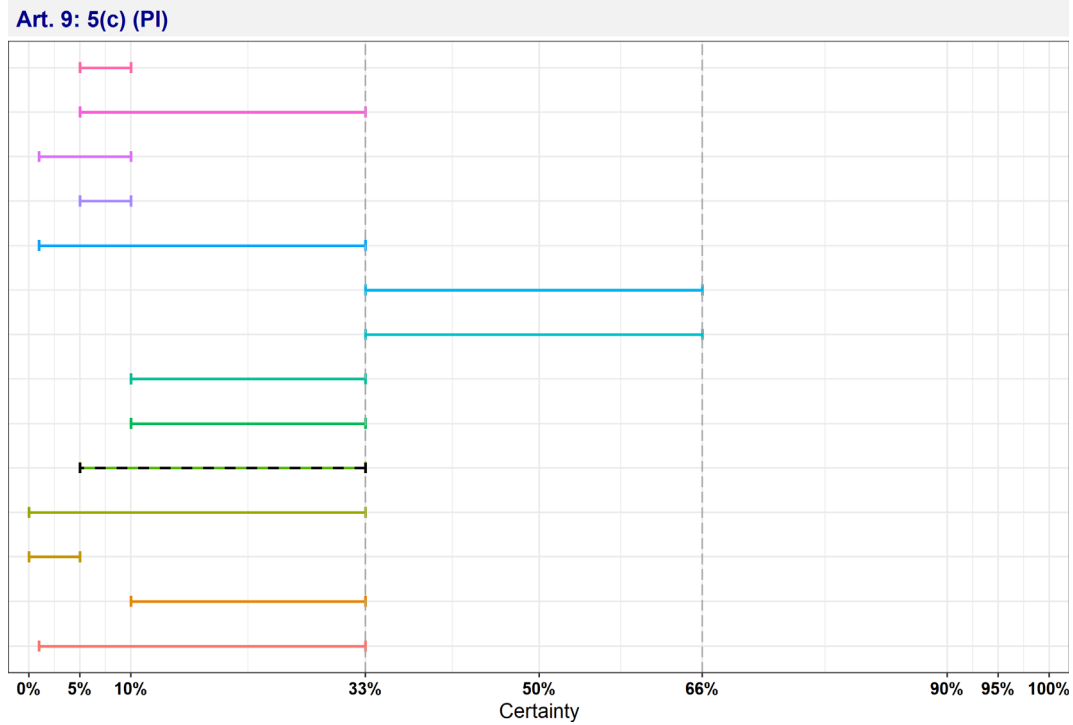
Collective Assessment



CI: current impact.  
 The median range is displayed as a dashed line.

**Figure A.27:** Individual probability ranges reflecting non-fulfilment of Criterion 5(c) (current impact) (the disease has a significant impact on the environment, due to the direct impact of the disease or due to the measures taken to control it) after the collective judgement

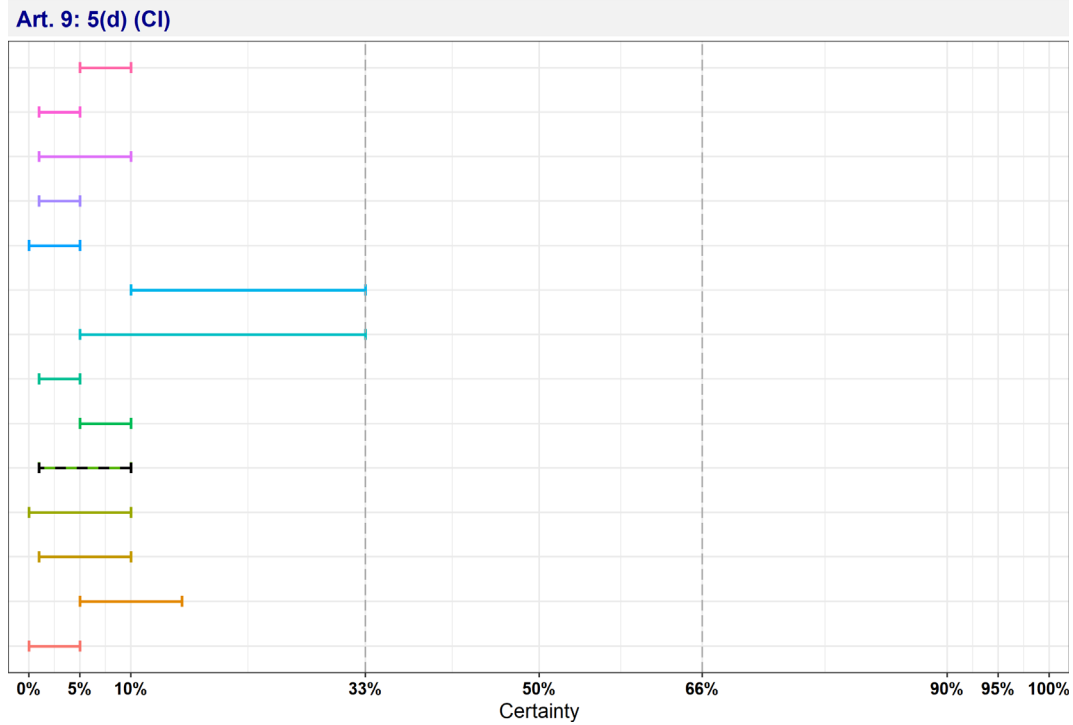
Collective Assessment



PI: potential impact.  
 The median range is displayed as a dashed line.

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

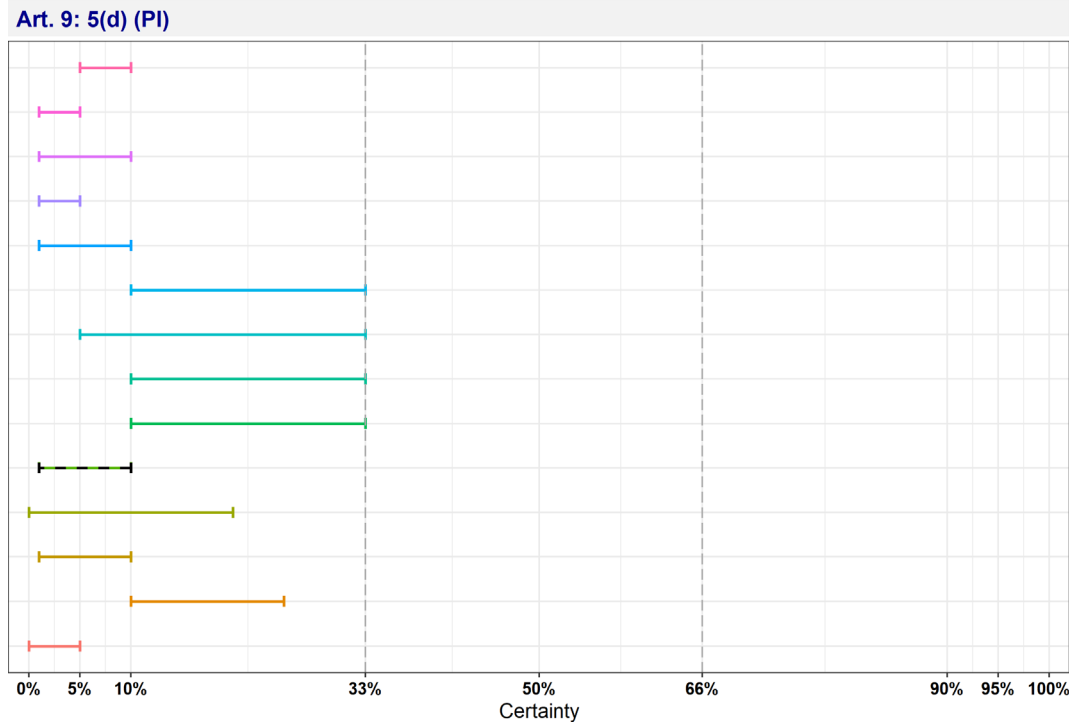
Collective Assessment



CI: current impact.  
 The median range is displayed as a dashed line.

**Figure A.29:** Individual probability ranges reflecting non-fulfilment of Criterion 5(d) (current impact) (the disease has a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds) after the collective judgement

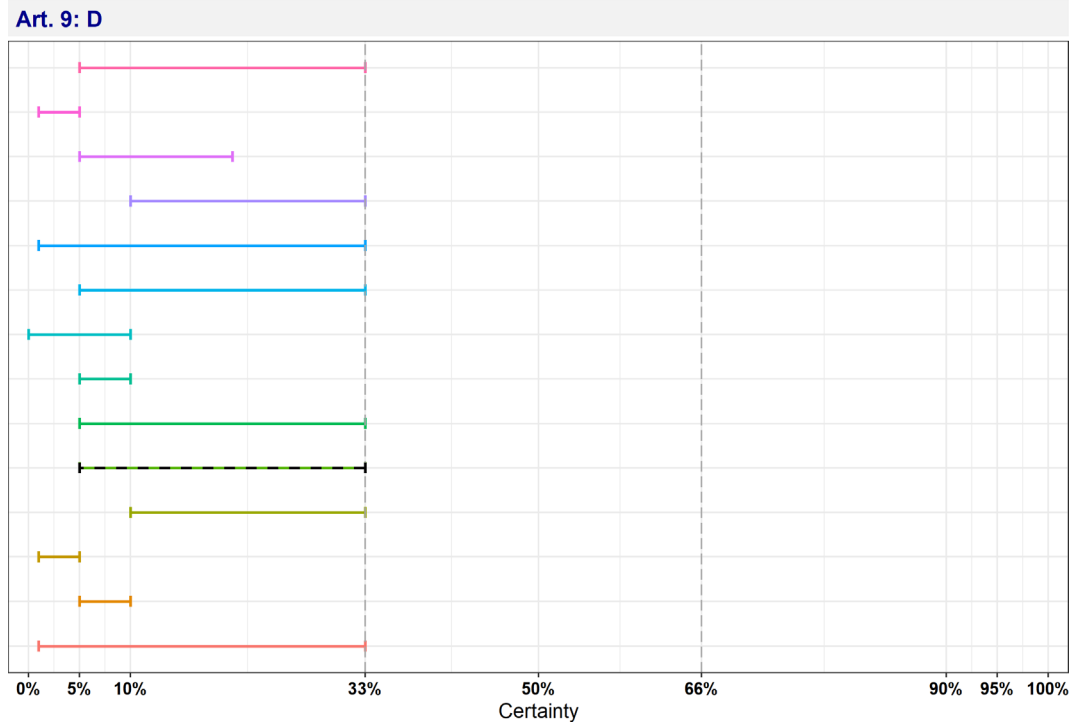
Collective Assessment



PI: potential impact.  
 The median range is displayed as a dashed line.

**Figure A.30:** 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

Collective Assessment



The median range is displayed as a dashed line.

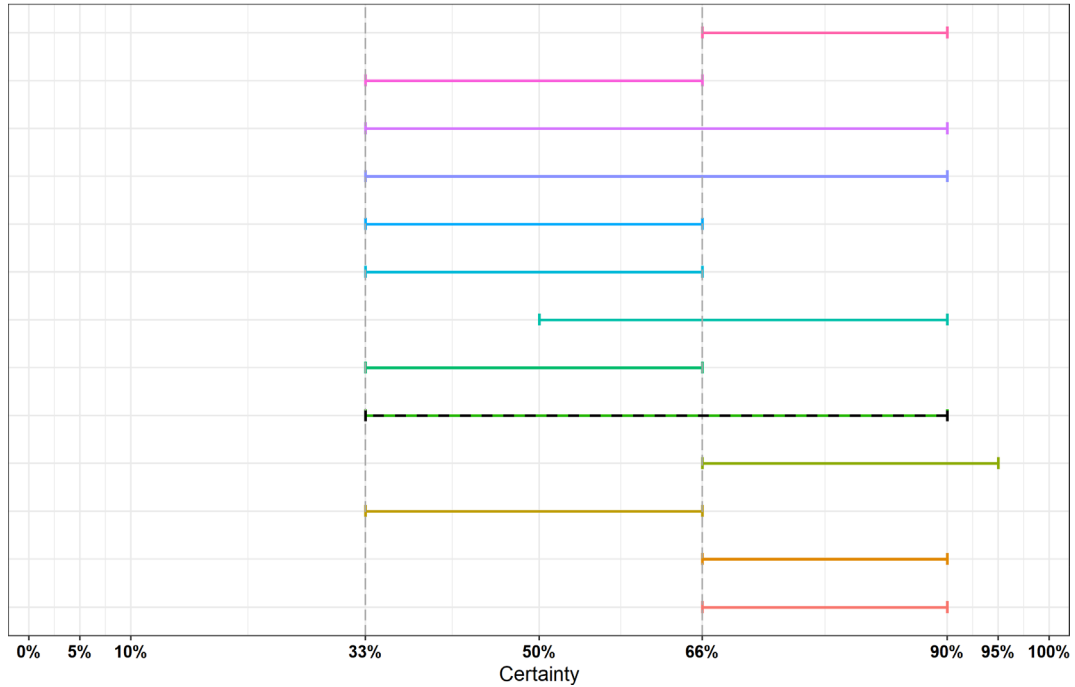
**Figure A.31:** Individual probability ranges reflecting non-fulfilment of Criterion D (the risk posed by the disease can be effectively and proportionately mitigated by measures concerning movements of animals and products in order to prevent or limit its occurrence and spread) after the collective judgement

## Appendix B – Criteria with uncertain outcome

### B.1. Article 5 criteria

Collective Assessment

Art. 5: A(i)

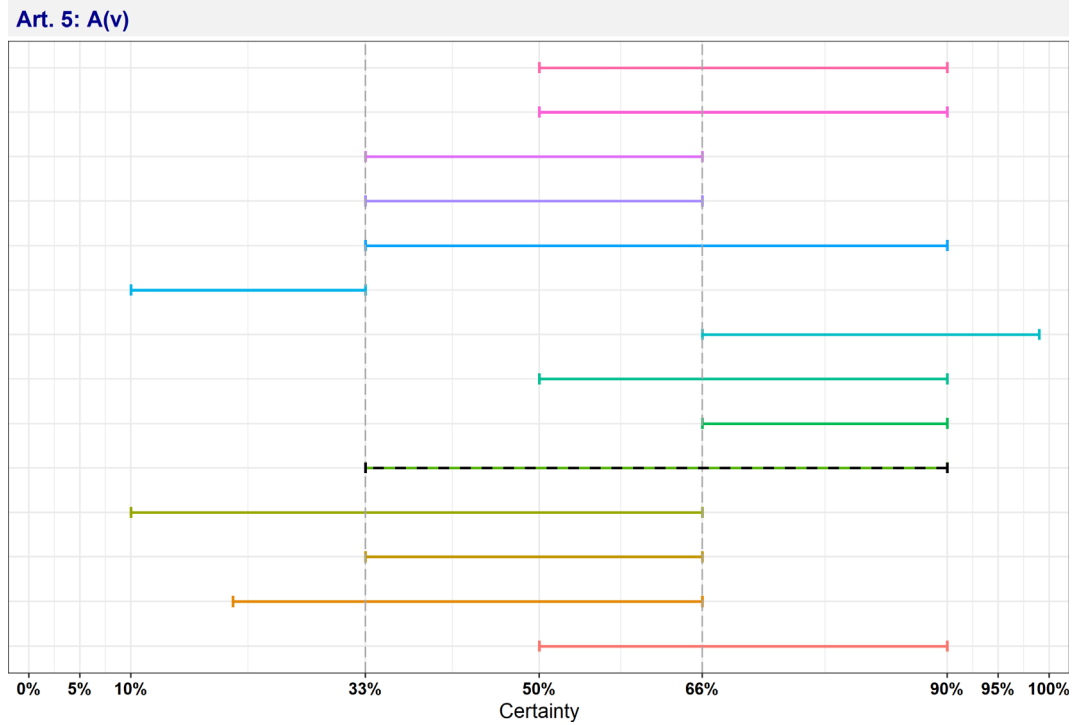


The median range is displayed as a dashed line.

**Figure B.1:** Individual probability ranges reflecting uncertain outcome on Criterion A(i) (the disease is transmissible) after the collective judgement



Collective Assessment

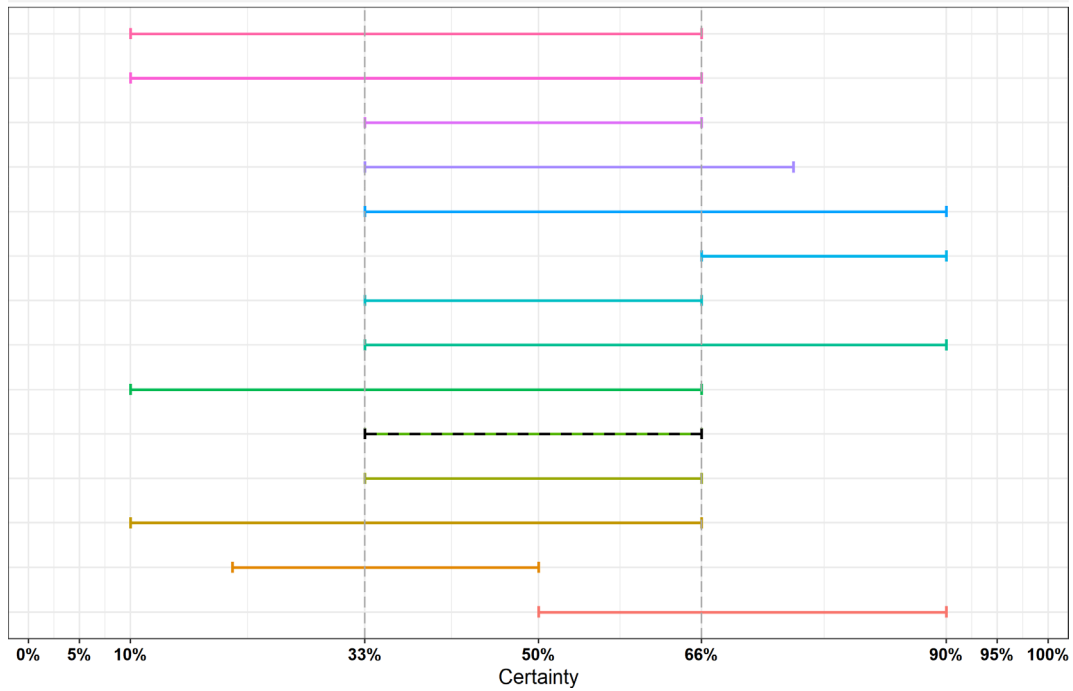


The median range is displayed as a dashed line.

**Figure B.2:** 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

Collective Assessment

Art. 5: B(i)



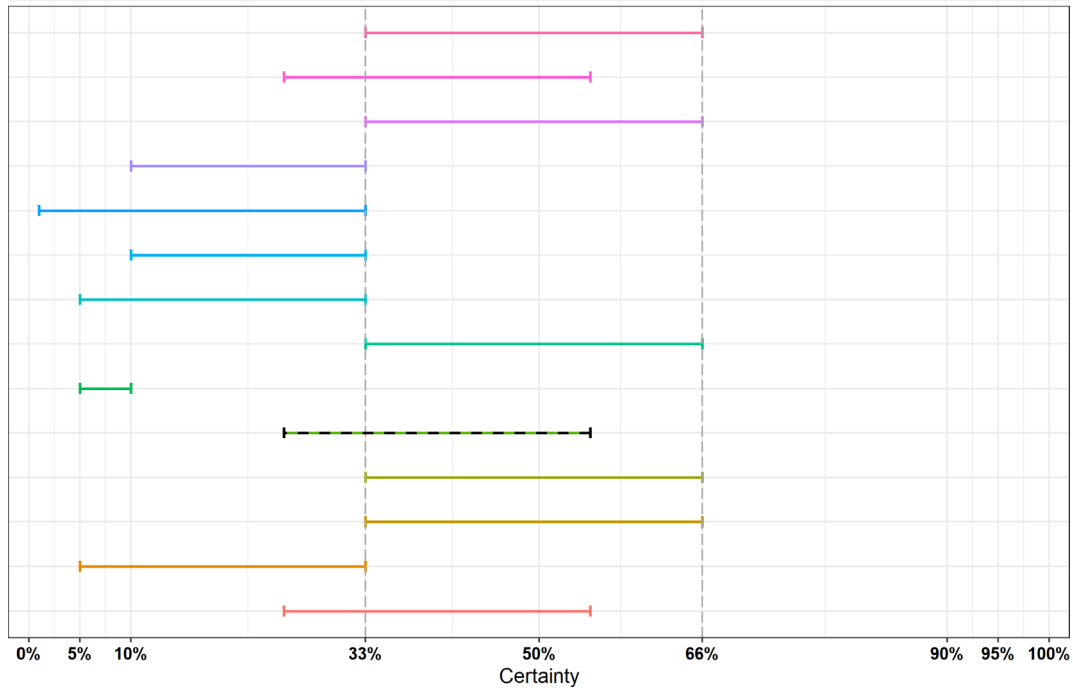
The median range is displayed as a dashed line.

**Figure B.3:** 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

### Collective Assessment

#### Art. 9: 5(b) (CI)

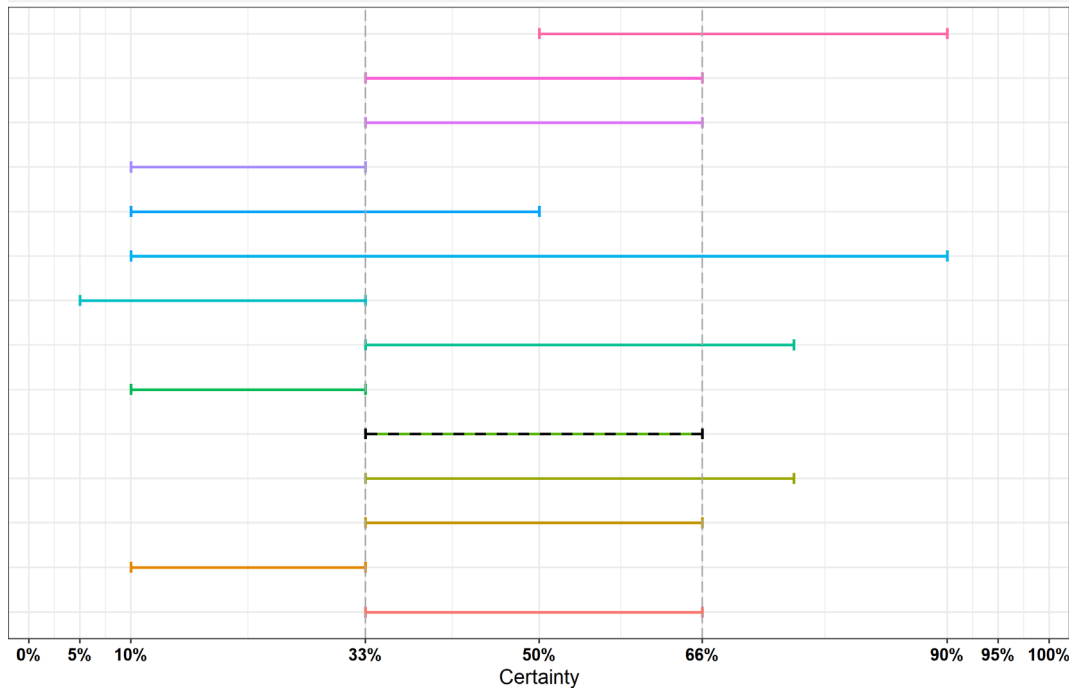


CI: current impact.  
The median range is displayed as a dashed line.

**Figure B.4:** Individual probability ranges reflecting uncertain outcome on Criterion 5(b) current impact) (the disease has a significant impact on animal welfare, by causing suffering of large numbers of animals) after the collective judgement

Collective Assessment

Art. 9: 5(b) (PI)



PI: potential impact.  
The median range is displayed as a dashed line.

**Figure B.5:** 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