SCIENTIFIC OPINION

efsa JOURNAL

ADOPTED: 27 September 2023

doi: 10.2903/j.efsa.2023.8326

Assessment of listing and categorisation of animal diseases within the framework of the Animal Health Law (Regulation (EU) 2016/429): Bacterial kidney disease (BKD)

EFSA Panel on Animal Health and Welfare (AHAW),
Søren Saxmose Nielsen, Julio Alvarez, Paolo Calistri, Elisabetta Canali, Julian Ashley Drewe, Bruno Garin-Bastuji, José Luis Gonzales Rojas, Christian Gortázar, Mette S Herskin, Virginie Michel, Miguel Ángel Miranda Chueca, Barbara Padalino, Helen Clare Roberts, Hans Spoolder, Karl Ståhl, Antonio Velarde, Arvo Viltrop, Christoph Winckler, James Bron, Niels Jorgen Olesen, Hilde Sindre, David Stone, Niccolò Vendramin, Sotiria Eleni Antoniou, Inma Aznar, Alexandra Papanikolaou, Anna Eleonora Karagianni and Dominique Joseph Bicout

Abstract

Bacterial kidney disease (BKD) was assessed according to the criteria of the Animal Health Law (AHL), in particular the 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 laid out in Article 9 and Article 8 for listing animal species related to BKD. The assessment was performed following the ad hoc method on data collection and assessment developed by AHAW Panel and already published. The outcome reported 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 an uncertain outcome. According to this assessment, BKD can be considered eligible to be listed for Union intervention according to Article 5 of the AHL (66–90% 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 BKD does not meet the criteria in Sections 1, 2 and 3 (Categories A, B and C; 1–5%, 33–66% and 33–66% probability of meeting the criteria, respectively) but meets the criteria in Sections 4 and 5 (Categories D and E; 66–90% and 66–90% probability of meeting the criteria, respectively). The animal species to be listed for BKD according to Article 8 criteria are provided.

Keywords: aquatic animals, Animal Health Law, bacterial kidney disease, listing, categorisation, impact

Requestor: European Commission

Question number: EFSA-Q-2023-00064

Correspondence: ahaw@efsa.europa.eu

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

Declarations of interest: If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

Acknowledgements: The AHAW Panel wishes to acknowledge the expert Dr Tim Regan selected through the Individual Scientific Advisor schema (ISA expert; EOI/EFSA/SCIENCE/2022/01 – CT 02 BIOHAW contract) for conducting the literature review on the disease profile and the parameters of the criteria of Article 7 of AHL and drafting the fact sheet.

Suggested citation: EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare), Nielsen, S. S., Alvarez, J., Calistri, P., Canali, E., Drewe, J. A., Garin-Bastuji, B., Gonzales Rojas, J. L., Gortázar, C., Herskin, M. S., Michel, V., Miranda Chueca, M. A., Padalino, M., Roberts, H. C., Spoolder, H., Ståhl, K., Velarde, A., Viltrop, A., Winckler, C., … Bicout, D. J. (2023). Assessment of listing and categorisation of animal diseases within the framework of the Animal Health Law (Regulation (EU) 2016/429): Bacterial kidney disease (BKD). *EFSA Journal, 21*(10), 1–76. https://doi.org/10.2903/j.efsa.2023.8326

ISSN: 1831-4732

Table of contents

1. Introduction

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

1.1.1. Background

Article 5 of the Regulation (EU) 2016/429 of the European Parliament and of the Council on transmissible animal diseases [Animal Health Law (AHL)],[1] provides for the list of diseases to which the rules set out in the AHL apply. These rules include the assessment provided for in Article 7 and the categorisation of those diseases as provided for in Article 9 of that Regulation.

In addition to the list of five significant diseases laid down in Article 5(1) of the AHL, a further list of animal diseases is set out in Annex II to that Regulation, which may be amended by means of a delegated regulation.

In addition, there are other transmissible diseases of aquatic animals for which certain control or trade measures apply today in accordance with Article 226(3) of the AHL, and which are not included in Annex II to the AHL.

Details of those diseases and the Member States or parts thereof which are regarded as being free from one or more of them, or which are subject to an eradication programme, are set out in Annexes I and II to Commission Implementing Decision (EU) 2021/260.[2] The aquatic species which are considered to be susceptible to those diseases are set out in Annex III to that Implementing Decision.

At least some of these diseases may fulfil the criteria to be listed in accordance with Article 5(3), following assessment in accordance with Article 7. In cases where listing is justified, these diseases should also be categorised in accordance with Article 9(1) and Annex IV of the AHL, and species, or groups of animal species, that are either susceptible to the diseases in question or have the capability to act as vectors, should be listed in accordance with Article 8(3) of the AHL.

The Commission, therefore, requires scientific advice concerning the following diseases, within the framework described above:

- Spring viraemia of carp (SVC)
- Bacterial kidney disease (BKD)
- Infectious pancreatic necrosis (IPN)
- Infection with *Gyrodactylus salaris* (GS)
- Infection with salmonid alphavirus (SAV)

1.1.2. Disease specific information

(a) Spring viraemia of carp (SVC)

Specific international trade standards for infection with spring viraemia of carp virus are provided for in Chapter 10.9. of WOAH (formerly OIE) Aquatic Animal Health Code (the WOAH [formerly OIE] Code), as well as in Chapter 2.3.9. of the WOAH (formerly OIE) Manual of Diagnostic for Aquatic Animals (the WOAH [formerly OIE] Manual).

In the existing EU legislative acts, spring viraemia of carp is referred to in Commission Implementing Decision (EU) 2021/260 of 11 February 2021, approving national measures designed to limit the impact of certain diseases of aquatic animals in accordance with Article 226(3) of Regulation (EU) 2016/429 of the European Parliament and of the Council and repealing Commission Decision 2010/221/EU.

(b) Bacterial kidney disease (BKD)

Specific international trade standards for bacterial kidney disease are not provided in the Aquatic Animal Health Code (the WOAH [formerly OIE] Code) or in the WOAH (formerly OIE) Manual of Diagnostic for Aquatic Animals (the WOAH [formerly OIE] Manual).

Bacterial kidney disease is however, referred to in Commission Implementing Decision (EU) 2021/260 of 11 February 2021, approving national measures designed to limit the impact of certain diseases of

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

[2] Commission Implementing Decision (EU) 2021/260 of 11 February 2021 approving national measures designed to limit the impact of certain diseases of aquatic animals in accordance with Article 226(3) of Regulation (EU) 2016/429 of the European Parliament and of the Council and repealing Commission Decision 2010/221/EU. OJ L 59, 19.2.2021, p. 1–9.

aquatic animals in accordance with Article 226(3) of Regulation (EU) 2016/429 of the European Parliament and of the Council and repealing Commission Decision 2010/221/EU.

(c) Infectious pancreatic necrosis (IPN)

Specific international trade standards for infectious pancreatic necrosis are not provided in the Aquatic Animal Health Code (the WOAH [formerly OIE] Code) or in the WOAH (formerly OIE) Manual of Diagnostic for Aquatic Animals (the WOAH [formerly OIE] Manual).

Infectious pancreatic necrosis is however, referred to in Commission Implementing Decision (EU) 2021/260 of 11 February 2021, approving national measures designed to limit the impact of certain diseases of aquatic animals in accordance with Article 226(3) of Regulation (EU) 2016/429 of the European Parliament and of the Council and repealing Commission Decision 2010/221/EU.

(d) Infection with *Gyrodactylus salaris* (GS)

Specific international trade standards for infection with *Gyrodactylus salaris* are provided for in Chapter 10.3 of the WOAH (formerly OIE) Aquatic Animal Health Code (the WOAH [formerly OIE] Code), as well as in Chapter 2.3.3 of the WOAH (formerly OIE) Manual of Diagnostic for Aquatic Animals (the WOAH [formerly OIE] Manual).

In the existing EU legislative acts, infection with *Gyrodactylus salaris* is referred to in Commission Implementing Decision (EU) 2021/260 of 11 February 2021, approving national measures designed to limit the impact of certain diseases of aquatic animals in accordance with Article 226(3) of Regulation (EU) 2016/429 of the European Parliament and of the Council and repealing Commission Decision 2010/221/EU.

(e) Infection with salmonid alphavirus (SAV)

Specific international trade standards for infection with salmonid alphavirus are provided for in Chapter 10.5. of the WOAH (formerly OIE) Aquatic Animal Health Code (the WOAH [formerly OIE] Code), as well as in Chapter 2.3.8 of the WOAH (formerly OIE) Manual of Diagnostic for Aquatic Animals (the WOAH [formerly OIE] Manual).

In the existing EU legislative acts, salmonid alphavirus is referred to in Commission Implementing Decision (EU) 2021/260 of 11 February 2021, approving national measures designed to limit the impact of certain diseases of aquatic animals in accordance with Article 226(3) of Regulation (EU) 2016/429 of the European Parliament and of the Council and repealing Commission Decision 2010/221/EU.

1.1.3. Terms of Reference

In view of the above, the Commission asks EFSA for a scientific opinion as follows:

1) for each of the diseases referred to above, an assessment, taking into account the criteria laid down in Article 7 of the AHL, on the eligibility of the disease to be listed for Union intervention as laid down in Article 5(3) of the AHL;
2) for each of the diseases mentioned above:
    a) an assessment of its compliance with each of the criteria in Annex IV to the AHL for the purpose of categorisation of diseases in accordance with Article 9(1) of the AHL;
    b) a list of animal species that should be considered candidates for listing in accordance with Article 8 of the AHL.

1.2. Interpretation of the Terms of Reference

The interpretation of the ToRs for this Scientific Opinion on BKD is as in Section 1.2 of the Scientific Opinion on the ad hoc method to be followed for the assessment on listing and categorisation of animal diseases within the AHL framework (EFSA AHAW Panel et al., 2017).

The present document reports the results of the assessment on the BKD according to the criteria of the AHL articles as follows:

- Article 7: BKD profile and impact;
- Article 5: eligibility of BKD to be listed;
- Article 9: categorisation of BKD according to disease prevention and control rules as in Annex IV. Each category foresees the application of certain disease prevention and control rules to the

respective listed diseases when the disease in question fulfils the criteria laid down in the relevant Section of Annex IV of AHL (Sections 1–5 which correspond to Categories A–E, respectively):

Category A: listed diseases that do not normally occur in the Union and for which immediate eradication measures must be taken as soon as a disease are detected.
Category B: listed diseases, which must be controlled in all Member States with the goal of eradicating them throughout the Union.
Category C: listed diseases which are of relevance to some Member States and for which measures are needed to prevent them from spreading to parts of the Union that are officially disease-free or that have eradication programmes for the listed disease concerned.
Category D: listed diseases for which measures are needed to prevent them from spreading on account of their entry into the Union or movements between Member States.
Category E: listed diseases for which there is a need for surveillance within the Union;

- Article 8: list of animal species related to BKD.

2. Data and methodologies

In order to address the ToRs as provided by the Commission, regarding the listing and categorisation of animal diseases within the framework of AHL, the EFSA AHAW Panel has developed an ad hoc methodology for the data collection and the assessment (EFSA AHAW Panel et al., 2017). This ad hoc methodology has been used for assessing any animal diseases in a uniform and consistent way and is the one used also for the current Scientific Opinion and constitutes the Protocol of the Assessment.

For the needs of the listing and categorisation of aquatic animal diseases the following deviations in Sections 2.1.2 and 2.3.1 of the ad hoc Methodology (EFSA AHAW Panel et al., 2017) were considered necessary for the assessment:

a) An EFSA working group (WG) of experts with expertise in aquatic animal diseases was established to support the assessment of the EFSA AHAW panel.
b) Section 2.1.2: The fact sheet on the disease profile and on the parameters of the criteria and of Article 7 of AHL has been outsourced not only to experts with disease specific expertise but also to experts with expertise in veterinary epidemiology or in aquatic animal diseases. The fact sheet was reviewed by the EFSA WG of experts and the comments provided were addressed by the contractor.
c) Section 2.3.1: In addition to AHAW Panel experts as foreseen in the Methodology (EFSA AHAW Panel et al., 2017), four experts from the EFSA WG with expertise in aquatic animal diseases participated in the judgement.

The following assessment was performed by the EFSA AHAW Panel based on the information collected and compiled in a 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, accompanied by verbal interpretations only when they fall within the ranges as spelt out in Table 1.

Table 1: Approximate probability scale recommended for harmonised use in EFSA (EFSA Scientific Committee et al., 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%

Section 3.1 below includes the information of the fact sheet on the disease profile and the parameters of the criteria of Article 7 of AHL and has been drafted by the selected expert through the Individual Scientific Advisor schema (ISA expert; EOI/EFSA/SCIENCE/2022/01 – CT 02 BIOHAW contract) and reviewed by the EFSA working group of experts.

3. Assessment

3.1. Assessment according to Article 7 criteria

This section presents the assessment of bacterial kidney disease (BKD) according to the criteria of Article 7 of the AHL and the related parameters in Table 2 of the Scientific Opinion on ad hoc methodology (EFSA AHAW Panel et al., 2017). The assessment is based on the information contained in the fact sheet on the disease profile and the parameters of the criteria of Article 7 of AHL (see Section 2.1 of the Scientific Opinion on the ad hoc methodology).

3.1.1. Article 7(a) Disease Profile

BKD is an infectious disease that can cause mortalities in freshwater and anadromous fish, particularly salmonids. The disease is caused by the intracellular bacterium *Renibacterium salmoninarum*, which can be transmitted vertically through infected eggs or horizontally through contact with infected fish, contaminated water or organic matter shed from infected fish. BKD primarily affects the kidneys of infected fish, and then the fish become swollen and discoloured. Other clinical signs of BKD include lethargy, loss of appetite and abnormal swimming behaviour.

BKD diagnosis can be challenging, as BKD is a chronic disease progressing slowly and may not show clinical signs until the later stages of infection and therefore can remain subclinical over the lifetime of an infected fish leading to further transmission. Treatment for BKD involves the use of antibiotics, although the effectiveness of treatment may vary depending on the severity of the infection, the strain of bacteria involved and the environment in which the fish live. Prevention of BKD typically involves implementing biosecurity measures, such as disinfecting equipment and preventing the introduction of infected fish into healthy populations.

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

Susceptible animal species

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

The disease was first reported in wild Atlantic salmon (*Salmo salar*) in Scotland (Smith, 1964). Since then, it has been reported in many other salmonid species including brown trout (*S. trutta*) (Mitchum et al., 1979), Arctic charr (*Salvelinus alpinus*) (Souter et al., 1987), rainbow trout (*Onchorynchus mykiss*) (Evelyn et al., 1973), brook trout (*Salvelinus fontinalis*) (Mitchum et al., 1979), lake trout (*Salvelinus namaycush*) (Souter et al., 1987) and cutthroat trout (*Oncorhynchus clarkii*) (Riepe et al., 2023) including all five Pacific salmon species: Chinook (*O.tshawytscha*), coho (*O. kisutch*), chum (*O. keta*), pink (*O. gorbuscha*) and sockeye (*O. nerka*) (Banner et al., 1986) (Table 2).

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

Farmed Salmonidae i.e. Atlantic salmon (Balfry et al., 1996), Arctic charr (Souter et al., 1987), grayling (*Thymallus thymallus*) (Kettler et al., 1986), rainbow trout and Pacific salmon (*O.* spp.) (Banner et al., 1986) are naturally susceptible (Table 2).

Table 2: Species susceptible to bacterial kidney disease (BKD) through natural infection (wild and farmed)

Fish Species (common name (scientific name))	Wild/farmed	Reference
Arctic charr *(Salvelinus alpinus)*	Wild and farmed	Souter et al. (1987)
Atlantic salmon (*Salmo salar)*	Wild and farmed	Balfry et al. (1996)
Grayling (*Thymallus thymallus*)	Wild and farmed	Kettler et al. (1986)
Brown trout (*Salmo trutta*)	Wild	Mitchum et al. (1979)
Charr (*Salvelinus* spp.)	Wild and farmed	Souter et al. (1987)

Fish Species (common name (scientific name))	Wild/farmed	Reference
Rainbow trout, (*Oncorhynchus mykiss*)	Wild and farmed	Banner et al. (1986)
Cutthroat trout (*Oncorhynchus clarkii*)	Wild	Riepe et al. (2023)
Chinook salmon (*Oncorhynchus tshawytscha*)	Wild	Banner et al. (1986)
Coho salmon (*Oncorhynchus kisutch*)	Wild	Banner et al. (1986)
Chum salmon (*Oncorhynchus keta*)	Wild	Banner et al. (1986)
Pink salmon (*Oncorhynchus gorbuscha*)	Wild	Banner et al. (1986)
Sockeye salmon (*Oncorhynchus nerka*)	Wild	Banner et al. (1986)
American brook trout (*Salvelinus fontinalis*)	Wild	Mitchum et al. (1979)
Lake trout (*Salvelinus namaycush*)	Wild	Souter et al. (1987)

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

Wild fish species that were found to be experimentally susceptible to BKD are: sablefish (*Anoplopoma fimbria*) (Bell et al., 1990), Pacific herring (*Clupea harengus pallasi*) (Traxler and Bell, 1988), burbot (*Lota lota*) (Polinski et al., 2010), shiner (*Notropis cornutus*) (Inglis et al., 1993), minnow (*Pimephales promelas*) (Inglis et al., 1993), ayu (*Plecoglossus altivelis*) (Nagai and Iida, 2002) and grayling (*Thymallus thymallus*) (Kettler, 1987) (Table 3).

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

Domestic/farmed fish species that were found to be experimentally susceptible to BKD are: Farmed Salmonidae, i.e. Atlantic salmon (Rozas-Serri et al., 2020), Arctic charr (Gudmundsdóttir et al., 2017) and *Oncorhynchus* genus salmonids (e.g. rainbow trout and Pacific salmon) (Banner et al., 1986) (Table 3).

Clinical signs of BKD have been reported in lumpfish (*Cyclopterus lumpus*) following intraperitoneal inoculation of *R. salmoninarum* (Gnanagobal et al., 2021) without evidence of being susceptible.

Table 3: List of farmed and wild fish species that are susceptible to experimental infection

Fish species	Wild/farmed	Experiment setting	Reference
Arctic charr (*Salvelinus alpinus*)	Farmed	Intraperitoneal inoculation	Gudmundsdóttir et al. (2017)
Atlantic salmon (*Salmo salar*)	Farmed	Intraperitoneal inoculation	Rozas-Serri et al. (2020)
Ayu (*Plecoglossus altivelis*)	Farmed	Intraperitoneal inoculation	Nagai and Iida (2002)
Burbot (*Lota lota*)	Wild	Intraperitoneal inoculation	Polinski et al. (2010)
Grayling (*Thymallus thymallus*)	Wild	Intraperitoneal inoculation	Kettler (1987)
Lumpfish (*Cyclopterus lumpus*)	Farmed	Intraperitoneal inoculation	Gnanagobal et al. (2021)
Minnow (*Pimephales promelas*)	Wild	Intraperitoneal inoculation	Inglis et al. (1993)
Oncorhynchus genus salmonids (e.g. rainbow trout and Pacific salmon)	Farmed	Oral intubation	Balfry et al. (1996)
Pacific herring (*Clupea harengus pallasi*)	Wild	Intraperitoneal inoculation	Traxler and Bell (1988)
Sablefish (*Anoplopoma fimbria*)	Wild	Intraperitoneal inoculation	Bell et al. (1990)
Shiner (*Notropis cornutus*)	Wild	Intraperitoneal inoculation	Inglis et al. (1993)

Reservoir animal species

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

Wild Salmonidae are known to act as reservoirs (Wiens, 2011; Murray et al., 2012).

R. salmoninarum has also been detected in several other species although clinical signs or deaths have not been reported; therefore, there is not enough evidence for their susceptibility to BKD. These species include Pacific hake (*Merluccius productus*) (Kent et al., 1998), Pacific herring (*Clupea harengus pallasi*) (Eissa et al., 2006), perch (*Cymatogaster aggregata*) (Inglis et al., 1993), European eel (*Anguilla anguilla*) (Chambers et al., 2008), minnow (*Phoxinus phoxinus*) (Wallace et al., 2017), three-spined stickleback (*Gasterosteus aculeatus*) (Wallace et al., 2017) and sea lamprey (*Petromyzon marinus*) (Eissa et al., 2006) (Table 4).

Table 4: Wild fish species reservoirs of *Renibacterium salmoninarum*

Fish species	Wild/farmed	Reference
Eurasian Minnow (*Phoxinus phoxinus*)	Wild	Wallace et al. (2017)
European eel (*Anguilla anguilla*)	Wild	Chambers et al. (2008)
Pacific hake (*Merluccius productus*)	Wild	Kent et al. (1998)
Pacific herring (*Clupea harengus pallasi*)	Wild	Eissa et al. (2006)
Sea lamprey (*Petromyzon marinus*)	Wild	Eissa et al. (2006)
Shiner perch (*Cymatogaster aggregata*)	Wild	Inglis et al. (1993)
Three-spined stickleback (*Gasterosteus aculeatus*)	Wild	Wallace et al. (2017)

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

Farmed Salmonidae, i.e. Atlantic salmon (Balfry et al., 1996) and *Oncorhynchus* genus salmonids (e.g. rainbow trout and Pacific salmons) (Banner et al., 1986) are known to act as reservoirs of the bacterium.

Beyond salmonids, some other species can be found infected with *R. salmoninarum* in natural environment without enough evidence for being susceptible. Similarly, infection can be seen in outbreaks in farmed common whitefish (*Coregonus lavaretus*) (Rimaila-Pärnänen, 2002) and ayu (*P. altivelis*) (Nagai and Iida, 2002), respectively.

Vector species

Parameter 7 – Wild vector species (or family/orders)

There is no evidence in the literature that there are other species than those listed as susceptible here that can transmit the bacterium *R. salmoninarum* to other susceptible species.

Parameter 8 – Domestic/farmed vector species (or family/orders)

There is no evidence in the literature that there are other species except those listed as susceptible here that can transmit the bacterium *R. salmoninarum* to other susceptible species.

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

Morbidity

Parameter 1 – Prevalence or incidence

BKD is highly prevalent and although predominantly occurring in freshwater, it can also occur in saltwater (Banner et al., 1983). To date, it has been detected in farmed salmonids throughout North and South America, Japan and Europe (Delghandi et al., 2020a). Specifically in Europe, infections have been reported in Austria, Denmark, Finland, France, Germany, Italy, Norway, Slovenia, Sweden and the United Kingdom (WAHIS/WOAH; Banner et al., 1981; Fryer and Sanders, 1981; Hoffman et al., 1984; Austin and Austin, 2016; Delghandi et al., 2020b; Cefas, 2023). A broad range of *R. salmoninarum* prevalence has been reported in the literature, from low prevalence (0.22%) in wild and escaped salmonids in Scotland (Wallace et al., 2011), to 5–15% in salmonids throughout England and Wales (Chambers et al., 2008) and from 6% to 100% in Iceland (Guðmundsdóttir et al., 2017).

No information about the incidence was found in the literature.

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

There are knowledge gaps surrounding the % of clinically diseased animals out of the infected ones, but there have been recorded instances of a prevalence of infection of 5–15% with no evidence of clinical signs (Chambers et al., 2008).

Parameter 3 – Case-fatality rate

Mortalities can vary between salmonid species with 17% recorded in *O. kisutch* (Fryer and Sanders, 1981), up to 40% in *S. salar* and 80% in *Oncorhynchus* sp. (Bruno, 1986; Evenden et al., 1993).

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

Presence

Parameter 1 – Report of zoonotic human cases (anywhere)

There is no evidence in the literature that bacterium *R. salmoninarum* infects humans.

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

Antibiotic therapy is not very effective in treating BKD. Due to the intracellular nature of *R. salmoninarum* and its low susceptibility, prolonged treatment of up to a month is required (Rhodes et al., 2008). Antibiotic resistance has also been reported (Elliott et al., 1989; Wiens, 2011).

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

The infectious period for BKD has been described in the literature as occurring throughout the duration of infection, which can persist over the lifetime of fish without clinical signs. Infected animals can transfer BKD at any time both horizontally and vertically through shedding in the water column (Balfry et al., 1996; Murray et al., 2012). *R. salmoninarum* has been reported to persist for up to 21 days in faeces and sediments (Bullock and Leek, 1986).

Parameter 2 – Presence and duration of latent infection period

R. salmoninarum is often transmitted vertically through eggs in aquaculture settings, but clinical signs of disease usually do not develop until salmonids are 6–12 months old (Evelyn, 1993; Wiens, 2011). Clinical signs begin at 10 days post inoculation (dpi) in artificially infected rainbow trout (Watson et al., 2023). The interval from infection until onset of clinical signs depends on multiple environmental and management factors, such as the season of stocking and husbandry (Boerlage et al., 2018), as does bacterial shedding (Purcell et al., 2016).

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

Adults can be chronically infected and continue shedding *R. salmoninarum* without showing any clinical sign (Suzuki et al., 2017; Boerlage et al., 2019). It has been suggested that low pathogenicity chronic infection over the entire lifetime of the host, followed by vertical transmission to offspring via eggs, may be the main strategy of the pathogen to propagate in low-density host populations (Boerlage et al., 2019).

Environment

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

Horizontal transmission can occur through contaminated water sources, faeces or skin tissue in addition to vertical transmission through the eggs but the bacteria are not believed to be able to survive for more than 7 days outside the host (Boerlage et al., 2018; Plumb, 2018).

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)

Both horizontal transmission through the shedding of faeces or skin in the water column (Balfry et al., 1996) and vertical transmission through direct infection of the eggs (Pascho et al., 1991) are known to occur.

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

No transmission of *R. salmoninarum* between animals and humans has been reported.

Speed of transmission

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

Infected salmonids upstream from a hatchery are known to act as a reservoir for infection and transmission can occur via eggs, skin lesions, eyes and ingestion (Hoar et al., 1997). No transmission of *R. salmoninarum* between animals and humans has been reported.

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

No transmission of *R. salmoninarum* between animals and humans has been reported. Data on transmission rate to other salmonid hosts are lacking. It is known that transmission can occur in under 4 weeks (Gudmundsdóttir et al., 2017), although this depends on multiple factors including, stocking season, environmental stress and husbandry, with higher mortalities seen at lower temperatures (Purcell et al., 2016; Boerlage et al., 2018).

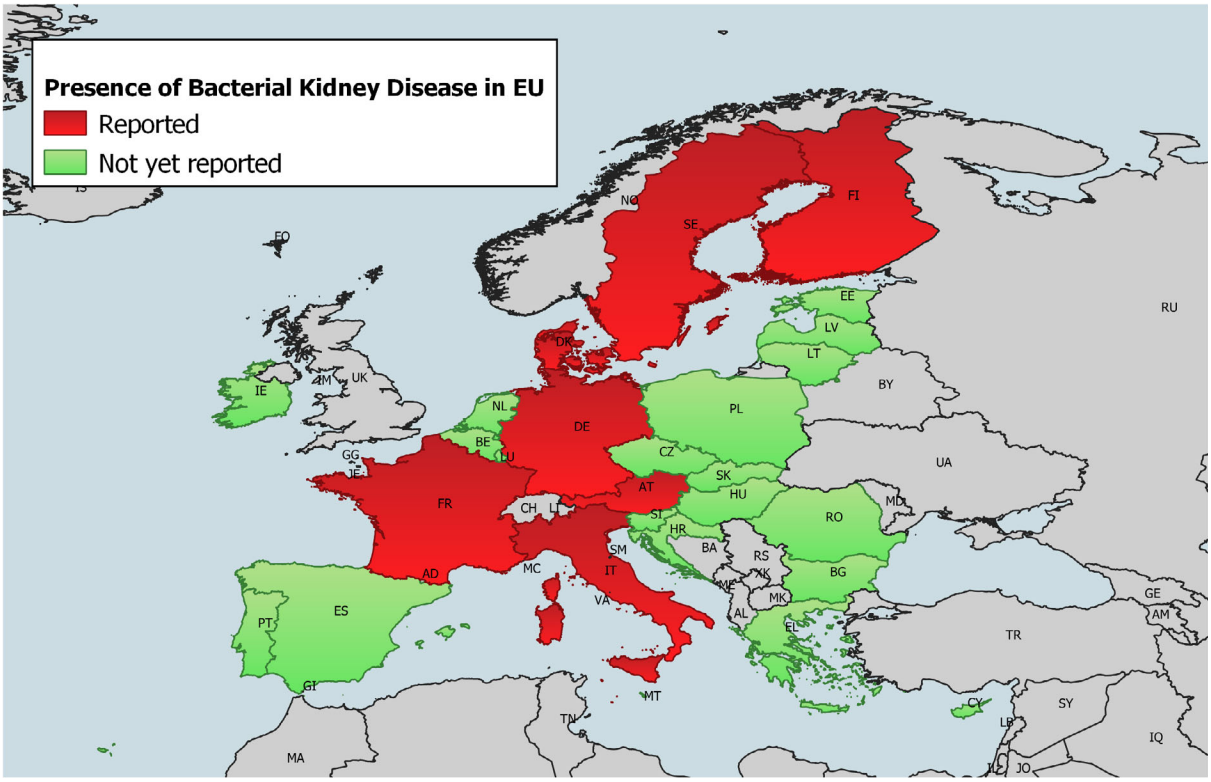
3.1.1.7. Article 7(a)(vii) The absence or presence and distribution of the disease in the Union, and, where the disease is not present in the Union, the risk of its introduction into the Union

Presence and distribution

Parameter 1 – Map where the disease is present in EU

Among EU MSs the presence of the disease has been reported in Austria, Denmark, Finland, France, Germany, Italy and Sweden in (Figure 1) (WAHIS/WOAH; Banner et al., 1981; Fryer and Sanders, 1981; Hoffman et al., 1984; Austin and Austin, 2016; Delghandi et al., 2020b; Cefas, 2023). Nevertheless according to Annex I to Commission Implementing Decision (EU) 2021/260[3] as currently amended, the whole territory of Ireland and the United Kingdom (Northern Ireland) and some individual compartments of Denmark and Finland are currently free from BKD.

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02021D0260-20230415&qid=1695763221847



Note: *Kosovo - this designation is without prejudice to positions on status and is in line with United Nations Security Council Resolution 1244 and the International Court of Justice Opinion on the Kosovo Declaration of Independence.

Figure 1: Map showing the presence of *R. salmoninarum* (causative agent of bacterial kidney disease) throughout EU Member States based on the information found in the literature and in WAHIS. Please note that according to Annex I to Commission Implementing Decision (EU) 2021/260, the whole territory of Ireland and the United Kingdom (Northern Ireland) and some individual compartments of Denmark and Finland are currently free from BKD. Source of map: map produced through QGIS (free and open-source Geographic Information System).

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

It is likely that the bacterium (*R. salmoninarum*) is present endemically in any country, which has a domestic salmon population or practices salmonid aquaculture (Persson et al., 2022).

Risk of introduction

Parameter 3 – Routes of possible introduction

While the bacteria are likely endemic at a low pathogenicity level in any domestic salmonid population, introduction of *R. salmoninarum* to areas which do not have domestic salmonid populations will most likely occur through vertical transmission via eggs produced in salmonid aquaculture and transported from one farm to another (Brynildsrud et al., 2014).

Parameter 4 – Number of animals moving and/or shipment size

In 2020, the EU imported over 1 million tonnes of salmonids from non-EU countries, while exporting approximately 136,000 t of salmonids to non-EU countries (Eumofa elaboration of Eurostat data, report of 2021[4]). Trade of live salmonids and their eggs for aquaculture, angling and stock enhancement occurs on a global scale. This is believed to have contributed to the distribution of BKD (Brynildsrud et al., 2014).

[4] https://www.eumofa.eu/documents/20178/477018/EN_The+EU+fish+market_2021.pdf/27a6d912-a758-6065-c973-c1146ac93d30?t=1636964632989

Parameter 5 – Duration of infectious period in animal and/or commodity

Adults can be chronically infected and continue shedding *R. salmoninarum* without showing clinical signs (Suzuki et al., 2017; Boerlage et al., 2019). It has been suggested that low pathogenicity chronic infection over the entire lifetime of the host, followed by vertical transmission to offspring via eggs, may be the main strategy of the pathogen to propagate in low-density host populations (Boerlage et al., 2019).

Parameter 6 – List of control measures at borders (testing, quarantine, etc.)

Many countries attempt to routinely screen aquaculture stocks to limit vertical transmission of *R. salmoninarum* (Persson et al., 2022). However, due to the prevalence of subclinical infections and vertical transmission, there are limitations in the effectiveness of screening and diagnostic tools. For instance, polymerase chain reaction (PCR) and enzyme-linked immunosorbent assay (ELISA) are not always sensitive enough to detect infection (Delghandi et al., 2020a). Most countries do not allow the movement of fish or eggs from farms known to be infected (Murray et al., 2012).

Parameter 7 – Presence and duration of latent infection and/or carrier status

Lifetime subclinical infection is known to occur (Suzuki et al., 2017; Boerlage et al., 2019).

Parameter 8 – Risk of introduction by possible entry routes (considering parameters from 3 to 7)

There is a high risk of introduction if salmonid aquaculture is practised, especially if wild salmonids are also present (Balfry et al., 1996; Boerlage et al., 2018).

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

Diagnostic tools

Parameter 1 – Existence of diagnostic tools

Multiple diagnostic tools are available. Multiple diagnostic tools are available, including bacterial culture, ELISA and PCR (see Section 4.1.4.1, Parameter 2 for accuracy estimates). *R. salmoninarum* is isolated on a modified kidney disease medium (MKDM) and confirmed by characteristic growth, additional biochemical testing and confirmatory nested PCR (nPCR). Due to the slow growing nature of *R. salmoninarum*, it takes one to 2 weeks for colonies to grow (Faisal et al., 2012), this is not always effective when a quick confirmation is needed, though (Delghandi et al., 2020a; Jia et al., 2023). Immunohistochemical diagnostics such as ELISA and immunofluorescence antibody test (IFAT) (Verdugo et al., 2020), using antibodies against the p57 bacterial protein (Aguilar et al., 2023) are widely used. These methods are more appropriate for later stages of infection, while qPCR molecular detection methods are more often used for early stages of infection due to higher sensitivity (Delghandi et al., 2020a). Diagnosis is most effective after clinical signs manifest, e.g. irregular swimming behaviour, lesions and haemorrhages on skin and fins (Delghandi et al., 2020a). However, due to the subclinical and chronic nature of the infection, it may take time for these clinical signs to appear. For that reason, qPCR is more commonly used in detecting low levels of infection to prevent vertical transmission via contaminated eggs or horizontal transmission via subclinically infected individuals (Delghandi et al., 2020a). Primers targeting the p57 gene are most commonly used, as formerly recommended by WOAH (Brown et al., 1994) and they show high sensitivity and specificity (Watson et al., 2023). Loop-mediated isothermal amplification (LAMP) assays to detect *R. salmoninarum* are also available (Brown et al., 1994). These have comparable sensitivity and specificity to qPCR but do not require laboratory equipment, meaning they could be quite useful for use in the field.

Control tools

Parameter 2 – Existence of control tools

Due to the subclinical nature of *R. salmoninarum* and its vertical transmission, control of BKD is difficult. Vaccination is not currently effective, so strategies to control infection largely rely on segregation and culling of brood stock from infected farms (Delghandi et al., 2020a).

3.1.2. Article 7(b) The impact of disease

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

The level of presence of the disease in the Union

Parameter 1 – Number of MSs where the disease is present

The disease has been reported in Austria, Denmark, Finland, France, Germany, Italy and Sweden in (Figure 1) (WAHIS/WOAH; Banner et al., 1981; Fryer and Sanders, 1981; Hoffman et al., 1984; Austin and Austin, 2016; Delghandi et al., 2020b; Cefas, 2023).

Denmark and Finland have a number of compartments with BKD-free broodstock farms. It is likely that *R. salmoninarum* is present in any country which has a domestic salmon population or practices salmonid aquaculture (Persson et al., 2022). An exception is Ireland, possibly due to the fact that salmonid aquaculture in Ireland is predominantly marine, whereas *R. salmoninarum* is predominantly a freshwater pathogen (Delghandi et al., 2020a).

The loss of production of the disease

Parameter 2 – Proportion of production losses (%) by epidemic/endemic situation (growth, semen, meat, etc.)

Due to the chronic nature of the disease, production losses are very difficult to accurately quantify. However, losses as high as 40% have been reported for Atlantic salmon (*S. salar)* and 80% for rainbow trout (*O. mykiss*) (Bruno, 1986; Evenden et al., 1993).

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

No transmission of *R. salmoninarum* between animals and humans has been reported.

Parameter 2 – Incidence of zoonotic cases

No transmission of *R. salmoninarum* between animals and humans has been reported.

Transmissibility between humans

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

No transmission of *R. salmoninarum* between animals and humans has been reported.

Parameter 4 – Sporadic, endemic, epidemic or pandemic potential

No transmission of *R. salmoninarum* between animals and humans has been reported.

Parameter 5 – Disability-adjusted life year (DALY)

No transmission of *R. salmoninarum* between animals and humans has been reported.

The availability of effective prevention or medical treatment in humans

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

No transmission of *R. salmoninarum* between animals and humans has been reported.

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

No transmission of *R. salmoninarum* between animals and humans has been reported.

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

From birth to spawning *R. salmoninarum* can persist chronically at a subclinical level in a population of salmonids and therefore can be vertically transmitted (Suzuki et al., 2017; Boerlage et al., 2019).

However, severe signs of clinical infection have been reported from 4 weeks post exposure through horizontal infection (Gudmundsdóttir et al., 2017). These clinical signs present significant welfare issues for infected fish. External clinical signs of infection include abnormal swimming behaviour, exophthalmia and ocular lesions (Eissa et al., 2006; Richards et al., 2017). Fin, midline and anal haemorrhages, anaemia, skin lesions and discolouration as well as belly rash are also seen in adults (Plumb, 2018). Anatomopathological signs of infection include swelling of the heart, spleen, kidney and liver with lesions visible on the viscera (Evenden et al., 1993). Brain lesions have been reported in multiple *Oncorhynchus* species (Plumb, 2018).

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

R. salmoninarum is considered a pathogen of salmonids (Guz and Puk, 2020), meaning that several wild salmonids are potentially at risk. Of these, Danube salmon (*Hucho hucho*), flathead trout (*S. platycephalus*), Garda trout (*S. carpio*), Prespa trout (*S. peristericus*), *S. ezenami*, soft-mouthed trout (*S*. obyusirostris), pollan (*Coregonus pollan*), schelly (*Coregonus stigmaticus*), vendace (*C. vandesius*), gwyniad (*C. pennantii*), whitefish *(C. trybomi),* Ammersee Kilch *(C. bavaricus),* Schwebrenke (*C. hoferi), blunt-nosed Irish charr (Salvelinus obtusus),* Lonsdale's charr *(S. lonsdalii),* Grey's charr *(S. grayi)* and Willoughby's charr (*S. wiloughbii*) are on the IUCN red list as endangered.

R. salmoninarum has been detected in one out of 45 European eels (*A. anguilla*) tested in the UK without clinical signs and therefore without enough evidence of susceptibility (Chambers et al., 2008). The European eel is on the CITES endangered list (Appendix II).

Parameter 2 – Mortality in wild species

The prevalence of *R. salmoninarum* in wild and escaped salmonids in Scotland was reported as 0.22% (Wallace et al., 2011), whereas the prevalence among wild salmonids in Iceland ranged from 6% to 100% (Guðmundsdóttir et al., 2017). Mortalities are known to mostly occur in 6 to 12-month-old juvenile salmon (Wiens, 2011), but data on mortality among wild populations are lacking.

Environment

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

R. salmoninarum is believed to be able to persist in aquatic environments for up to 7 days in the absence of its host (Boerlage et al., 2018). For this reason, horizontal or vertical transmission via gamete infection to other wildlife is possible and has been known to occur near salmonid fish farms (Chambers et al., 2008).

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

Parameter 1 – Listed in WOAH/CFSPH classification of pathogens

Currently, BKD is not listed as a notifiable disease by the WOAH.[5] It was listed by the WOAH until 2006 when it ceased being internationally notifiable (WOAH, 2006).

BKD is not listed by the Centre for Food Security and Public Health (CFSPH).[6]

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

R. salmoninarum is not listed in the Encyclopaedia of Bioterrorism Defence of Australia Group.[7]

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

R. salmoninarum is not listed as a potential bio-agro-terrorism agent.

[5] https://www.woah.org/en/home/
[6] https://www.cfsph.iastate.edu/diseaseinfo/
[7] http://www.australiagroup.net/en/human_animal_pathogens.html

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, WOAH certified

There are no officially/internationally recognised diagnostic tools that are certified or recommended by the WOAH for BKD, since BKD is not listed anymore.

Common diagnostic tools for BKD include ELISA, IFAT, bacterial culture and conventional, quantitative, real-time and nested PCR (Jaramillo et al., 2017; Richards et al., 2017; Laurin et al., 2019; Verdugo et al., 2020).

Effectiveness

Parameter 2 – Sensitivity (Se) and Specificity (Sp) of diagnostic tests

There are no officially/internationally recognised diagnostic tools.

PCR tests are often reported to have the highest sensitivity in fish with and without visible lesions or clinical signs whereas ELISA tests have the highest specificity independently of the salmonid species tested (Jaramillo et al., 2017; Laurin et al., 2019). The sensitivity of all the tests was significantly lower in the absence of lesions (0.23–0.82) than in the presence of lesions (0.78–0.98). A comparison of ELISA, PCR and bacterial culture (Richards et al., 2017) showed that the specificity and sensitivity of the tests depend on the tissue used, with blood and mucus giving a higher test specificity than uro-faecal samples. Based on an expert elicitation study conducted through a questionnaire by Verdugo et al., 2020 the median estimate of the experts on the specificity of quantitative PCR was 0.96 and 0.91 for the sensitivity, which is higher than the median estimates of the specificity of IFAT (0.90). The experts did not agree on the sensitivity of the IFAT test (Verdugo et al., 2020).

The values of the sensitivity and specificity of the diagnostic tests in several publications vary: (i) ELISA: Sp = 0.89–1.0, Se = 0.25–0.82, (ii) IFAT: Sp = 0.87–0.91, Se = 0.28–0.62 and (iii) (q)PCR: Sp = 0.93–0.98, Se = 0.87–0.93 (Jaramillo et al., 2017; Richards et al., 2017; Laurin et al., 2019; Verdugo et al., 2020).

Feasibility

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

The most commonly used samples for detection of BKD are samples of the kidney and spleen, which require killing the animal. However, non-lethal sampling of mucus, blood, uro-faecal mixture and ovarian fluid is also possible (Richards et al., 2017; Laurin et al., 2019).

3.1.4.2. Article 7(d)(ii) Vaccination

Availability

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

There is one live vaccine, Renogen® commercialised by Elanco Aqua that contains live cell culture of the non-virulent *Arthrobacter davidanieli* that shares antigenic determinants with *R. salmoninarum* against BKD. It is approved for use in Canada, Chile and USA (Salonius et al., 2005; Ma et al., 2019). Vaccines against BKD are not currently authorised in the EU.

Parameter 2 – Availability/production capacity (per year)

The vaccine Renogen® is only licenced against BKD in salmonids in Canada, Chile and the USA (Ma et al., 2019). The production capacity per year is unknown.

Effectiveness

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

Studies on the effectiveness of vaccination against BKD are limited. In juvenile Atlantic salmon, a vaccine efficacy of 72–91% for Renogen® was reported as achieved when mortality of vaccinated fish was compared to an unvaccinated group in a laboratory challenge involving juvenile Atlantic salmon

(Salonius et al., 2005). The same study reported protection with relative survival of 80% in Renogen® vaccinated vs. unvaccinated fish during a two month field challenge (Salonius et al., 2005). Burnley et al. (2010) evaluated the effectiveness of three commercially available vaccines, including Renogen® and Lipogen Forte® (not licenced for BKD), and one experimental booster vaccine against salmon anaemia (ISA) after a natural outbreak of BKD at sea in Atlantic salmon. The authors reported that the risk of dying during the outbreak (hazard ratio) was significantly decreased by vaccination with combined Renogen® and Lipogen Forte® (Burnley et al., 2010).

The effectiveness of Renogen® to protect Chinook salmon (*O. tshawytscha*) against *R. salmoninarum* has been reported low (Rhodes et al., 2004; Stewart et al., 2005). The use of Renogen® in coho salmon (*O. kisutch*) in Chile remained low with a coverage below 10% in 2003 (Bravo and Midtlyng, 2007). Nevertheless, it seems that Renogen has a therapeutic effect by increasing the survival of Chinook salmon already infected by *R. salmoninarum* (Rhodes et al., 2004).

Overall, the results across different trials varied considerably suggesting that the immune response induced by these vaccines might not be reliable (Rhodes et al., 2004; Delghandi et al., 2020a).

The effectiveness of this vaccine in other fish species susceptible to BKD has not been demonstrated.

Parameter 4 – Duration of protection

This has not been determined for Renogen® or other vaccines. It is mentioned by (Salonius et al., 2005) that in experimental field trials in Atlantic salmon, the duration of protection of Renogen® lasted up to 23 months.

Feasibility

Parameter 5 – Way of administration

Renogen® is administered via intraperitoneal injection (Salonius et al., 2005).

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

Availability

Parameter 1 – Types of drugs available on the market

Antibiotics such as erythromycin, azithromycin and enrofloxacin have been used outside of Europe as treatment against BKD in salmonids but none of them are able to completely eliminate *R. salmoninarum* (Delghandi et al., 2020a). The efficiency of antibiotic treatment against R*. salmoninarum* is relatively low and treatment times are usually from 14 to 30 days depending on the molecule used (Rhodes et al., 2008). The mentioned antibiotics are not licenced as BKD treatment in EU MSs.

Erythromycin has been used to reduce the risk of vertical transmission from female broodstock and has been shown to be effective in the 1990s in Chinook salmon (Bullock and Leek, 1986) and coho salmon (Brown et al., 1990) but not in rainbow trout (*O. mykiss*) (Fetherman et al., 2020).

Parameter 2 – Availability/production capacity (per year)

Unknown.

Parameter 3 – Therapeutic effect in the field (effectiveness)

Recent data from the field are lacking and there are known issues with antimicrobial resistance (Elliott et al., 1989; Rhodes et al., 2008; Wiens, 2011).

Feasibility

Parameter 4 – Way of administration

The antibiotics can be administered by injection, bath or as medical feed (Wiens, 2011; Fetherman et al., 2020).

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

Availability

Parameter 1 – Available movement restriction measures

In the UK, movement restriction is in place on sites affected by BKD and eggs from infected farms are not permitted to be used as broodstock (Murray et al., 2012). In Sweden, farms, which have been

found to contain BKD, cannot move any fish onto or off the farm until culling of all fish and complete disinfection of the site have taken place (Persson et al., 2022). As stipulated in Commission Implementing Decision (EU) 2021/260, Countries regarded as being free or partially free of the disease such as Denmark, Finland, Ireland, the UK-Northern Ireland are allowed to apply restrictions of movements of fish from countries with a lesser health status with respect to BKD.

Effectiveness

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

Since the early 1990s, Sweden has had a BKD screening programme for farmed fish (SJVFS 1994:94). If an infection is found, all fish must be culled and the farm disinfected. Until this is complete, no fish is allowed to be moved into or out of the farm. Delayed culling is allowed to minimise losses, but this has hindered eradication as it allows time for the infection to spread to wild fish and cause reinfection when new fish are introduced to the farm (Persson et al., 2022). In the UK, the imposition of movement restrictions on sites affected by BKD, among other methods of control, was found to be a cost-effective policy for Atlantic salmon production (Hall et al., 2014).

Feasibility

Parameter 3 – Feasibility of restriction of animal movement

While movement restrictions between aquaculture sites can have a significant economic cost, such restrictions are feasible and are in place in the EU (Hall et al., 2014; Persson et al., 2022).

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

Availability

Parameter 1 – Available methods for killing animals

Gill cutting can be used for adults (exsanguination). In-water electric stunning has become increasingly common for farmed salmonids (Bouwsema et al., 2022). Killing by anaesthetic overdose is, at present, the only approach to this task considered humane (EFSA, 2009).

Effectiveness

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

Culling of infected broodstock has proven to be efficient in reducing the prevalence of BKD in hatcheries (Munson et al., 2010; Faisal et al., 2012), decreasing the proportion of adult female Chinook salmon with *R. salmoninarum* positive test in the following generation from 56% to 85% (Munson et al., 2010). In Iceland, the culling of infected Atlantic salmon broodstock led to a decrease in the incidence of infection from 35% to less than 2% after a few years (Guðmundsdóttir et al., 2000).

Feasibility

Parameter 3 – Feasibility of killing animals

Killing using an overdose of anaesthetic administered while fish are kept in small volumes of water is the most feasible. Details of tank sizes and dosing per biomass of fish are not publicly available. Exsanguination is also applied and in-water electric stunning, if the equipment is available, is also a feasible option which is increasingly used (Bouwsema et al., 2022). A knowledge gap exists, as there are no published data comparing rates of killing by different methods.

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

Availability

Parameter 1 – Available disposal option

Rules for the management of animal by-products and derived products can be found in EC Regulation 1069/2009[8] and EC Regulation 142/2011[9]. Fish killed for the control of BKD or found dead due to BKD constitute category II materials. The carcases and any relevant by-product must be transported in a sealed container, recorded on both arrival and departure to any site and should be disposed of and processed at an approved establishment. A list of approved premises by MS can be found on European Commission web page.[10]

Effectiveness

Parameter 2 – Effectiveness of disposal option

Rendering offers an effective method of disposal, which destroys pathogens. Additionally, rendering converts waste animal tissue into stable, value-added products by drying the material and separating the fat from the bone and protein. Tissues are first macerated, then heated and finally separated through centrifugation.

Feasibility

Parameter 3 – Feasibility of disposal option

If approved establishments are located within a reasonable distance from the farm and accept fish carcasses, and provided transport is available, rendering offers a feasible disposal option.

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

Availability

Parameter 1 – Available biosecurity measures

Use of separate brushes, nets and buckets for each raceway in which fish are reared as well as regular cleaning and disinfection of the material along with footbath and mats for visitors and staff at the entrance of facilities to reduce the risk of cross-contamination (Russell Danner and Merrill, 2005).

In biosecurity measures could be included surveillance activities in broodstock with clinical inspection (examination of disease signs such as haemorrhages, exophthalmia and congested organ) and testing for the presence of bacteria and culling of infected broodstock and eggs from infected broodstock (Faisal et al., 2012).

Disinfection of eggs in iodine (100 to 500 mg/L for 15–20 min) or chlorine solutions (0.05 mg/L for 18 s) (Pascho et al., 1998) can inactivate most bacteria but do not prevent vertical transmission.

Effectiveness

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

The disinfection of eggs is not 100% effective as the bacteria can be transferred inside the egg (Austin and Austin, 2016).

Screening broodstock with test (ELISA) and culling of infected broodstock have been shown to be efficient in reducing the prevalence of BKD in hatcheries (Munson et al., 2010; Faisal et al., 2012), decreasing the proportion of adult female Chinook salmon with BKD positive test in the following generation by 56–85% (Munson et al., 2010). In Iceland, the culling of infected Atlantic salmon broodstock led to an important decrease in the incidence of infection from 35% to less than 2% after a few years (Guðmundsdóttir et al., 2000).

[8] Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 as amended: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1069-20191214

[9] Commission Regulation (EU) No 142/2011 of 25 February 2011 as amended: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02011R0142-20220417&qid=1686220344747

[10] EC list of approved ABM establishments: https://food.ec.europa.eu/safety/animal-products/approved-establishments-abp_en

Feasibility

Parameter 3 – Feasibility of biosecurity measures

Good practice and cleaning of material as well as egg disinfection are feasible at relatively low cost. The clinical examination of fish and testing for the presence of the bacteria present a cost in manpower as well as the cost of sampling the tissue/blood and performing diagnostic tests (ELISA, PCR, IFAT, etc.). The culling of infected fish and eggs represents a significant cost.

The cost-effectiveness of BKD control in farmed Atlantic salmons was evaluated (Hall et al., 2014) and the authors suggested that the policy in place to control BKD is beneficial in the UK in the absence of licenced preventive treatment. Similar to elsewhere in Europe, this policy consists of limiting *R. salmoninarum* spread through movement restrictions on BKD-affected sites and the requirement to eradicate *R. salmoninarum* before movement restrictions are lifted.

3.1.4.8. Article 7(d)(viii) Selective breeding; Genetic resistance to infection

Availability

Parameter 1 – Available breeds resistant to the pathogen

While relatively resistant to disease, farmed salmonids of *Oncorhynchus* spp. are very susceptible to infection. This enables increased transmission of disease as infection often occurs without clinical manifestation for some time (Persson et al., 2022). Meanwhile, native EU salmonids, Atlantic salmon (*S. salar*) and Arctic charr (*S. alpinus*), can be very susceptible to disease (Persson et al., 2022). Studies on genetic resistance to BKD in Atlantic salmon date from 1995 with encouraging heritability estimates for resistance (h^2 = 0.23) (Gjedrem and Gjøen, 1995). Since then, genome wide analyses have identified resistance as being a polygenic trait with multiple markers in the genome related to resistance (Holborn et al., 2018; Rozas-Serri et al., 2020). This may indicate that breeding resistant stock is not straightforward.

Effectiveness

Parameter 2 – Effectiveness of having resistant breeds

Resistant breeds are not yet available; however, for reasons outlined earlier, resistance to infection will be more effective than resistance to disease to prevent the persistence of the causative bacteria and further spread (*R. salmoninarum*).

Feasibility

Parameter 3 – Feasibility of having resistant breeds

Due to the polygenic nature of resistance to BKD, resistant breeds may be difficult to achieve (Rozas-Serri et al., 2020). Furthermore, genotype by environment (GxE) effects may pose a significant challenge due to the differences in virulence seen in *R. salmoninarum* over a range of water temperatures (Purcell et al., 2016; Boerlage et al., 2018).

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)

The vaccines against *R. salmoninarum* have not been licenced for use in Europe, so biosecurity via movement restrictions or antibiotic treatments are the only available options for control. Economic losses due to movement restrictions are difficult to estimate and no published data are available detailing the cost of control for BKD.

Parameter 2 – Cost of eradication (culling, compensation)

No published data are available detailing the cost of culling for BKD. These values will also vary significantly depending on the size of the farm where culling is applied.

Parameter 3 – Cost of surveillance and monitoring

No publications were found in the literature to estimate the cost of monitoring and surveillance activities.

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

Trade restrictions have been foreseen in Article 226 of Animal Health Law[11] and in Commission Implementing Decision (EU) 2021/260[12] concerning BKD in susceptible species.

No publications were found in the literature to estimate the costs of the trade loss.

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

Due to the prevalent subclinical and chronic nature of *R. salmoninarum* infection, accurate estimates of losses directly attributable to BKD are difficult to achieve. Mortality rates can increase slowly over a long period of time before the pathogen is detected. In some cases, subclinical infections do not reach mortality levels high enough to trigger the suspicion of the presence of a disease during the entire production cycle and BKD remains undiagnosed (Boerlage et al., 2019). However, losses as high as 40% have been reported for Atlantic salmon (*S. salar)* and 80% for rainbow trout (*O. mykiss*) (Bruno, 1986; Evenden et al., 1993).

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

This review was unable to find published studies on the societal acceptance of disease prevention and control measures for BKD.

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

Parameter 1 – Welfare impact of control measures on domestic/farmed animals

In situations where culling is applied as a control measure, care must be taken to ensure that methods considered humane are applied to ensure the welfare of the stock.

Parameter 2 – Wildlife depopulation as control measure

Wild salmonids are known to act as potential reservoirs; however, depopulation of wild salmonids is not feasible as an option due to the prevalence of the bacteria and the protected or regulated status of certain wild aquatic animals.

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

Environment

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

Increased antibiotic resistance to drugs used to treat and control the disease has been demonstrated for erythromycin in *Aeromonas hydrophila* (Vivekanandhan et al., 2002), *Flavobacterium columnare* (Declercq et al., 2013), *Vibrio spp and Renibacterium* (Rhodes et al., 2008).

Biodiversity

Parameter 2 – Mortality in wild species

The prevalence and severity of BKD can vary considerably between populations of wild salmonids and regions. In Scotland, the prevalence of *R. salmoninarum* in wild and escaped salmonids has been reported as 0.22% (Wallace et al., 2011). However, prevalence among wild salmonids in Sweden was recorded as 5–18% (Persson et al., 2022) and in Iceland from 6% to 100% (Guðmundsdóttir et al., 2017). Mortalities are known to mostly occur in 6- to 12-month-old juvenile salmon (Wiens, 2011), but data on mortality among wild populations are lacking.

3.2. Assessment of bacterial kidney disease according to Article 5 criteria of AHL on its eligibility to be listed

3.2.1. Detailed outcome on Article 5 criteria

In Table 5 and Figure 2, the results of the collective expert judgement on the criteria of Article 5 of the AHL for BKD are presented.

[11] Animal Health Law: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02016R0429-20210421
[12] Commission Implementing Decision (EU) 2021/260: https://eur-lex.europa.eu/eli/dec_impl/2021/260/oj

The distribution of the individual answers (probability ranges) provided by each expert for each criterion are reported in Appendix A.

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

Criteria to be met by the disease: According to the AHL, a disease shall be included in the list referred to in point (b) of paragraph 1 of Article 5 if it has been assessed in accordance with Article 7 and meets all of the following criteria		**Outcome**			
		Median range (%)	**Criterion fulfilment**	**Number of NA**	**Number of experts**
A(i)	The disease is transmissible	95–100	Fulfilled	0	14
A(ii)	Animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union	95–100	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	66–95	Fulfilled	0	14
A(iv)	Diagnostic tools are available for the disease	90–99	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	66–90	Fulfilled	0	14
At least one criterion to be met by the disease: In addition to the criteria set out above at point A(i)–A(v), the disease needs to fulfil at least one of the following criteria					
B(i)	The disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic character	66–90	Fulfilled	0	14
B(ii)	The disease agent has developed resistance to treatments which poses a significant danger to public and/or animal health in the Union	10–33	Not fulfilled	0	14
B(iii)	The disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union	35–70	Uncertain	0	14
B(iv)	The disease has the potential to generate a crisis or the disease agent could be used for the purpose of bioterrorism	5–10	Not fulfilled	0	14
B(v)	The disease has or could have a significant negative impact on the environment, including biodiversity, of the Union	10–33	Not fulfilled	0	14

NA: not applicable.

In Figure 2, the outcome of the expert judgement is graphically shown together with the estimated overall probability of BKD meeting the criteria of Article 5 on the eligibility to be listed.

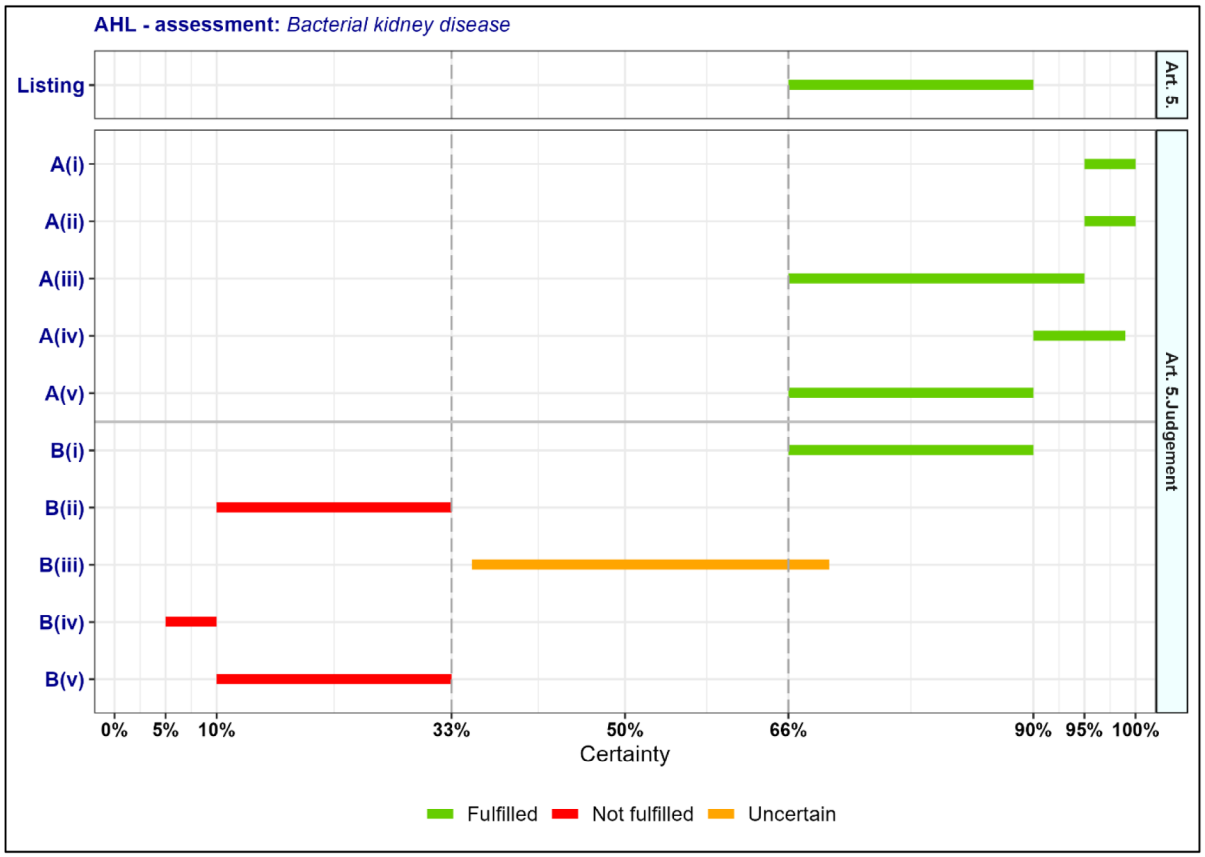


Figure 2: Outcome of the expert judgement on Article 5 criteria of AHL and overall probability of BKD on eligibility to be listed

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 of AHL 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 5 and Figure 2, BKD complies with all the criteria of the first set (A(i)–A(v)), and with one criterion from the second set, criterion B(i).

Therefore, BKD 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 BKD being eligible to be listed is **66–90%** (see Figure 2).

3.3. Assessment of bacterial kidney disease according to criteria in Annex IV for the purpose of categorisation as in Article 9 of the AHL

In Tables 6–10 and the related graphs (Figures 3–5), the results of the expert judgement on bacterial kidney disease according to the criteria in Annex IV of the AHL, for the purpose of categorisation as in Article 9, are presented.

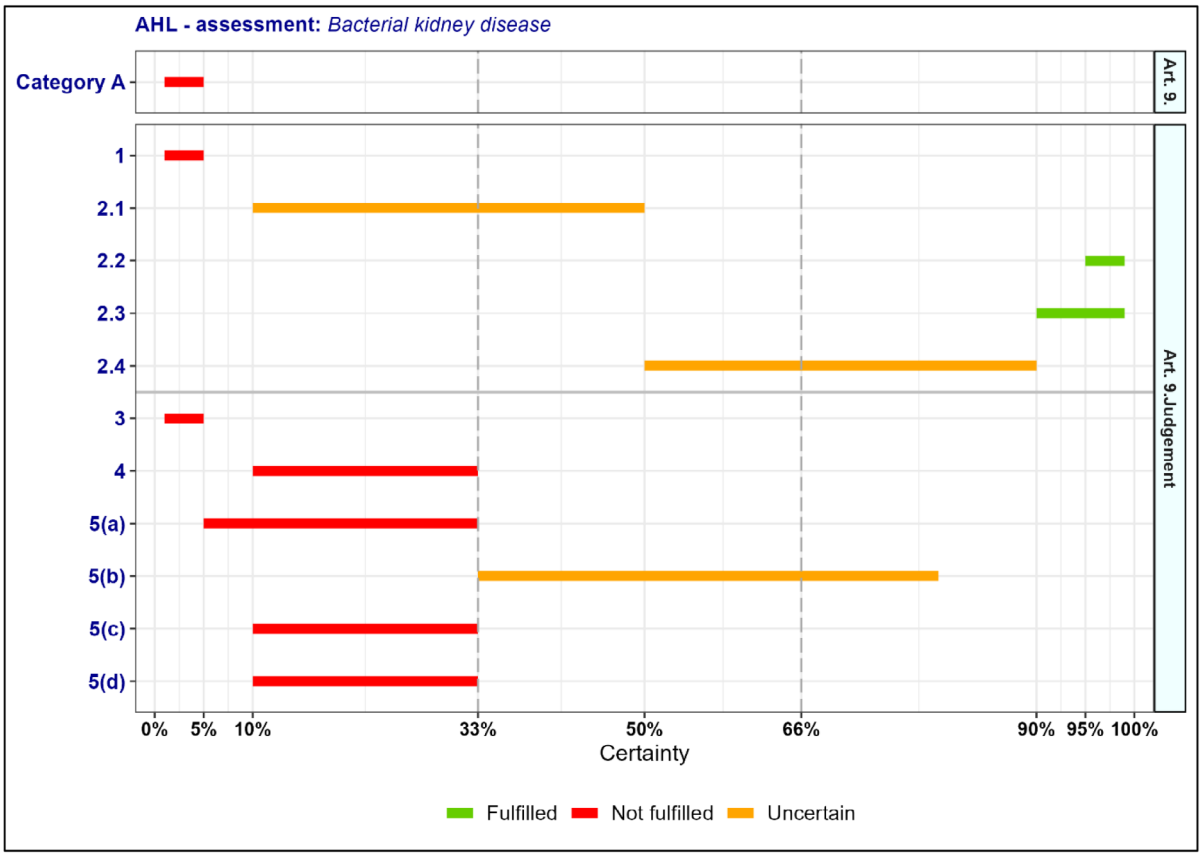
The distribution of the individual answers (probability ranges) provided by each expert for each criterion are reported in Appendix A.

3.3.1. Detailed outcome on Category A criteria

Table 6: Outcome of the expert judgement related to the criteria of Section 1 of Annex IV of AHL (Category A of Article 9 of AHL)

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		**Outcome**			
		Median range (%)	**Criterion fulfilment**	**Number of NA**	**Number of experts**
1	The disease is not present in the territory of the Union or present only in exceptional cases (irregular introductions) or present in only in a very limited part of the territory of the Union	1–5	Not fulfilled	0	14
2.1	The disease is highly transmissible	10–50	Uncertain	0	14
2.2	There are possibilities of airborne or waterborne or vector-borne spread	95–99	Fulfilled	0	14
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	14
2.4	The disease may result in high morbidity and significant mortality rates	50–90	Uncertain	0	14
At least one criterion to be met by the disease: In addition to the criteria set out above at point 1–2.4, the disease needs to fulfil at least one of the following criteria					
3	The disease has a zoonotic potential with significant consequences for public health, including epidemic or pandemic potential or possible significant threats to food safety	1–5	Not fulfilled	0	14
4	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	10–33	Not fulfilled	0	14
5(a)	The disease has a significant impact on society, with in particular an impact on labour markets	5–33	Not fulfilled	0	14
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	33–80	Uncertain	0	14
5(c)	The disease has a significant impact on the environment, due to the direct impact of the disease or due to the measures taken to control it	10–33	Fulfilled	0	14
5(d)	The disease has a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	10–33	Not fulfilled	0	14

NA: not applicable.



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

Figure 3: Outcome of the expert judgement on the criteria of Section 1 of Annex IV of AHL and overall probability of bacterial kidney disease be fitting in Category A of Article 9 of AHL

3.3.1.1. Reasoning for uncertain outcome on Category A criteria

Criterion 2.1: (*the disease is highly transmissible*):

- There is no information on the transmission rates in the literature and it is difficult to determine if BKD is highly, moderate or low transmissible.
- The results in experimental trials show that BKD can be highly transmissible, while this may not be the case under field conditions.
- Both horizontal and vertical transmission occur in BKD that may lead to higher transmission.
- BKD is a chronic infectious disease and the transmission may be slow; nevertheless, it can reach high prevalence in some populations.

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

- Based on the available information in the literature both morbidity and mortality may vary from high to low depending on the farming system, the species and the age/stage of the host.
- Mortality can vary from 17% to 80% in different species.
- There is lack of information on morbidity rates in the literature. The clinical signs are not always observed in a population although the prevalence may vary from 0.22% to 100%.

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

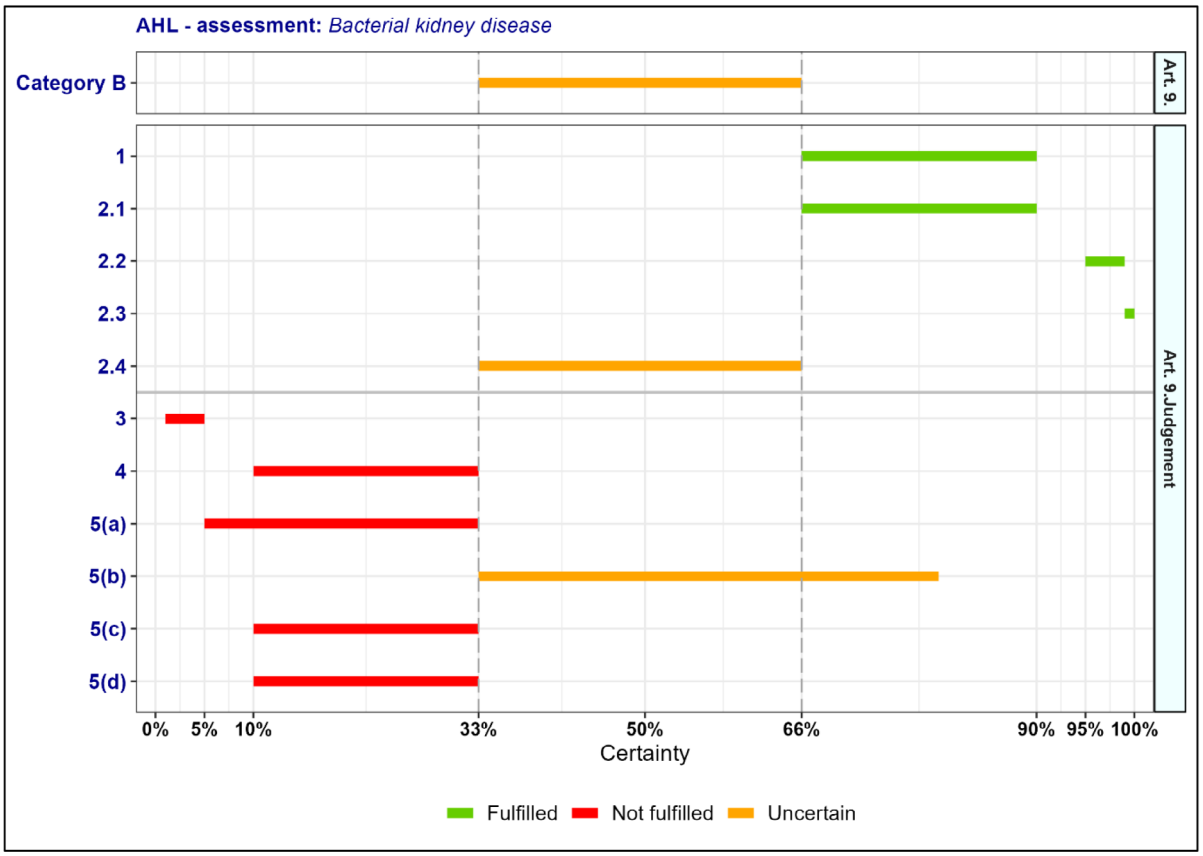
- Both the current and the potential impact on animal welfare have been assessed under this criterion.
- Based on the available information in the literature it seems that there is a knowledge gap on the impact of the disease on animal welfare.
- Severe clinical signs and changes in fish behaviour have been reported in the literature reflecting the impact of BKD on fish welfare.
- Given the variability in morbidity and mortality rates among affected farms there seems to be potential for animal welfare concerns, particularly if no control measures are in place.
- In some populations, where chronic infection occurs, it seems that the fish are well adapted to the disease without production losses.
- The current impact was considered low since the number of outbreaks is limited and concerns few countries.

3.3.2. Detailed outcome on Category B criteria

Table 7: Outcome of the expert judgement related to the criteria of Section 2 of Annex IV of AHL (Category B of Article 9 of AHL)

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	66–90	Fulfilled	0	14
2.1	The disease is moderately to highly transmissible	66–90	Fulfilled	0	14
2.2	There are possibilities of airborne or waterborne or vector-borne spread	95–99	Fulfilled	0	14
2.3	The disease affects single or multiple species[(a)]	–	Fulfilled	0	14
2.4	The disease may result in high morbidity with in general low mortality	33–66	Uncertain	0	14
At least one criterion to be met by the disease: In addition to the criteria set out above at point 1–2.4, the disease needs to fulfil at least one of the following criteria					
3	The disease has a zoonotic potential with significant consequences for public health, including epidemic potential or possible significant threats to food safety	1–5	Not fulfilled	0	14
4	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	10–33	Not fulfilled	0	14
5(a)	The disease has a significant impact on society, with in particular an impact on labour markets	5–33	Not fulfilled	0	14
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	33–80	Uncertain	0	14
5(c)	The disease has a significant impact on the environment, due to the direct impact of the disease or due to the measures taken to control it	10–33	Not fulfilled	0	14
5(d)	The disease has a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	10–33	Not fulfilled	0	14

NA: not applicable.
(a): This criterion is always fulfilled for Category B.



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

Figure 4: Outcome of the expert judgement on criteria of Section 2 of Annex IV of the AHL and overall probability of the bacterial kidney disease to be fitting in Category B of Article 9 of AHL

3.3.2.1. Reasoning for uncertain outcome on category B criteria

Criterion 2.4 *(the disease may result in high morbidity with in general low mortality):*

- Based on the available information in the literature, both morbidity and mortality may vary from high to low depending on the species, the farming systems and the age/stage of the host.
- Mortality has been described to vary from 17% to 80% in different species.
- There is lack of information on morbidity rates in the literature. The clinical signs are not always observed in a population, although the prevalence has been reported to vary from 0.22% to 100%.
- BKD is a chronic infectious disease, and the transmission may be slow, but it can reach high prevalence in a population.
- The clinical signs are not always observed in a population although the prevalence may be high.

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

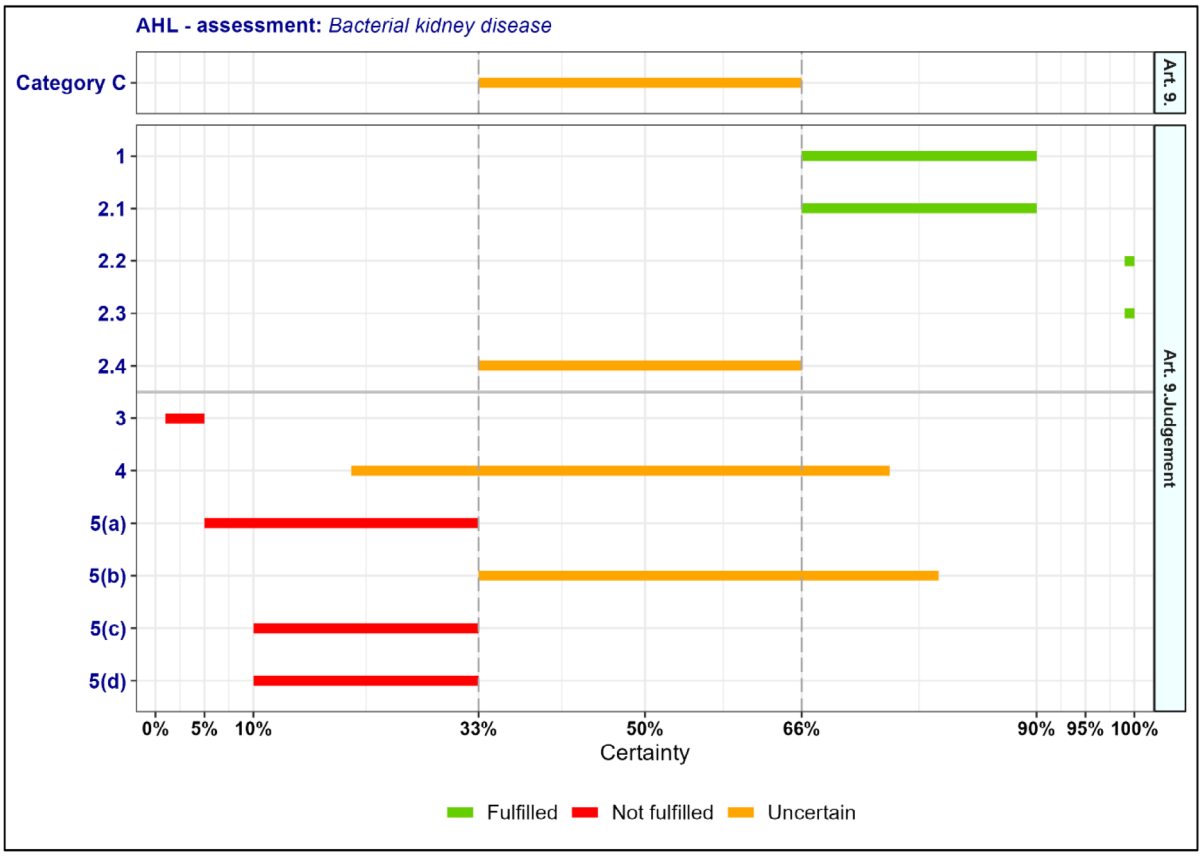
- The reasoning for this criterion has been described in Section 3.3.1.1.

3.3.3. Detailed outcome on Category C criteria

Table 8: Outcome of the expert judgement related to the criteria of Section 3 of Annex IV of AHL (Category C of Article 9 of AHL)

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**
1Caqua	The disease is present in the whole OR part of the Union territory with an endemic character OR in **aquatic animals** several Member States or zones of the Union are free of the disease	66–90	Fulfilled	0	14
2.1	The disease is moderately to highly transmissible	66–90	Fulfilled	0	14
2.2	The disease is transmitted mainly by direct or indirect transmission[(a)]	–	Fulfilled	0	14
2.3	The disease affects single or multiple species[(a)]	–	Fulfilled	0	14
2.4	The disease may result in high morbidity and usually low mortality and often the most observed effect of the disease is production loss?	33–66	Uncertain	0	14
At least one criterion to be met by the disease: In addition to the criteria set out above at point 1–2.4, the disease needs to fulfil at least one of the following criteria					
3	The disease has a zoonotic potential with significant consequences for public health or possible significant threats to food safety	1–5	Not fulfilled	1	14
4	The disease has a significant impact on the economy of the Union, mainly related to its direct impact on certain types of animal production systems	20–75	Uncertain	0	14
5(a)	The disease has a significant impact on society, with in particular an impact on labour markets	5–33	Not fulfilled	0	14
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	33–80	Uncertain	0	14
5(c)	The disease has a significant impact on the environment, due to the direct impact of the disease or due to the measures taken to control it	10–33	Not fulfilled	0	14
5(d)	The disease has a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	10–33	Not fulfilled	0	14

NA: not applicable.
(a): This criterion is always fulfilled for Category C.



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

Figure 5: Outcome of the expert judgement on criteria of Section 3 of Annex IV of the AHL and overall probability of bacterial kidney diseases to be fitting in Category C of Article 9 of AHL

3.3.3.1. Reasoning for uncertain outcome on Category C criteria

Criterion 2.4: *(the disease may result in high morbidity and usually low mortality and often the most observed effect of the disease is production loss):*

- The reasoning for this criterion has been described in Section 3.3.2.1.

Criterion 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):*

- Both the current and the potential impact of the disease on the economy of the Union were assessed.
- There is not enough information on the current impact of the disease on the economy of the Union. Nevertheless, for the local economies based on wild fish fishing, the impact might be higher compared to the impact on the economy of the Union.
- In some populations where chronic infection occurs, it seems that the fish are well adapted to the disease without production losses.

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

- The reasoning for this criterion has been described in Section 3.3.1.1.

3.3.4. Detailed outcome on Category D criteria

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

Diseases in Category D **need to fulfil criteria of Section 1, 2, 3 or 5 of Annex IV** of the AHL **and the following:**		Outcome			
		Median range (%)	**Criterion fulfilment**	**Number of NA**	**Number of experts**
D	The risk posed by the disease can be effectively and proportionately mitigated by measures concerning movements of animals and products in order to prevent or limit its occurrence and spread	66–90	Fulfilled	0	14

NA: not applicable.

3.3.5. Detailed outcome on Category E criteria

Table 10: Outcome of the expert judgement related to the criteria of Section 5 of Annex IV of AHL (Category E of Article 9 of AHL)

Diseases in Category E **need to fulfil criteria of Section 1, 2 or 3 of Annex IV** of the AHL and/**or the following:**		Outcome	
		Median range (%)	**Fulfilment**
E	Surveillance of the disease is necessary for reasons related to animal health, animal welfare, human health, the economy, society or the environment (If a disease fulfils the criteria as in Article 5, thus being eligible to be listed, consequently Category E would apply.)	66–90	Fulfilled

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 5–9 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 BKD as in Article 9, is presented in Table 10 and Figure 6.

Table 11: Outcome of the assessment on criteria in Annex IV of the AHL for the purpose of categorisation as in Article 9 (fulfilled: green, not fulfilled: red, uncertain: orange)

Category	Article 9 criteria												Article 5 criteria
	1° set of criteria					2° set of criteria						D	
	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	mpact on animal welfare	Impact on environment	Impact on biodiversity		
A	1–5	10–50	95–99	90–99	50–90	1–5	10–33	5–33	33–80	10–33	10–33		
B	66–90	66–90	95–99	–[(a)]	33–66	1–5	10–33	5–33	33–80	10–33	10–33		
C	66–90	66–90	–[(b)]	–[(b)]	33–66	1–5	20–75	5–33	33–80	10–33	10–33		
D												66–90	
E													66–90

(a): This criterion is always fulfilled for Category B.
(b): This criterion is always fulfilled for Category C.

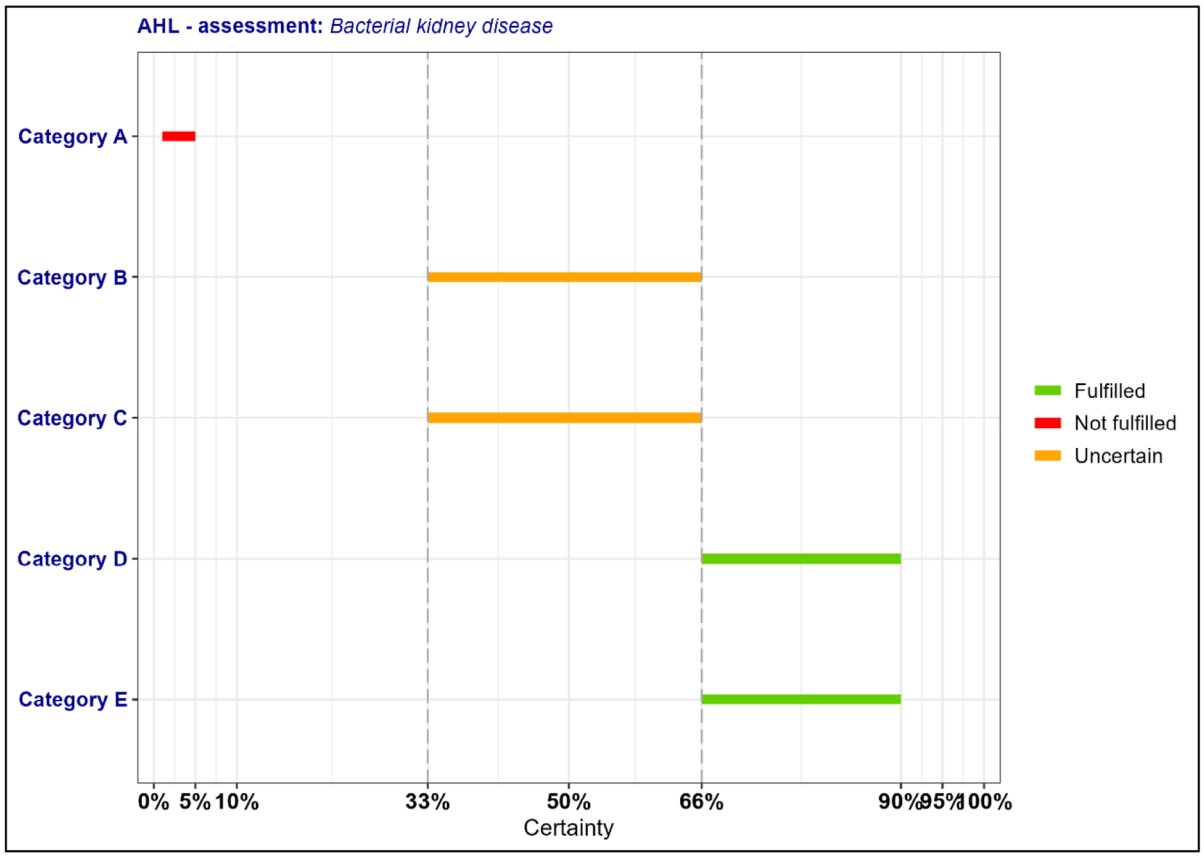


Figure 6: Outcome of the expert judgement on criteria in Annex IV of AHL and overall probabilities for categorisation of bacterial kidney diseases in accordance with Article 9 of AHL

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

1) To be assigned to **Category A**, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and, according to the assessment, BKD complies only with two out of five criteria (2.2 and 2.3). 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 BKD does not comply with any of them. Overall, it was assessed with **1–5% probability** that BKD may be assigned to Category A according to the 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, BKD complies only with four out of five criteria (1, 2.1, 2.2 and 2.3). 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 BKD does not comply with any of them. Overall, it was assessed with **33–66% probability** that BKD 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, BKD complies with four out of five criteria (1, 2.1, 2.2 and 2.3). 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 BKD does not comply with any of them. Overall, it was assessed with **33–66% probability** that BKD 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. BKD comply with criteria of Section 5 of Annex IV of the AHL and complies also with **66–90% probability** with criterion D.
5) To be assigned to **Category E**, a disease needs to comply with criteria of Sections 1, 2 or 3 of Annex IV of the AHL, and/or the surveillance of the disease is necessary for reasons 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 uncertain with **66–90% probability**.

3.4. Assessment of BKD 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 BKD 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 of AHL is based on the evidence as extrapolated from the relevant criteria of Article 7, i.e. the ones related to susceptible, vectors and reservoir species or routes of transmission, which cover also the possible role of biological or mechanical vectors.

According to the mapping, as presented in Table 5, Section 3.2, of the Scientific Opinion on the ad hoc methodology (EFSA AHAW Panel et al., 2017), the animal species to be listed for BKD according to the criteria of Article 8(3) of the AHL are as displayed in Table 11 (elaborated from information on animal species concerned reported in Section 3.1.1.1 of the present document).

The table contains all animal species in which BKD has been described, but also those animal species from which only the *R. salmoninarum* has been isolated. The latter makes susceptibility to BKD likely (Table 12).

Table 12: Animal species to be listed for BKD according to the criteria of Article 8 of AHL

Type	Class	Order	Family	Genus/Species	References
Susceptible	Actinopterygii	Cypriniformes	Cyprinidae	*Pimephales promelas*	Inglis et al. (1993)
			Leuciscidae	*Notropis cornutus*	Inglis et al. (1993)
		Gadiformes	Lotidae	*Lota lota*	Polinski et al. (2010)
		Osmeriformes	Plecoglossidae	*Plecoglossus altivelis*	Nagai and Iida (2002)
		Salmoniformes	Salmonidae	*Oncorhynchus clarkii*	Riepe et al. (2023)
				Oncorhynchus gorbuscha	Banner et al. (1986)
				Oncorhynchus keta	Banner et al. (1986)
				Oncorhynchus kisutch	Banner et al. (1986)
				Oncorhynchus mykiss	Banner et al. (1986)
				Oncorhynchus nerka	Banner et al. (1986)
				Oncorhynchus tshawytscha	Banner et al. (1986)
				Salvelinus alpinus	Gudmundsdóttir et al. (2017)
				Salvelinus fontinalis	Mitchum et al. (1979)
				Salvelinus namaycush	Souter et al. (1987)
				Salmo salar	Balfry et al. (1996); Banner et al. (1986)
				Salmo trutta	Mitchum et al. (1979)
				Thymallus thymallus	Kettler (1987)
		Scorpaeniformes	Anoplopomatidae	*Anoplopoma fimbria*	Bell et al. (1990)
Reservoirs	Actinopterygii	Anguilliformes	Anguillidae	*Anguilla anguilla*	Wallace et al. (2017)
		Clupeiformes	Clupeidae	*Clupea harengus pallasi*	Eissa et al. (2006)
		Cypriniformes	Cyprinidae	*Phoxinus phoxinus*	Wallace et al. (2017)
		Gasterosteiformes	Gasterosteidae	*Gasterosteus aculeatus*	Wallace et al. (2017)
		Perciformes	Embiotocidae	*Cymatogaster aggregata*	Inglis et al. (1993)
		Osmeriformes	Plecoglossidae	*Plecoglossus altivelis*	Nagai and Iida (2002)
		Salmoniformes	Salmonidae	*Coregonus lavaretus*	Rimaila-Pärnänen (2002)
		Scorpaeniformes	Cyclopteridae	*Cyclopterus lumpus*	Gnanagobal et al. (2021)
	Cephalaspidomorphi	Petromyzontiformes	Petromyzontidae	*Petromyzon marinus*	Eissa et al. (2006)

Type	Class	Order	Family	Genus/Species	References
	Osteichthyes	Gadiformes	Merlucciidae	*Merluccius productus*	Kent et al. (1998)
Vectors	No evidence in the literature for species able to transmit the *R. salmoninarum* to susceptible species				

Classification of susceptible, vector and reservoir species has been updated to the currently accepted scientific names according to Global Biodiversity Information Facility (GBIF), WorldRegister of Marine Species (WoRMS) and Integrated Taxonomic Information System (ITIS) taxonomy database.

4. Conclusions

TOR 1: *for each of the diseases referred to above, an assessment, taking into account the criteria laid down in Article 7 of the AHL, on the eligibility of the disease to be listed for Union intervention as laid down in Article 5(3) of the AHL;*

The AHAW Panel considered with **66–90% probability** ('likely') that BKD meets the criteria to be eligible to be listed for Union intervention as laid down in Article 5 of the AHL.

TOR 2(a): *for each of the diseases an assessment of its compliance with each of the criteria in Annex IV to the AHL for the purpose of categorisation of diseases in accordance with Article 9(1) of the AHL;*

- The AHAW Panel considered with **1–5% probability** ('extremely unlikely') that BKD meets the criteria of Category A 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 was uncertain (**33–66% probability**, 'about as likely as not') whether BKD meets the criteria of Category B, as in Section 2 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in point (b) of Article 9(1) of the AHL.
- The AHAW Panel was uncertain (**33–66% probability**, 'about as likely as not') whether BKD meets the criteria of Category C 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 **66–90% probability** ('likely') that BKD meets the criteria of Category D, 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 considered with **66–90% probability** ('likely') that BKD meets the criteria of Category E, 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 2(b): *for each of the diseases* 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 BKD according to Article 8(3) of the AHL are reported in Table 11 in Section 3.4 of the present document.

References

Aguilar M, Isla A, Barrientos CA, Flores-Martin SN, Blanco JA, Enríquez R, Figueroa J and Yañez AJ, 2023. Genomic and proteomic aspects of p57 protein from Renibacterium salmoninarum: characteristics in virulence patterns. Microbial Pathogenesis, 174, 105932. https://doi.org/10.1016/j.micpath.2022.105932

Austin B and Austin DA, 2016. Aerobic Gram-Positive Rods and Cocci. Bacterial Fish Pathogens: Disease of Farmed and Wild Fish. Cham, Springer International Publishing. pp. 83–160.

Balfry SK, Albright LJ and Evelyn TPT, 1996. Horizontal transfer of Renibacterium salmoninarum among farmed salmonids via the fecal-oral route. Diseases of Aquatic Organisms, 25, 63–69.

Banner C, Long J, Fryer J and Rohovec J, 1986. Occurrence of salmonid fish infected with Renibacterium salmoninarum in the Pacific Ocean. Journal of Fish Diseases, 9, 273–275.

Banner CR, Rohovec JS and Fryer JL, 1981. A new value for mol percent guanine + cytosine of DNA for the salmonid fish pathogen Renibacterium salmoninarum. Federation of European Microbiological Societies.

Banner CR, Rohovec J and Fryer J, 1983. Renibacterium salmoninarum as a cause of mortality among Chinook Salmon in salt water 1. Journal of the World Mariculture Society, 14, 236–239.

Bell GR, Hoffmann RW and Brown LL, 1990. Pathology of experimental infections of the sablefish, Anoplopoma fimbria (Pallas), with Renibacterium salmoninarum, the agent of bacterial kidney disease in salmonids. Journal of Fish Diseases, 13, 355–367. https://doi.org/10.1111/j.1365-2761.1990.tb00794.x

Boerlage AS, Elghafghuf A, Stryhn H, Sanchez J and Hammell KL, 2018. Risk factors associated with time to first clinical case of Bacterial Kidney Disease (BKD) in farmed Atlantic Salmon (Salmo salar L.) in New Brunswick. Canada. Preventive Veterinary Medicine, 149, 98–106. https://doi.org/10.1016/j.prevetmed.2017.11.014

Boerlage AS, Stryhn H, Armstrong B and Hammell KL, 2019. A 2-stage hierarchical interrupted time-series analysis to quantify the long-term effect of subclinical bacterial kidney disease on performance of farmed Atlantic salmon (Salmo salar L.). Preventive Veterinary Medicine, 172, 104776. https://doi.org/10.1016/j.prevetmed.2019.104776

Bouwsema JA, Ellis MA, Lines JA and Turnbull JF, 2022. In-water electric stunning as a humane commercial method for culling juvenile salmonids. Aquacultural Engineering, 99, 102286. https://doi.org/10.1016/j.aquaeng.2022.102286

Bravo S and Midtlyng PJ, 2007. The use of fish vaccines in the Chilean salmon industry 1999–2003. Aquaculture, 270, 36–42. https://doi.org/10.1016/j.aquaculture.2007.06.017

Brown L, Iwama G, Evelyn T, Nelson W and Levine R, 1994. Use of the polymerase chain reaction (PCR) to detect DNA from Renibacterium salmoninarum within individual salmonid eggs. Diseases of Aquatic Organisms, 18, 165–171.

Brown LL, Albright LJ and Evelyn TPT, 1990. Control of vertical transmission of Renibacterium salmoninarum by injection of antibiotics into maturing female coho salmon Oncorhynchus kisutch. Diseases of Aquatic Organisms, 9, 127–131.

Bruno DW, 1986. Scottish experience with bacterial kidney disease in farmed salmonids between 1976 and 1985. Aquaculture Research, 17, 185–190. https://doi.org/10.1111/j.1365-2109.1986.tb00100.x

Brynildsrud O, Feil EJ, Bohlin J, Castillo-Ramirez S, Colquhoun D, McCarthy U, Matejusova IM, Rhodes LD, Wiens GD and Verner-Jeffreys DW, 2014. Microevolution of Renibacterium salmoninarum: evidence for intercontinental dissemination associated with fish movements. ISME Journal, 8, 746–756. https://doi.org/10.1038/ismej.2013.186

Bullock GL and Leek SL, 1986. Use of erythromycin in reducing vertical transmission of bacterial kidney disease. Veterinary and Human Toxicology, 28(Suppl. 1), 18–20.

Burnley TA, Stryhn H, Burnley HJ and Hammell KL, 2010. Randomized clinical field trial of a bacterial kidney disease vaccine in Atlantic salmon, Salmo salar L. Journal of Fish Diseases, 33, 545–557. https://doi.org/10.1111/j.1365-2761.2010.01151.x

CEFAS, 2023. International database on aquatic animal diseases, disease cart, bacterial kidney diseases (*Renibacterium salmoninarum*). Available online: https://www.cefas.co.uk/international-database-on-aquatic-animal-diseases/disease-data/?id=14

Chambers E, Gardiner R and Peeler EJ, 2008. An investigation into the prevalence of Renibacterium salmoninarum in farmed rainbow trout, Oncorhynchus mykiss (Walbaum), and wild fish populations in selected river catchments in England and Wales between 1998 and 2000. Journal of Fish Diseases, 31, 89–96. https://doi.org/10.1111/j.1365-2761.2007.00868.x

Declercq AM, Boyen F, Van den Broeck W, Bossier P, Karsi A, Haesebrouck F and Decostere A, 2013. Antimicrobial susceptibility pattern of Flavobacterium columnare isolates collected worldwide from 17 fish species. Journal of Fish Diseases, 36, 45–55. https://doi.org/10.1111/j.1365-2761.2012.01410.x

Delghandi MR, El-Matbouli M and Menanteau-Ledouble S, 2020a. Renibacterium salmoninarum—the causative agent of bacterial kidney disease in salmonid fish. Pathogens, 9, 845. https://doi.org/10.3390/pathogens9100845

Delghandi MR, Menanteau-Ledouble S, Waldner K and El-Matbouli M, 2020b. Renibacterium salmoninarum and Mycobacterium spp.: two bacterial pathogens present at low levels in wild brown trout (Salmo trutta fario) populations in Austrian rivers. BMC Veterinary Research, 16, 40. https://doi.org/10.1186/s12917-020-2260-7

EFSA (European Food Safety Authority), 2009. Scientific Opinion of the Panel on Animal Health and Welfare on a request from the European Commission on welfare aspect of the main systems of stunning and killing of farmed Atlantic salmon. EFSA Journal 2009;7(4):1011, 77 pp. https://doi.org/10.2903/j.efsa.2009.1011

EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare), More S, Bøtner A, Butterworth A, Calistri P, Depner K, Edwards S, Garin-Bastuji B, Good M, Gortazar Schmidt C, Michel V, Miranda MA, Nielsen SS, Raj M, Sihvonen L, Spoolder H, Stegeman JA, Thulke H-H, Velarde A, Willeberg P, Winckler C, Baldinelli F, Broglia A, Candiani D, Gervelmeyer A, Zancanaro G, Kohnle L, Morgado J and Bicout D, 2017. Scientific opinion on an ad hoc method for the assessment on listing and categorisation of animal diseases within the framework of the Animal Health Law. EFSA Journal 2017;15(7):4783, 47 pp. https://doi.org/10.2903/j.efsa.2017.4783

EFSA (European Food Safety Authority) Scientific Committee, Benford D, Halldorsson T, Jeger MJ, Knutsen HK, More S, Naegeli H, Noteborn H, Ockleford C, Ricci A, Rychen G, Schlatter JR, Silano V, Solecki R, Turck D, Younes M, Craig P, Hart A, Von Goetz N, Koutsoumanis K, Mortensen A, Ossendorp B, Martino L, Merten C, Mosbach-Schulz O and Hardy A, 2018. Guidance on Uncertainty Analysis in Scientific Assessments. EFSA Journal 2018;16(1):5123, 39 pp. https://doi.org/10.2903/j.efsa.2018.5123

Eissa AE, Elsayed EE, McDonald R and Faisal M, 2006. First record of Renibacterium salmoninarum in the sea lamprey (Petromyzon marinus). Journal of Wildlife Disease, 42, 556–560. https://doi.org/10.7589/0090-3558-42.3.556

Elliott D, Pascho R and Bullock G, 1989. Developments in the control of bacterial kidney disease of salmonid fishes. Diseases of Aquatic Organisms, 6, 201–215.

Evelyn T, 1993. Bacterial kidney disease-BKD. Bacterial disease of fish.
Evelyn TPT, Hoskins GE and Bell GR, 1973. First record of bacterial kidney disease in an apparently wild salmonid in British Columbia. Journal of the Fisheries Research Board of Canada, 30, 1578–1580. https://doi.org/10.1139/f73-249
Evenden AJ, Grayson TH, Gilpin ML and Munn CB, 1993. Renibacterium salmoninarum and bacterial kidney disease — the unfinished jigsaw. Annual Review of Fish Diseases, 3, 87–104. https://doi.org/10.1016/0959-8030(93)90030-F
Faisal M, Schulz C, Eissa A, Brenden T, Winters A, Whelan G, Wolgamood M, Eisch E and VanAmberg J, 2012. Epidemiological investigation of Renibacterium salmoninarum in three Oncorhynchus spp. in Michigan from 2001 to 2010. Preventive Veterinary Medicine, 107, 260–274. https://doi.org/10.1016/j.prevetmed.2012.06.003
Fetherman ER, Neuschwanger B, Davis T, Wells CL and Kraft A, 2020. Efficacy of Erymicin 200 injections for reducing Renibacterium salmoninarum and controlling vertical transmission in an inland rainbow trout brood stock. Pathogens, 9, 547.
Fryer J and Sanders J, 1981. Bacterial kidney disease of salmonid fish. Annual Reviews in Microbiology, 35, 273–298.
Gjedrem T and Gjøen HM, 1995. Genetic variation in susceptibility of Atlantic salmon, Salmo salar L., to furunculosis, BKD and cold water vibriosis. Aquaculture Research, 26, 129–134. https://doi.org/10.1111/j.1365-2109.1995.tb00892.x
Gnanagobal H, Cao T, Hossain A, Dang M, Hall JR, Kumar S, Van Cuong D, Boyce D and Santander J, 2021. Lumpfish (Cyclopterus lumpus) is susceptible to Renibacterium salmoninarum infection and induces cell-mediated immunity in the chronic stage. Frontiers in Immunology, 12. https://doi.org/10.3389/fimmu.2021.733266
Guðmundsdóttir S, Helgason S, Sigurjónsdóttir H, Matthíasdóttir S, Jónsdóttir H, Laxdal B and Benediktsdóttir E, 2000. Measures applied to control Renibacterium salmoninarum infection in Atlantic salmon: a retrospective study of two sea ranches in Iceland. Aquaculture, 186, 193–203. https://doi.org/10.1016/S0044-8486(99)00375-0
Gudmundsdóttir S, Kristmundsson Á and Árnason Í, 2017. Experimental challenges with Renibacterium salmoninarum in Arctic charr Salvelinus alpinus. Diseases of Aquatic Organisms, 124, 21–30.
Guðmundsdóttir S, Applegate L, Árnason Í, Kristmundsson Á, Purcell MK and Elliott DG, 2017. Detecting Renibacterium salmoninarum in wild brown trout by use of multiple organ samples and diagnostic methods. Bulletin of the European Association of Fish Pathologists, 37, 31–40.
Guz L and Puk K, 2020. Molecular detection of in rainbow trout (*Oncorhynchus mykiss*) from Poland. Fisheries & Aquatic Life, 28, 234–237. https://doi.org/10.2478/aopf-2020-0028
Hall M, Soje J, Kilburn R, Maguire S and Murray AG, 2014. Cost-effectiveness of alternative disease management policies for Bacterial kidney disease in Atlantic salmon aquaculture. Aquaculture, 434, 88–92. https://doi.org/10.1016/j.aquaculture.2014.07.023
Hoar WS, Randall DJ, Iwama G and Nakanishi T, 1997. The fish immune system: organism, pathogen, and environment. Academic Press.
Hoffman R, Popp W and Vd G, 1984. Atypical BKD predominantly causing occular and skin lesions.
Holborn MK, Ang KP, Elliott JAK, Powell F and Boulding EG, 2018. Genome wide association analysis for bacterial kidney disease resistance in a commercial North American Atlantic salmon (Salmo salar) population using a 50 K SNP panel. Aquaculture, 495, 465–471. https://doi.org/10.1016/j.aquaculture.2018.06.014
Inglis V, Roberts RJ and Bromage NR, 1993. Bacterial kidney disease (BKD). Blackwell Scientific, Oxford.
Jaramillo D, Gardner IA, Stryhn H, Burnley H and Larry Hammell K, 2017. Bayesian latent class analysis of diagnostic sensitivity and specificity of tests for surveillance for bacterial kidney disease in Atlantic salmon Salmo salar. Aquaculture, 476, 86–93. https://doi.org/10.1016/j.aquaculture.2017.03.034
Jia B, Burnley H, Gardner IA, Saab ME, Doucet A and Hammell KL, 2023. Diagnosis of Renibacterium salmoninarum infection in harvested Atlantic salmon (Salmo salar L.) on the east coast of Canada: clinical findings, sample collection methods and laboratory diagnostic tests. Journal of Fish Diseases. https://doi.org/10.1111/jfd.13770
Kent ML, Traxler GS, Kieser D, Richard J, Dawe SC, Shaw RW, Prosperi-Porta G, Ketcheson J and Evelyn TPT, 1998. Survey of Salmonid Pathogens in Ocean-Caught Fishes in British Columbia, Canada. Journal of Aquatic Animal Health, 10, 211–219. https://doi.org/10.1577/1548-8667(1998)010<0211:SOSPIO>2.0.CO;2
Kettler S, Pfeil-Putzien C and Hoffmann R, 1986. Infection of grayling (Thymallus thymallus) with the agent of bacterial kidney disease (BKD). Bulletin of the European Association of Fish Pathologists, 6, 69–71.
Kettler S, 1987. Histological survey of bacterial kidney disease (BKD) of salmonides especially related to grayling (Thymallus thymallus).
Laurin E, Morrison D, Gardner IA, Siah A, Powell JFF and Kamaitis M, 2019. Bayesian latent class analysis of ELISA and RT-rPCR diagnostic accuracy for subclinical Renibacterium salmoninarum infection in Atlantic salmon (Salmo salar) broodstock. Journal of Fish Diseases, 42, 303–313. https://doi.org/10.1111/jfd.12933
Ma J, Bruce TJ, Jones EM and Cain KD, 2019. A review of fish vaccine development strategies: conventional methods and modern biotechnological approaches. Microorganisms, 7, 569. https://doi.org/10.3390/microorganisms7110569

Mitchum DL, Sherman LE and Baxter GT, 1979. Bacterial kidney disease in feral populations of brook trout (Salvelinus fontinalis), Brown Trout (Salmo trutta), and Rainbow Trout (Salmo gairdneri). Journal of the Fisheries Research Board of Canada, 36, 1370–1376. https://doi.org/10.1139/f79-196

Munson AD, Elliott DG and Johnson K, 2010. Management of bacterial kidney disease in chinook salmon hatcheries based on broodstock testing by enzyme-linked immunosorbent assay: a multiyear study. North American Journal of Fisheries Management, 30, 940–955. https://doi.org/10.1577/M09-044.1

Murray AG, Munro LA, Wallace IS, Allan CE, Peeler EJ and Thrush MA, 2012. Epidemiology of Renibacterium salmoninarum in Scotland and the potential for compartmentalised management of salmon and trout farming areas. Aquaculture, 324, 1–13.

Nagai T and Iida Y, 2002. Occurrence of bacterial kidney disease in cultured ayu. Fish pathology, 37, 77–81.

Pascho RJ, Elliott DG and Streufert JM, 1991. Brood stock segregation of spring chinook salmon Oncorhynchus tshawytscha by use of the enzyme-linked immunosorbent assay (ELISA) and the fluorescent antibody technique (FAT) affects the prevalence and levels of Renibacterium salmoninarum infection in progeny. Diseases of Aquatic Organisms, 12, 25–40. https://doi.org/10.3354/dao012025

Pascho RJ, Chase D and McKibben CL, 1998. Comparison of the membrane-filtration fluorescent antibody test, the enzyme-linked immunosorbent assay, and the polymerase chain reaction to detect Renibacterium salmoninarum in salmonid ovarian fluid. Journal of Veterinary Diagnostic Investigation, 10, 60–66. https://doi.org/10.1177/104063879801000111

Persson DB, Aspán A, Hysing P, Blomkvist E, Jansson E, Orsén L, Hällbom H and Axén C, 2022. Assessing the presence and spread of Renibacterium salmoninarum between farmed and wild fish in Sweden. Journal of Fish Diseases, 45, 613–621. https://doi.org/10.1111/jfd.13586

Plumb JA, 2018. Health maintenance of cultured fishes: principal microbial diseases. CRC Press.

Polinski MP, Fehringer TR, Johnson KA, Snekvik KR, Lapatra SE, Lafrentz BR, Ireland SC and Cain KD, 2010. Characterization of susceptibility and carrier status of burbot, Lota lota (L.), to IHNV, IPNV, Flavobacterium psychrophilum, Aeromonas salmonicida and Renibacterium salmoninarum. Journal of Fish Diseases, 33, 559–570. https://doi.org/10.1111/j.1365-2761.2010.01152.x

Purcell MK, McKibben CL, Pearman-Gillman S, Elliott DG and Winton JR, 2016. Effects of temperature on Renibacterium salmoninarum infection and transmission potential in Chinook salmon, Oncorhynchus tshawytscha (Walbaum). Journal of Fish Diseases, 39, 787–798. https://doi.org/10.1111/jfd.12409

Rhodes LD, Rathbone CK, Corbett SC, Harrell LW and Strom MS, 2004. Efficacy of cellular vaccines and genetic adjuvants against bacterial kidney disease in chinook salmon (Oncorhynchus tshawytscha). Fish & Shellfish Immunology, 16, 461–474. https://doi.org/10.1016/j.fsi.2003.08.004

Rhodes LD, Nguyen OT, Deinhard RK, White TM, Harrell LW and Roberts MC, 2008. Characterization of Renibacterium salmoninarum with reduced susceptibility to macrolide antibiotics by a standardized antibiotic susceptibility test. Diseases of Aquatic Organisms, 80, 173–180.

Richards CA, Murphy CA, Brenden TO, Loch TP and Faisal M, 2017. Detection accuracy of Renibacterium salmoninarum in Chinook salmon, Oncorhynchus tshawytscha (Walbaum) from non-lethally collected samples: effects of exposure route and disease severity. Preventive Veterinary Medicine, 145, 110–120. https://doi.org/10.1016/j.prevetmed.2017.06.001

Riepe TB, Fetherman ER, Neuschwanger B, Davis T, Perkins A and Winkelman DL, 2023. Vertical transmission of Renibacterium salmoninarum in cutthroat trout (Oncorhynchus clarkii). The Journal of Fish Disease, 46, 309–319. https://doi.org/10.1111/jfd.13745

Rimaila-Pärnänen E, 2002. First case of bacterial kidney disease (BKD) in whitefish (Coregonus lavaretus) in Finland. Bulletin of the European Association of Fish Pathologists, 22, 403–404.

Rozas-Serri M, Lobos C, Correa R, Ildefonso R, Vásquez J, Muñoz A, Maldonado L, Jaramillo V, Coñuecar D, Oyarzún C, Walker R, Navarrete C, Gayosa J, Mancilla P, Peña A, Senn C and Schwerter F, 2020. Atlantic salmon pre-smolt survivors of Renibacterium Salmoninarum infection show inhibited cell-mediated adaptive immune response and a higher risk of death during the late stage of infection at lower water temperatures. Frontiers Immunology, 11, 1378. https://doi.org/10.3389/fimmu.2020.01378

Russell Danner G and Merrill P, 2005. Disinfectants, Disinfection, and Biosecurity in Aquaculture. Aquaculture Biosecurity, 91–128.

Salonius K, Siderakis C, MacKinnon AM and Griffiths SG, 2005. Use of Arthrobacter davidanieli as a live vaccine against Renibacterium salmoninarum and Piscirickettsia salmonis in salmonids. Developmental Biology (Basel), 121, 189–197.

Smith IW, 1964. The occurrence and pathology of Dee disease. Freshwater and Salmon Fisheries Research, 34, 1–12.

Souter B, Dwilow A and Knight K, 1987. Renibacterium salmoninarum in wild Arctic charr Salvelinus alpinus and lake trout S. namaycush from the Northwest Territories, Canada. Diseases of Aquatic Organisms, 3, 151–154.

Stewart A, Anthony LM, Ronald JP and Jed V, 2005. A cohabitation challenge to compare the efficacies of vaccines for bacterial kidney disease (BKD) in chinook salmon Oncorhynchus tshawytscha. Diseases of Aquatic Organisms, 63, 151–160.

Suzuki K, Misaka N, Mizuno S and Sasaki Y, 2017. Subclinical infection of Renibacterium salmoninarum in fry and juveniles Chum salmon Oncorhynchus keta in Hokkaido, Japan. Fish Pathology, 52, 89–95.

Traxler GS and Bell GR, 1988. Pathogens associated with impounded Pacific herring Clupea harengus pallasi, with emphasis on viral erythrocytic necrosis (VEN) and atypical Aeromonas salmonicida. Diseases of Aquatic Organisms, 5, 93–100. https://doi.org/10.3354/dao005093

Verdugo C, Zimin-Veselkoff N, Gardner IA and Mardones FO, 2020. Expert elicitation of the diagnostic performance of two tests for Bacterial Kidney Disease (BKD) surveillance in Atlantic salmon (Salmo salar L.) broodstock in Chile. Aquaculture, 525, 735274. https://doi.org/10.1016/j.aquaculture.2020.735274

Vivekanandhan G, Savithamani K, Hatha AAM and Lakshmanaperumalsamy P, 2002. Antibiotic resistance of Aeromonas hydrophila isolated from marketed fish and prawn of South India. International Journal of Food Microbiology, 76, 165–168. https://doi.org/10.1016/S0168-1605(02)00009-0

WAHIS/WOAH, online. World Organisation of Animal Health Reports of Infection with *Renibacterium salmoninarum*. Available online: https://www.woah.org/en/home/

Wallace I, Munro L, Kilburn R, Hall M, Black J, Raynard R and Murray A, 2011. A report on the effectiveness of cage and farm-level fallowing of the control of bacterial kidney disease and sleeping disease on large cagebased trout farms in Scotland. Scottish Marine and Freshwater Science Reports, 2, 36.

Wallace IS, McKay P and Murray AG, 2017. A historical review of the key bacterial and viral pathogens of Scottish wild fish. Journal of Fish Diseases, 40, 1741–1756. https://doi.org/10.1111/jfd.12654

Watson TR, Bruce TJ, Ma J and Cain KD, 2023. Comparison of injection and immersion challenges of Renibacterium salmoninarum strains in Rainbow Trout. Journal of Aquatic Animal Health, 35, 34–40. https://doi.org/10.1002/aah.10175

Wiens GD, 2011. Bacterial kidney disease (Renibacterium salmoninarum). Fish diseases and disorders. 3. viral, bacterial and fungal infections, CABI, Wallingford, UK. pp. 338–374.

WOAH, 2006. Aquatic Animal Health Code 2006. 9th Edition. Available online: https://doc.woah.org/dyn/portal/index.xhtml?page=alo&aloId=23325

Abbreviations

AHAW	Animal Health and Welfare
AHL	Animal Health Law
BKD	bacterial kidney disease
CI	current impact
ELISA	Enzyme-linked immunosorbent assay
IFAT	Immunofluorescence antibody test
MS	Member State
MSs	Member States
NPCR	nested polymerase chain reaction
OIE	Office International des Épizooties (World Organisation For Animal Health)
PCR	polymerase chain reaction
PI	Potential Impact
QTL	quantitative trait loci
Se	sensitivity
Sp	specificity
ToR	Term Of Reference
WG	Working Group
WOAH	World Organisation for Animal Health

Appendix A – Expert judgement plotted by question

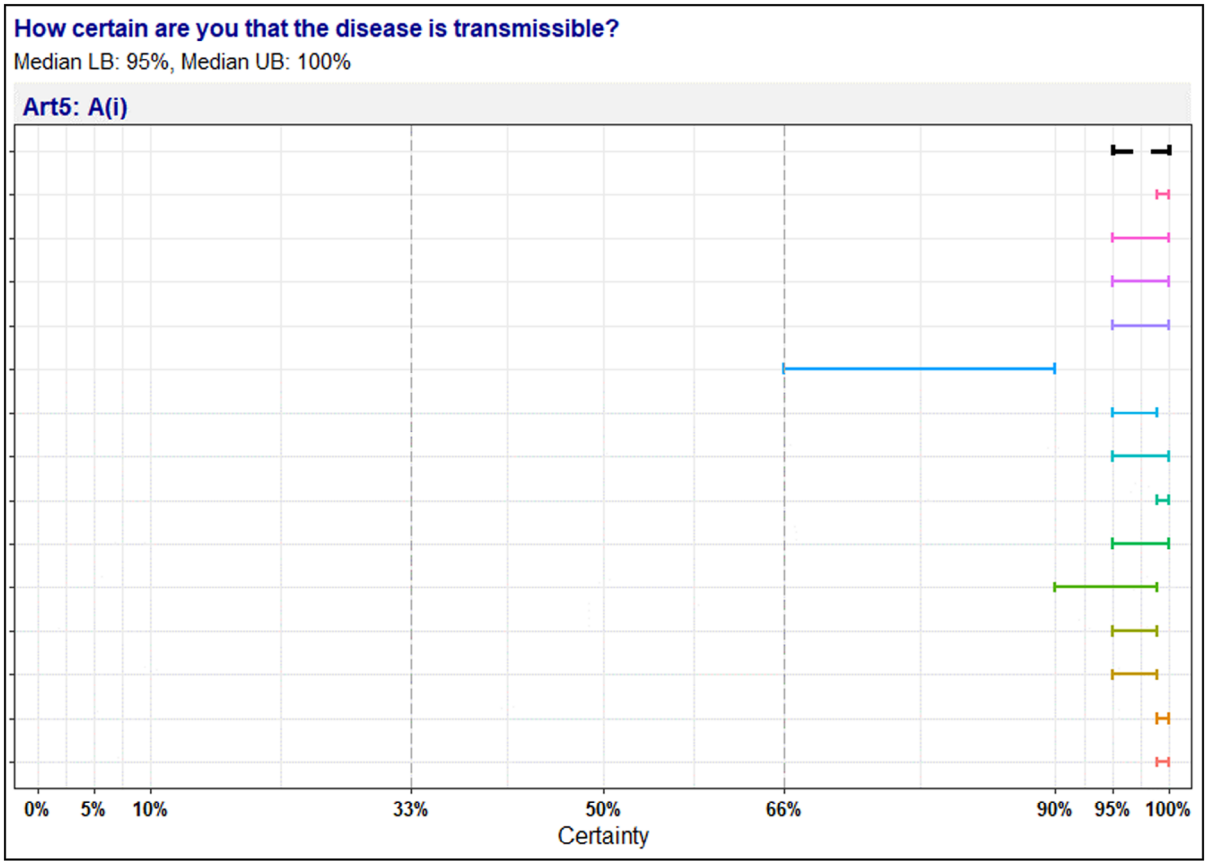


Figure A.1: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion A(i) (the disease is transmissible). The black dotted line on the top indicates the median

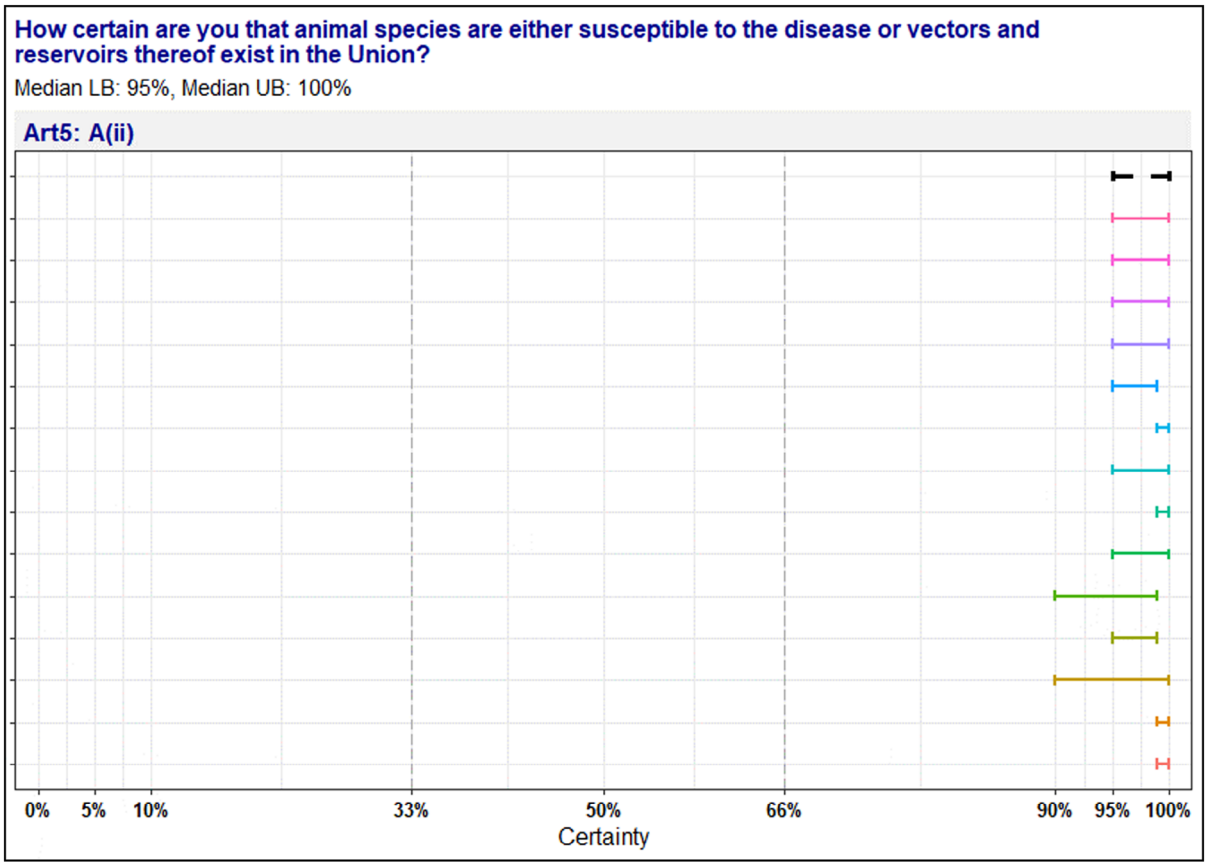


Figure A.2: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion A(ii) (animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union). The black dotted line on the top indicates the median

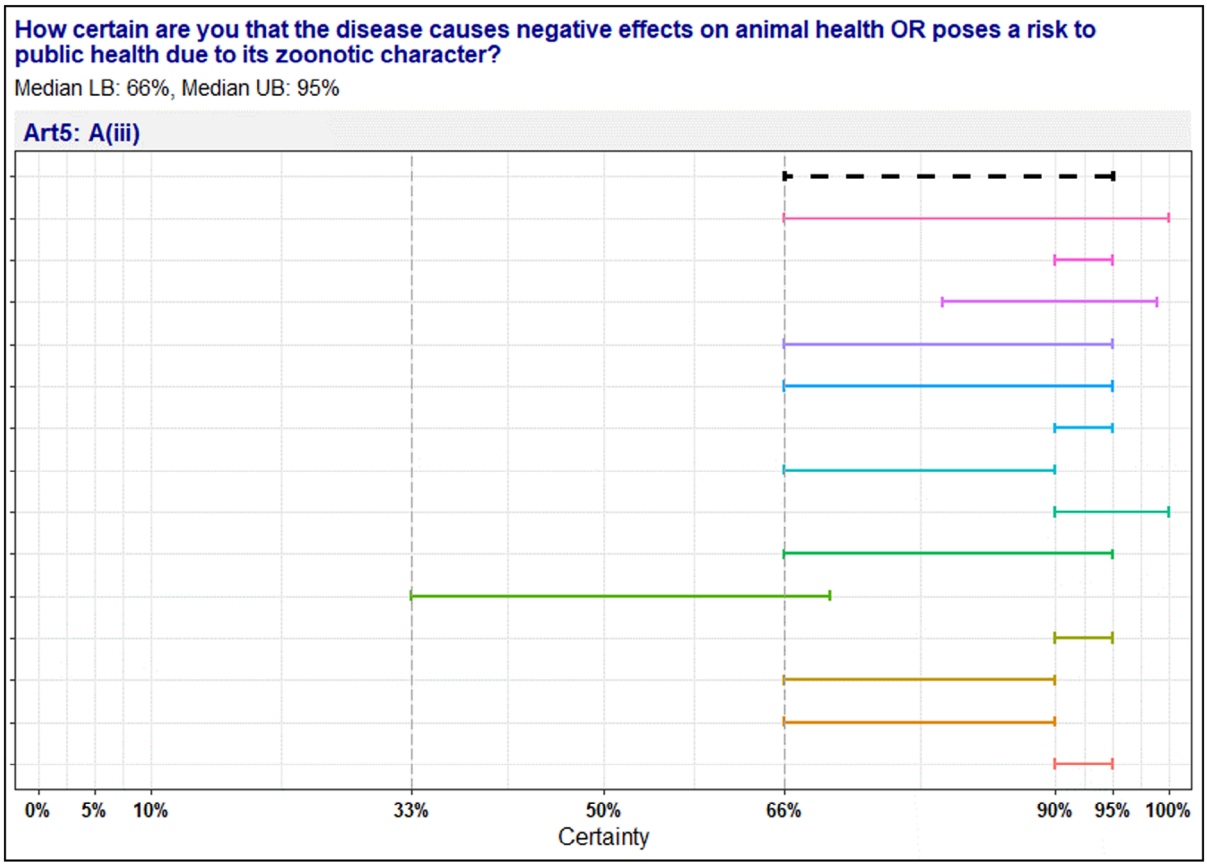


Figure A.3: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion A(iii) (the disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character). The black dotted line on the top indicates the median

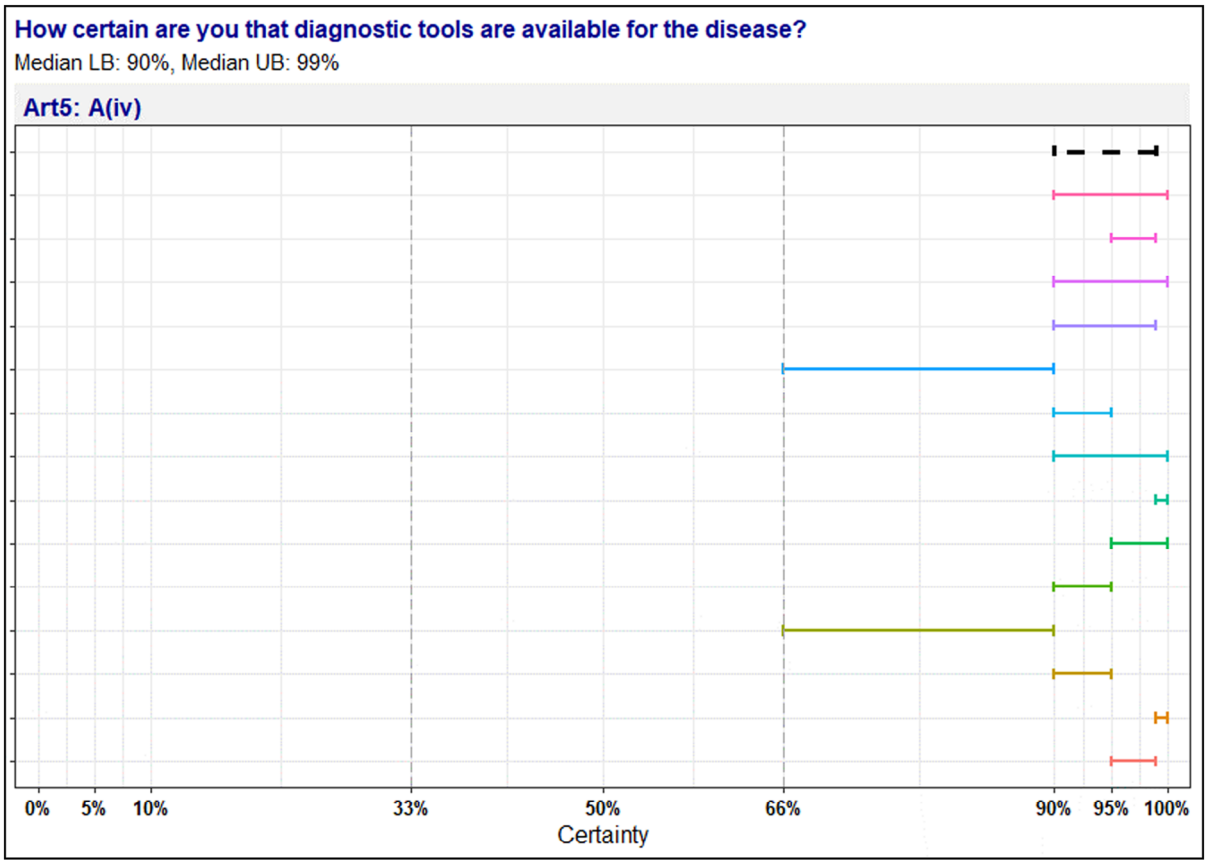


Figure A.4: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion A(iv) (diagnostic tools are available for the disease). The black dotted line on the top indicates the median

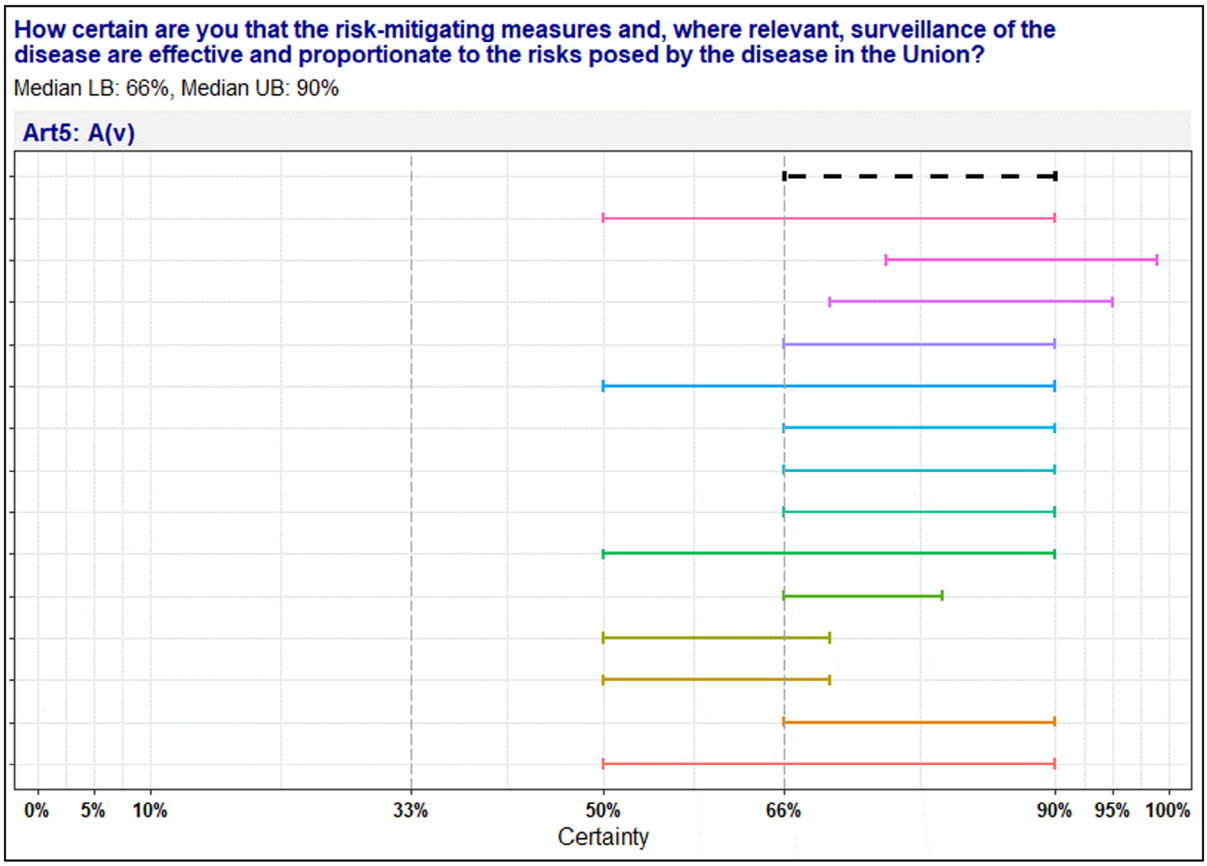


Figure A.5: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion A(v) (risk-mitigating measures and, where relevant, surveillance of the disease are effective and proportionate to the risks posed by the disease in the Union). The black dotted line on the top indicates the median

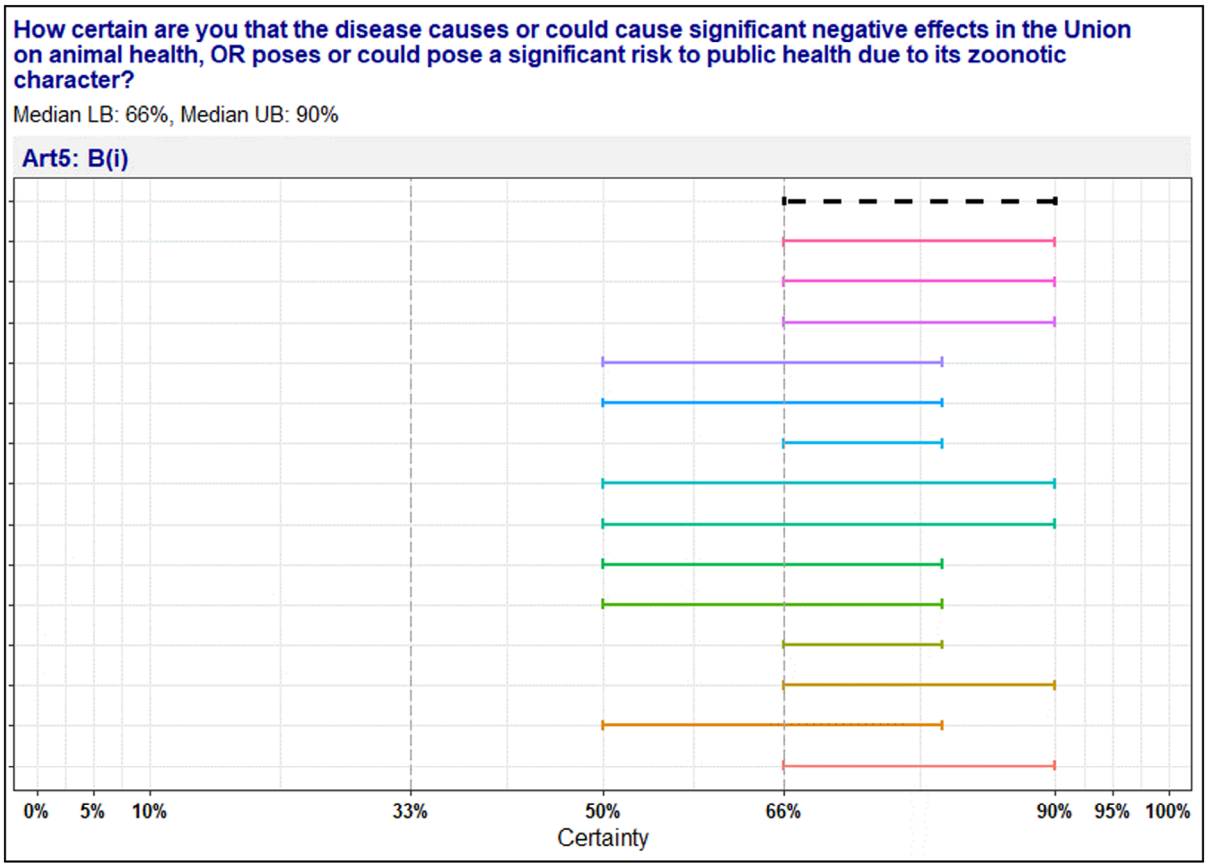


Figure A.6: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion B(i) (the disease causes or could cause significant negative effects in the Union on animal health or poses or could pose a significant risk to public health due to its zoonotic character). The black dotted line on the top indicates the median

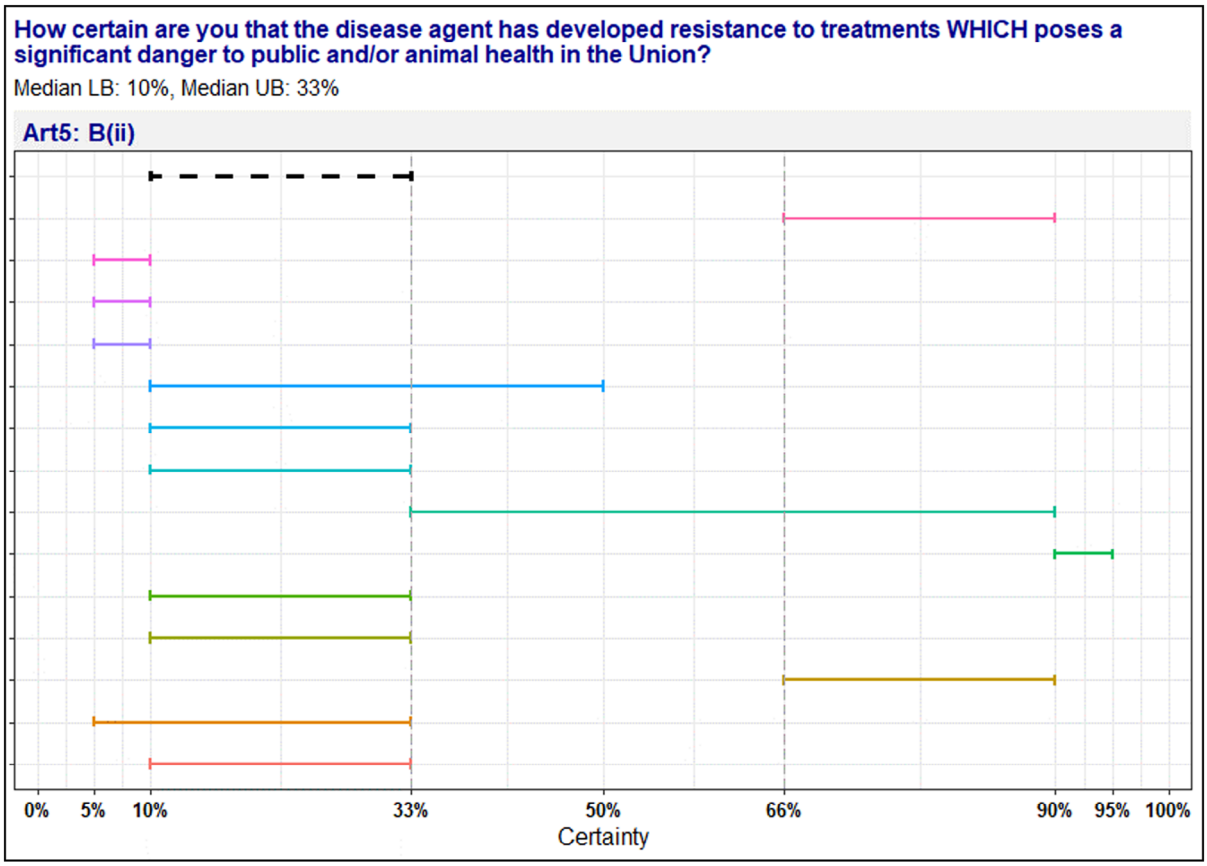


Figure A.7: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion B(ii) (the disease causes or could cause significant negative effects in the Union on animal health or poses or could pose a significant risk to public health due to its zoonotic character). The black dotted line on the top indicates the median

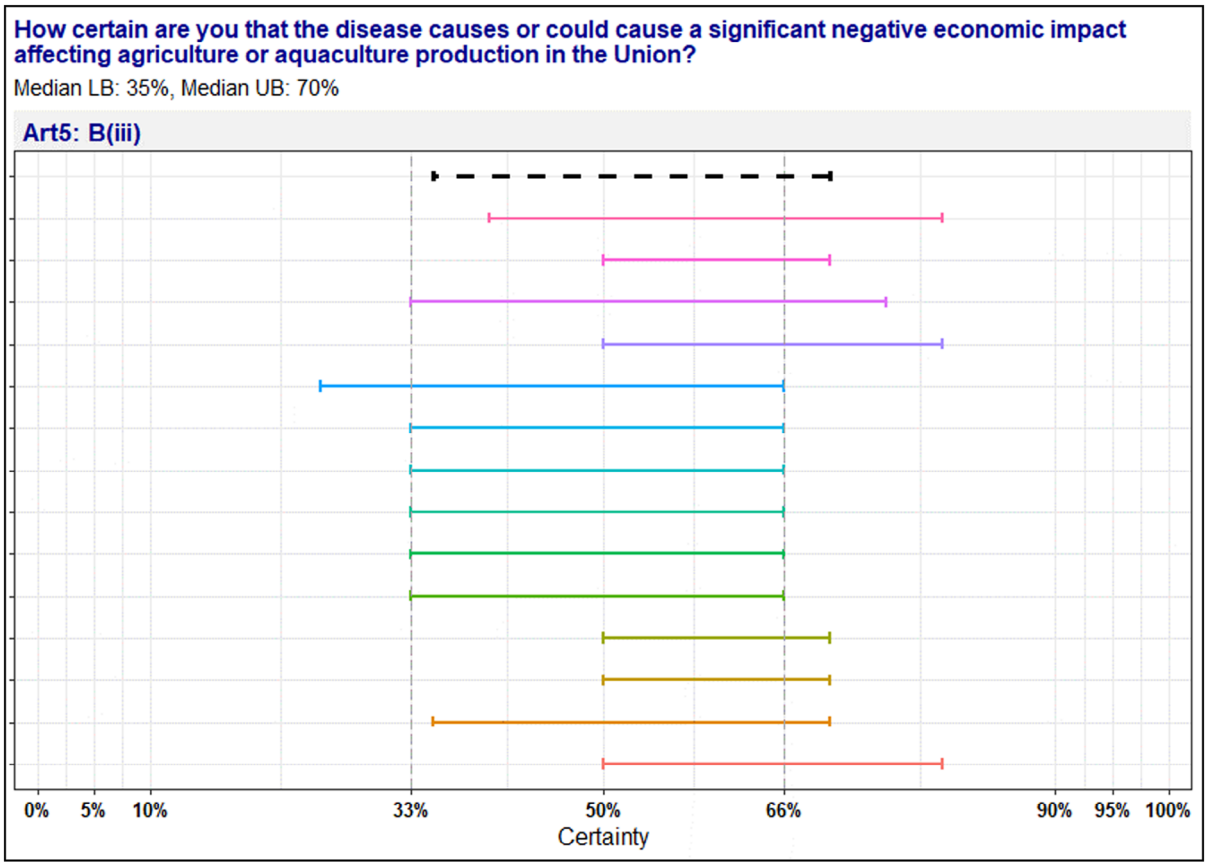


Figure A.8: Individual probability ranges, after the collective judgement, reflecting the uncertain outcome of the criterion B(iii) (the disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union). The black dotted line on the top indicates the median

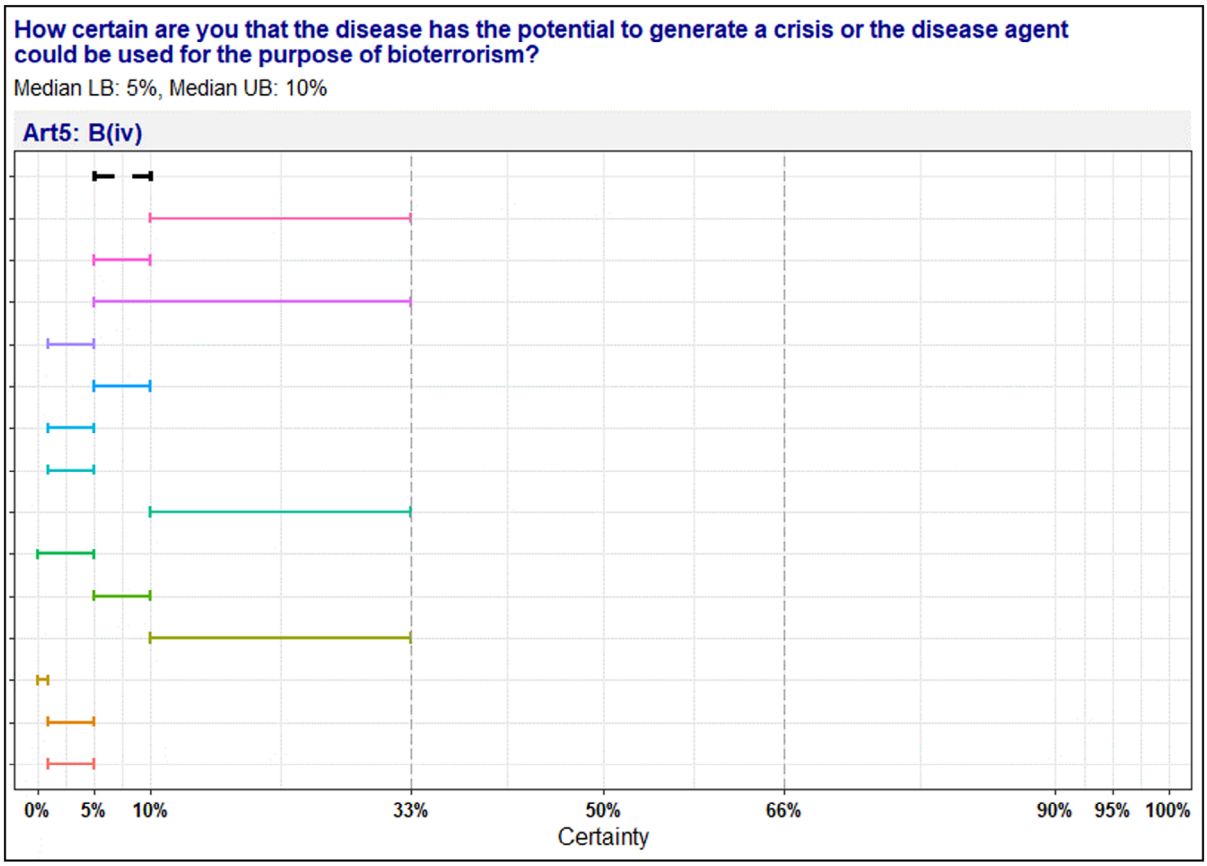


Figure A.9: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion B(iv) (the disease has the potential to generate a crisis or the disease agent could be used for the purpose of bioterrorism). The black dotted line on the top indicates the median

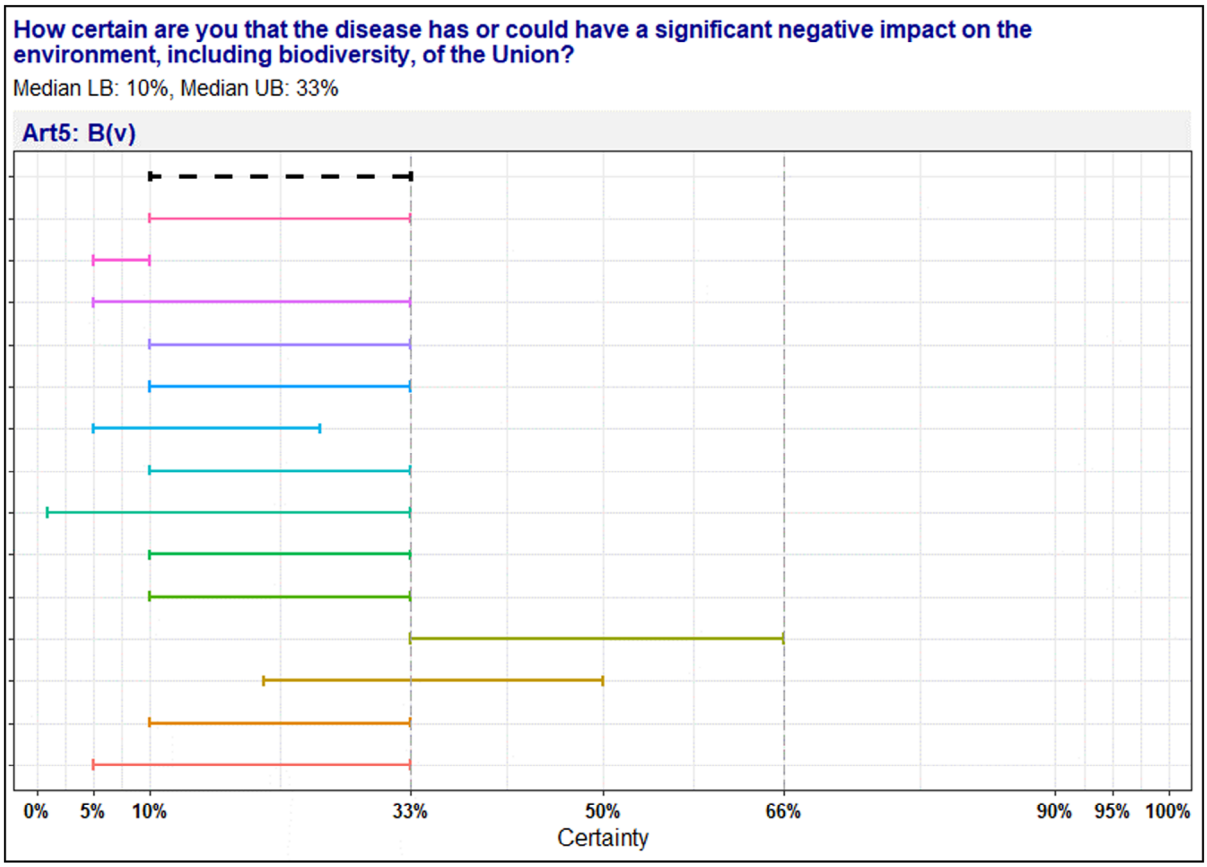


Figure A.10: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion B(v) (the disease has or could have a significant negative impact on the environment, including biodiversity, of the Union). The black dotted line on the top indicates the median

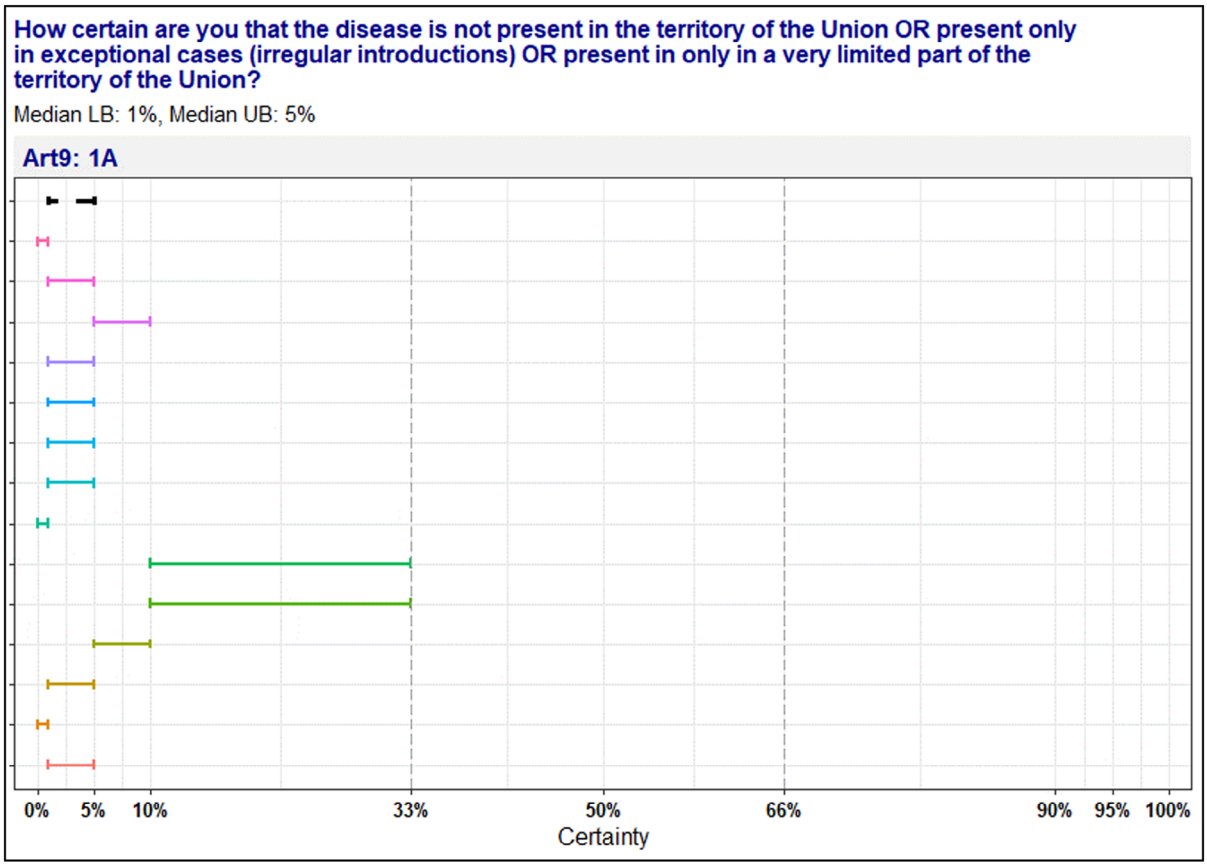


Figure A.11: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 1A (the disease is not present in the territory of the Union or present only in exceptional cases (irregular introductions) or present in only in a very limited part of the territory of the Union). The black dotted line on the top indicates the median

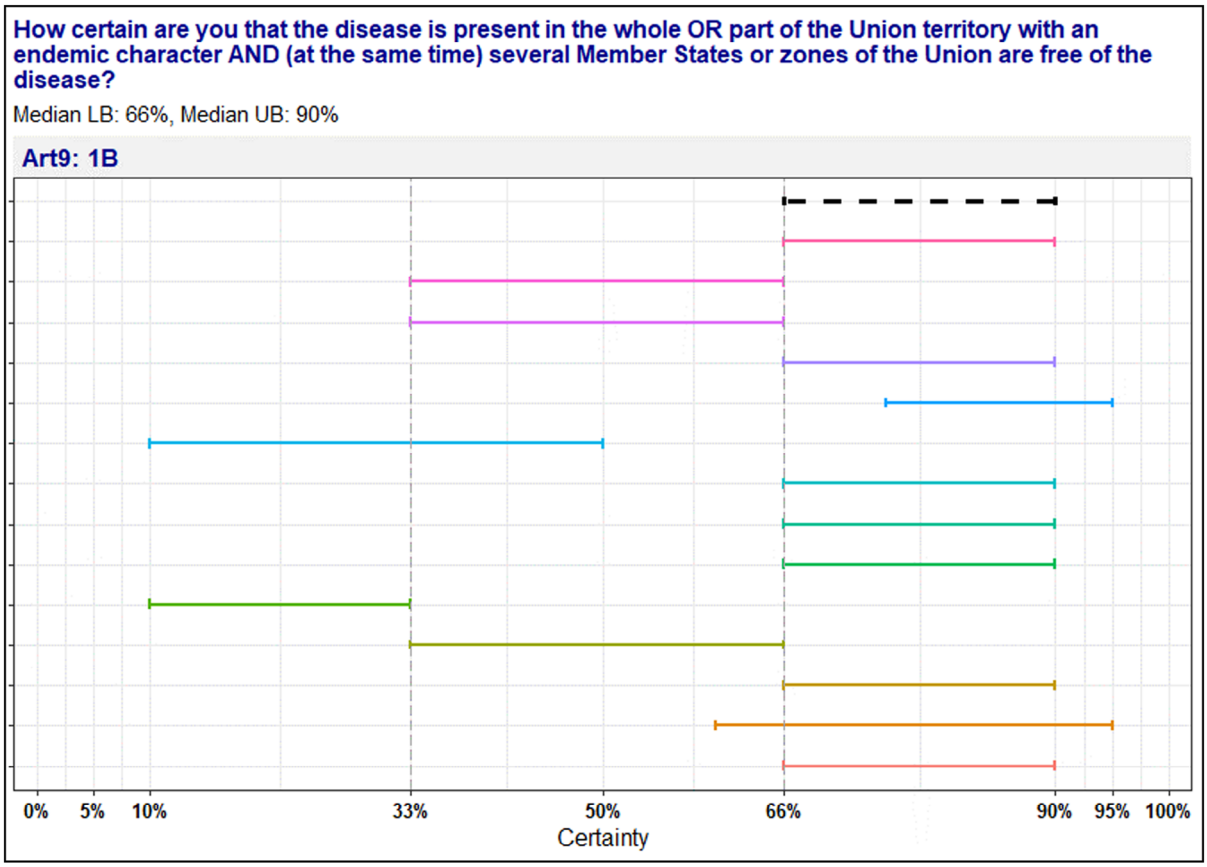


Figure A.12: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion 1B (the disease is present in the whole or part of the Union territory with an endemic character and (at the same time) several Member States or zones of the Union are free of the disease). The black dotted line on the top indicates the median)

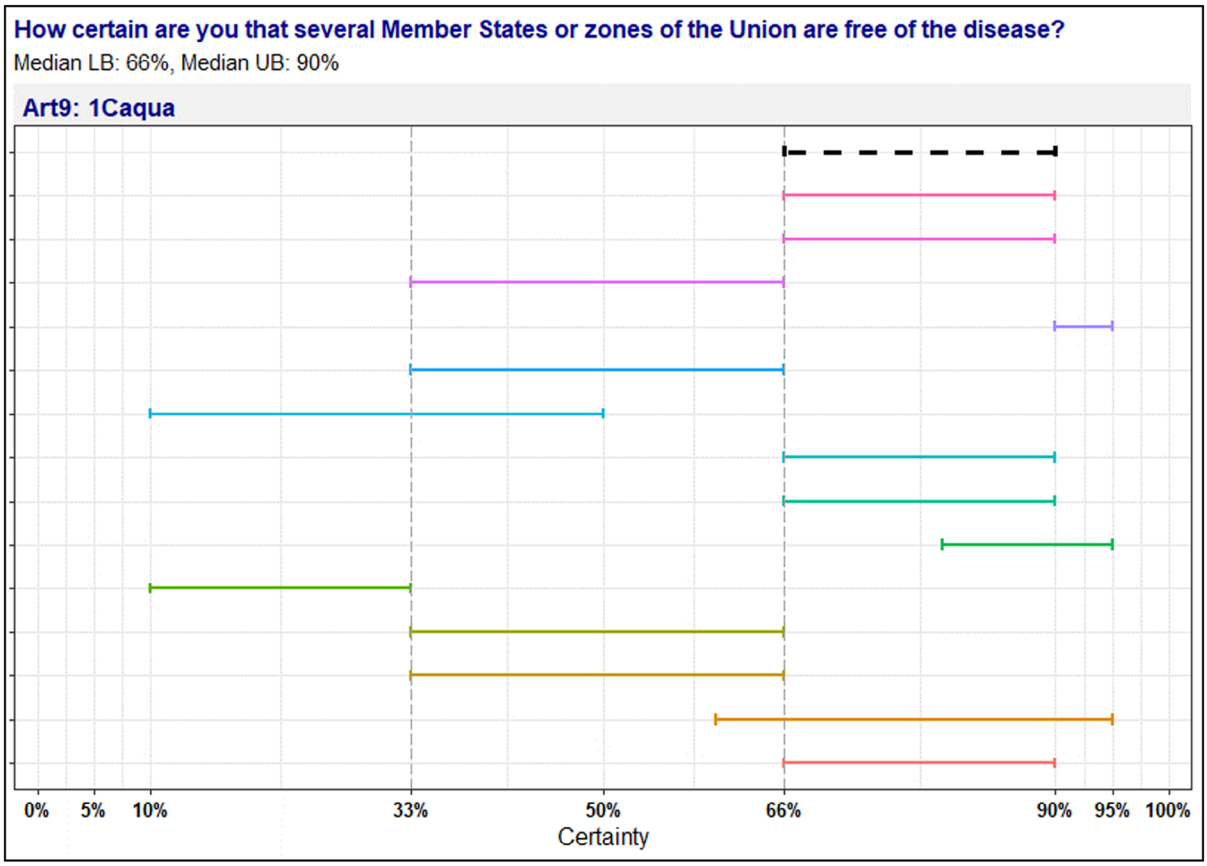


Figure A.13: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion 1Caqua (the disease is present in the whole or part of the Union territory with an endemic character). The black dotted line on the top indicates the median

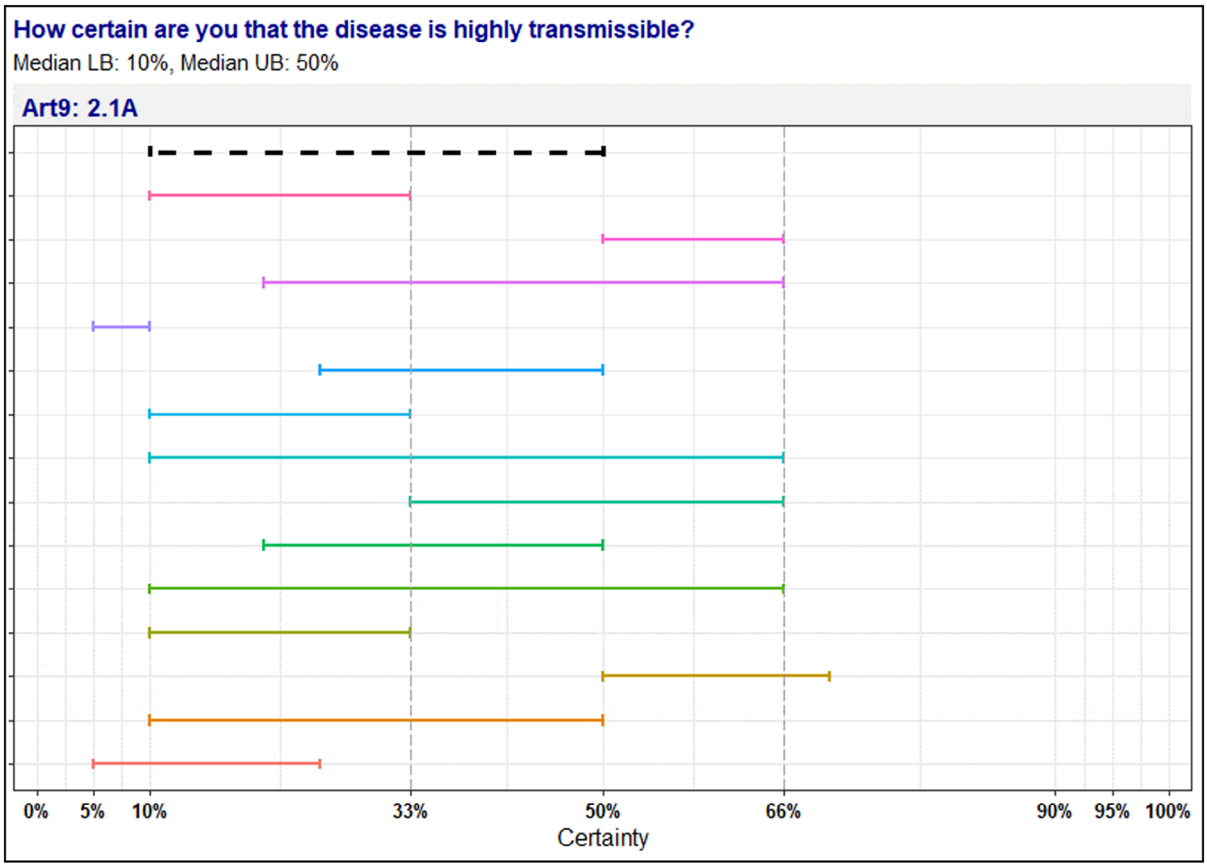


Figure A.14: Individual probability ranges, after the collective judgement, reflecting the uncertain outcome of the criterion 2.1A (the disease is highly transmissible). The black dotted line on the top indicates the median

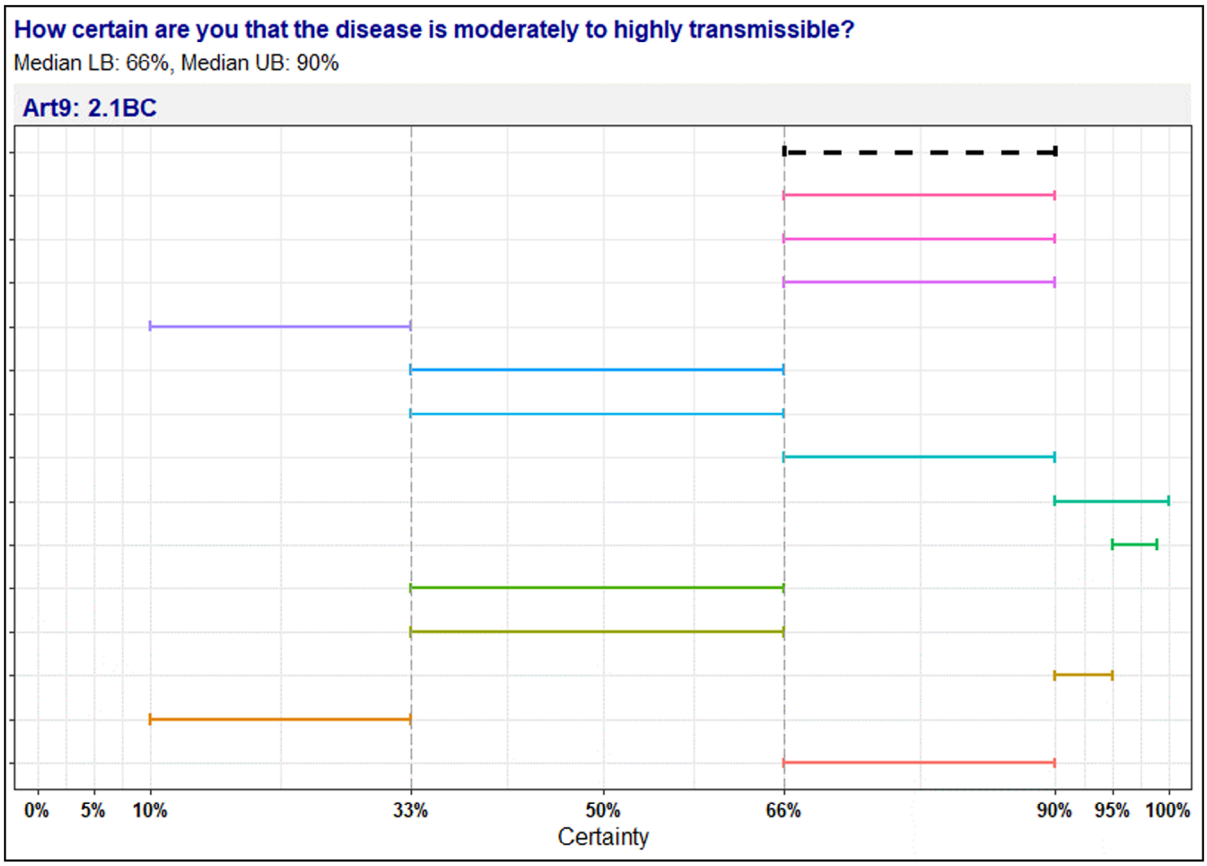


Figure A.15: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion 2.1 BC (the disease is moderately to highly transmissible). The black dotted line on the top indicates the median

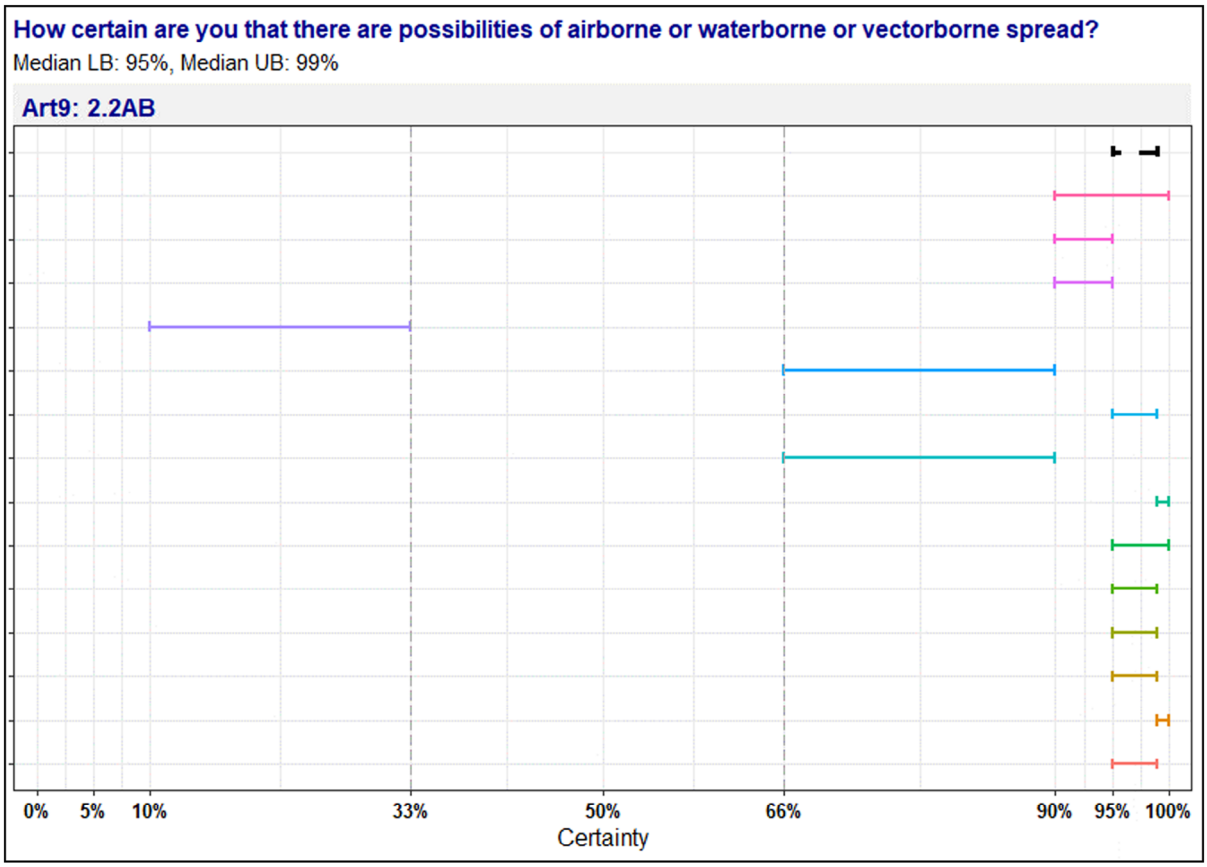


Figure A.16: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion 2.2AB (there are possibilities of airborne or waterborne or vector-borne spread). The black dotted line on the top indicates the median

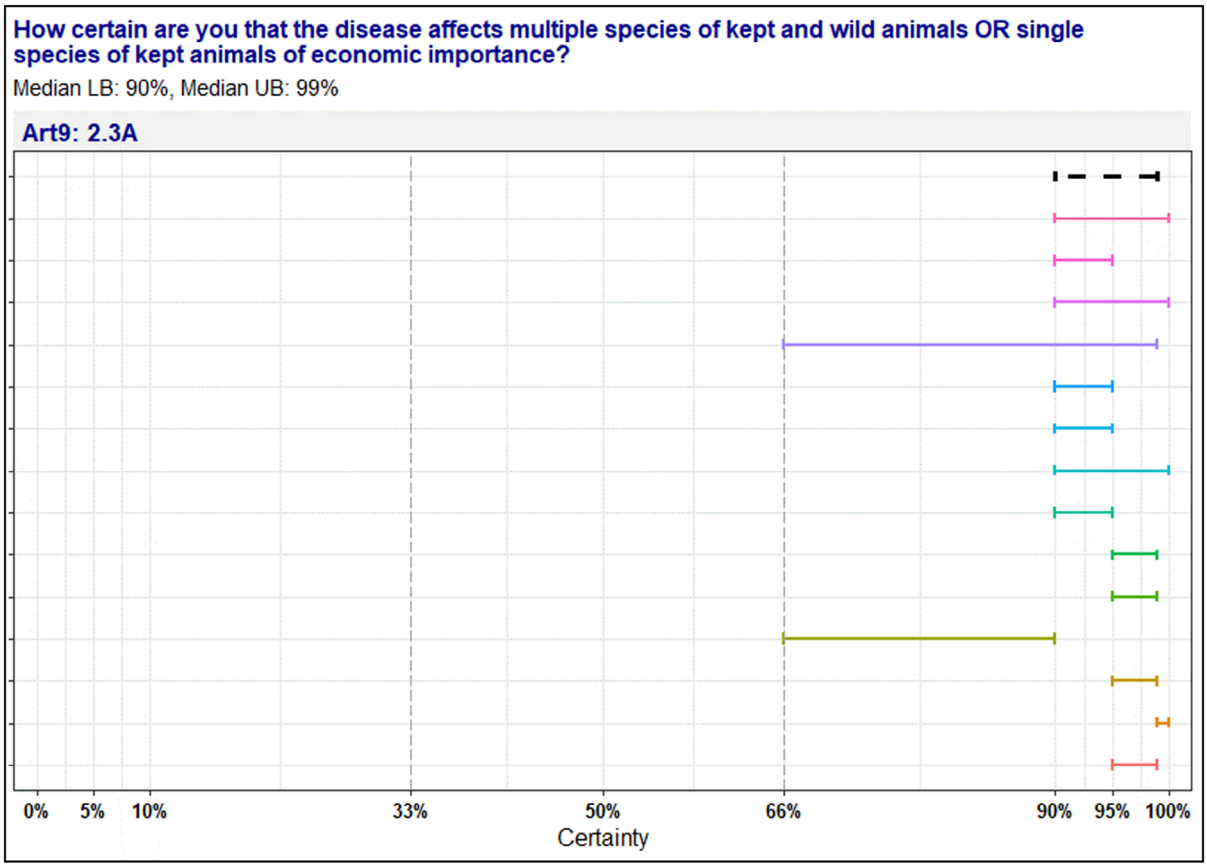


Figure A.17: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion 2.3A (the disease affects multiple species of kept and wild animals or single species of kept animals of economic importance). The black dotted line on the top indicates the median

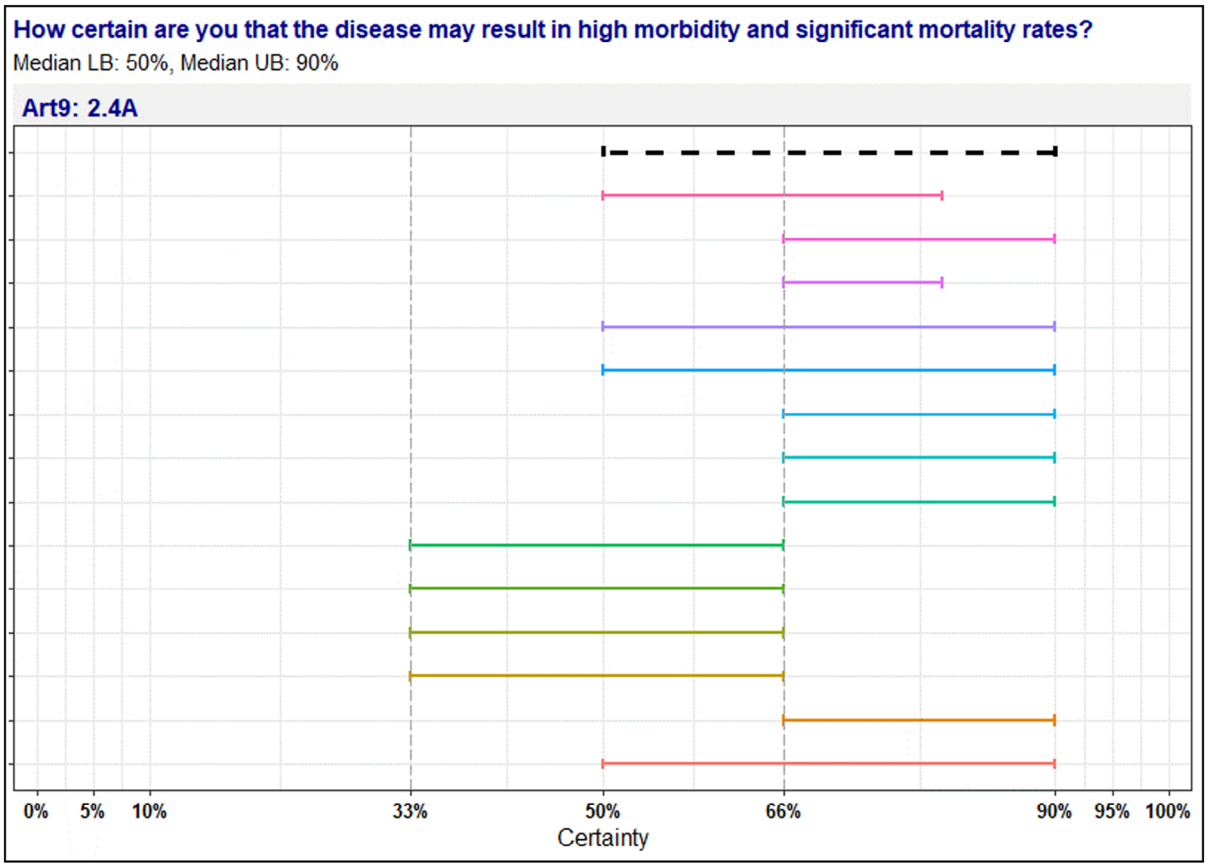


Figure A.18: Individual probability ranges, after the collective judgement, reflecting the uncertain outcome of the criterion 2.4A (the disease may result in high morbidity and significant mortality rates). The black dotted line on the top indicates the median

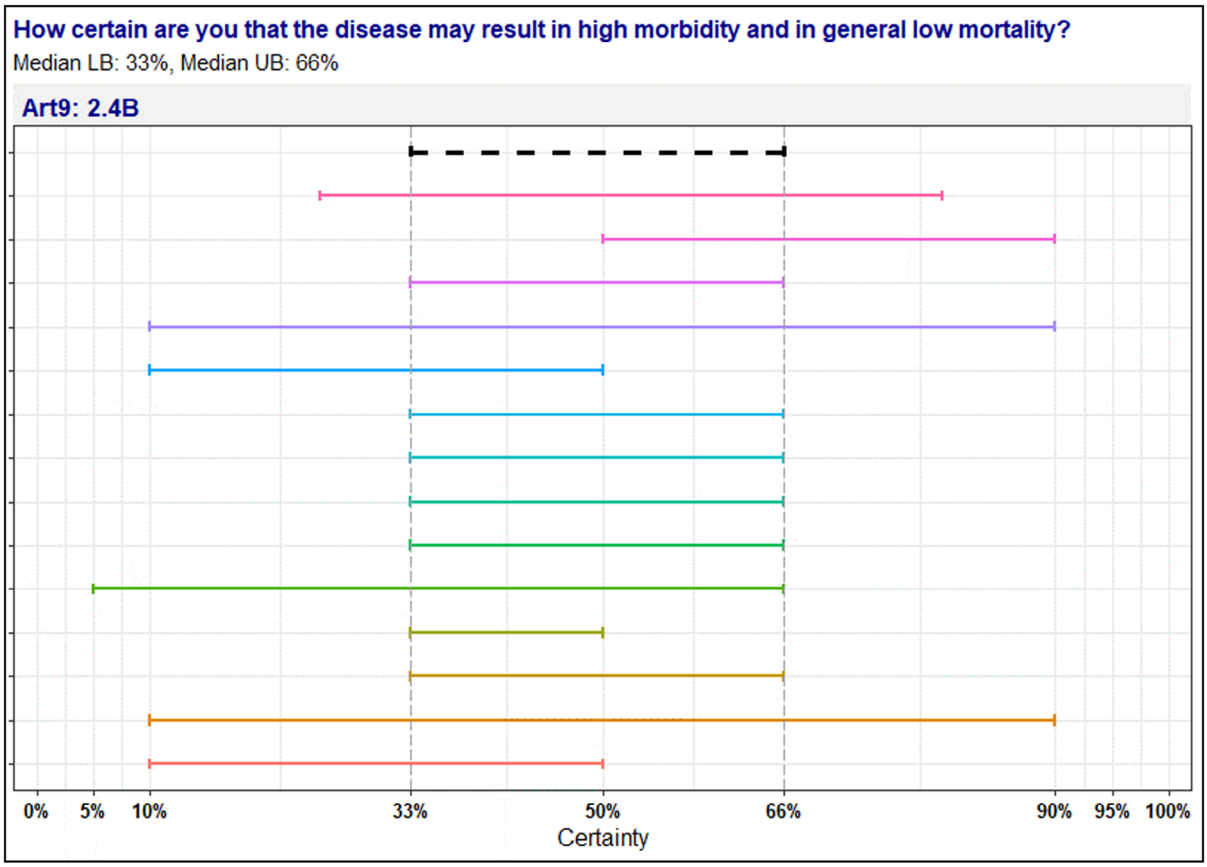


Figure A.19: Individual probability ranges, after the collective judgement, reflecting the uncertain outcome of the criterion 2.4B (the disease may result in high morbidity with in general low mortality). The black dotted line on the top indicates the median

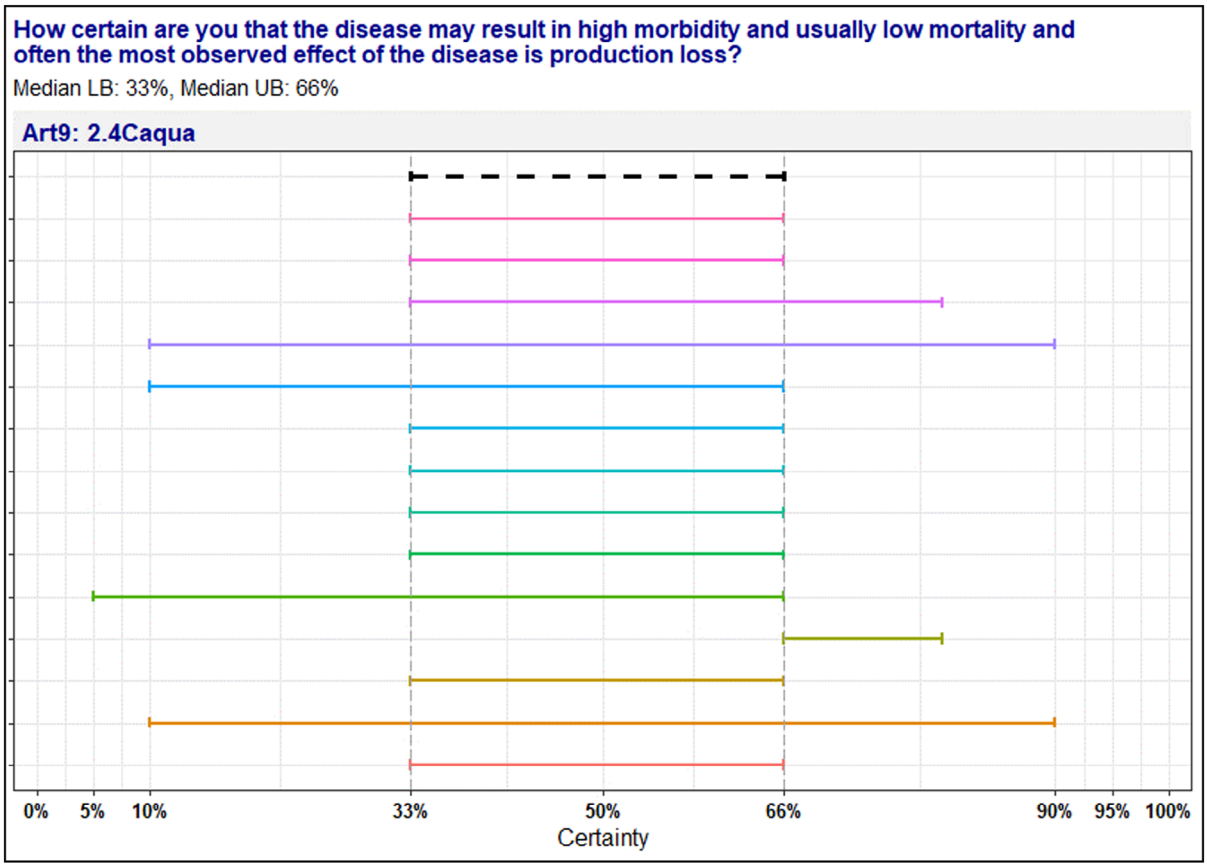


Figure A.20: Individual probability ranges, after the collective judgement, reflecting the uncertain outcome of the criterion 2.4Caqua (the disease usually does not result in high morbidity and has negligible or no mortality and often the most observed effect of the disease is production loss). The black dotted line on the top indicates the median

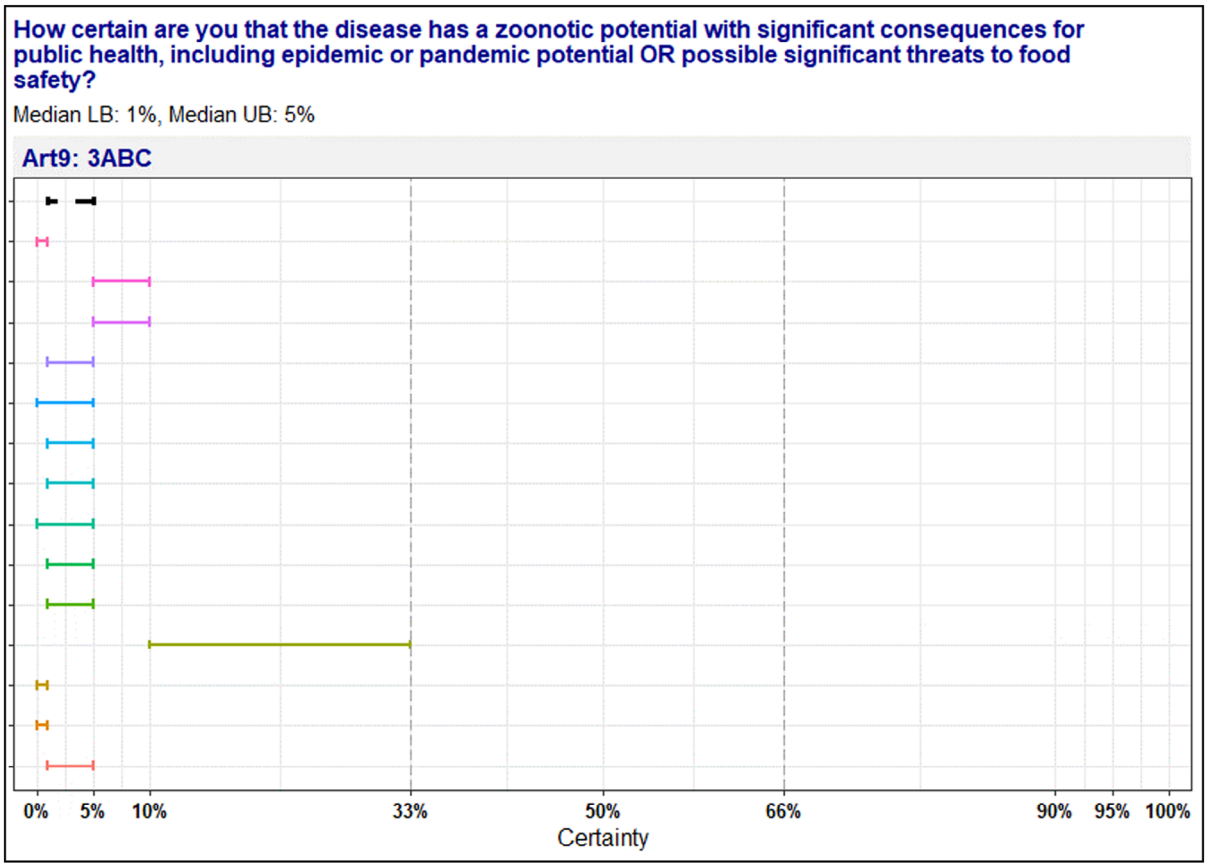


Figure A.21: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 3ABC (the disease has a zoonotic potential with significant consequences for public health or possible significant threats to food safety). The black dotted line on the top indicates the median

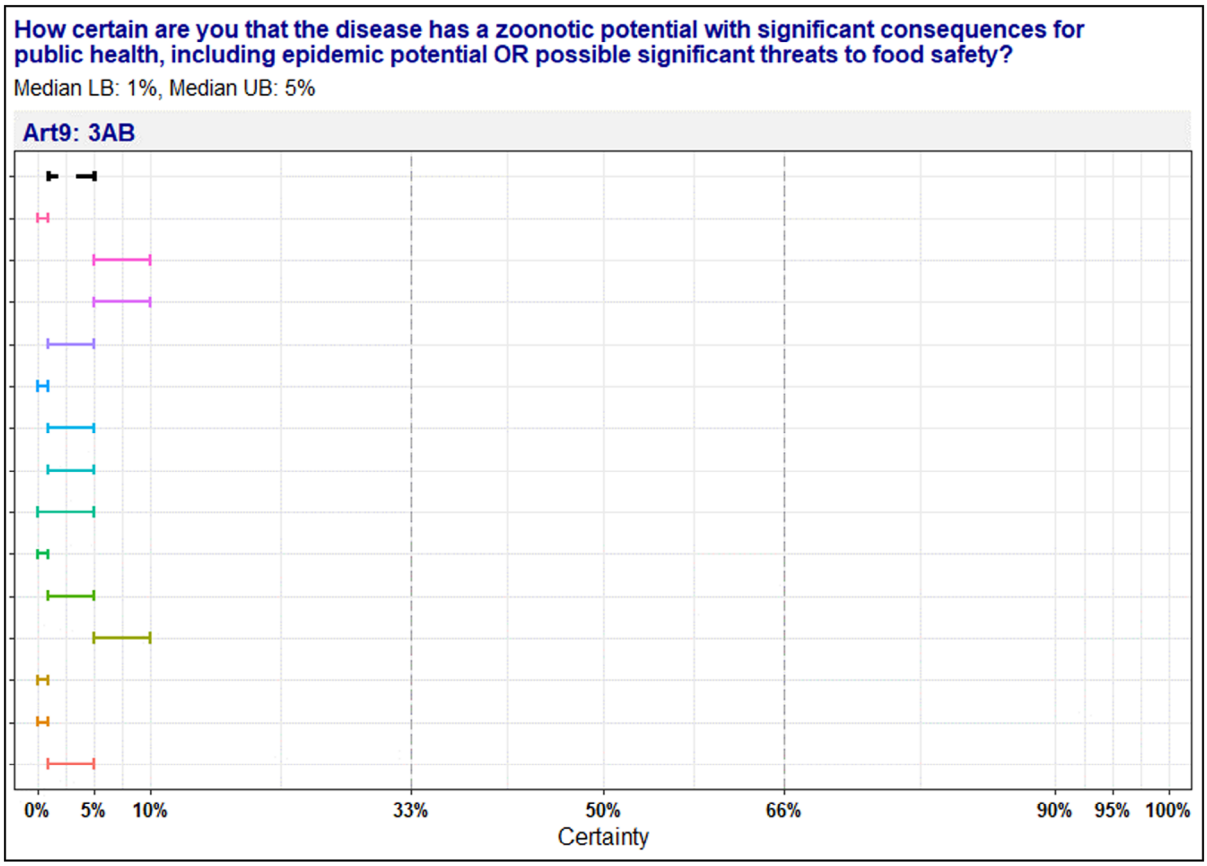


Figure A.22: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 3AB (the disease has a zoonotic potential with significant consequences for public health, including epidemic potential or possible significant threats to food safety). The black dotted line on the top indicates the median

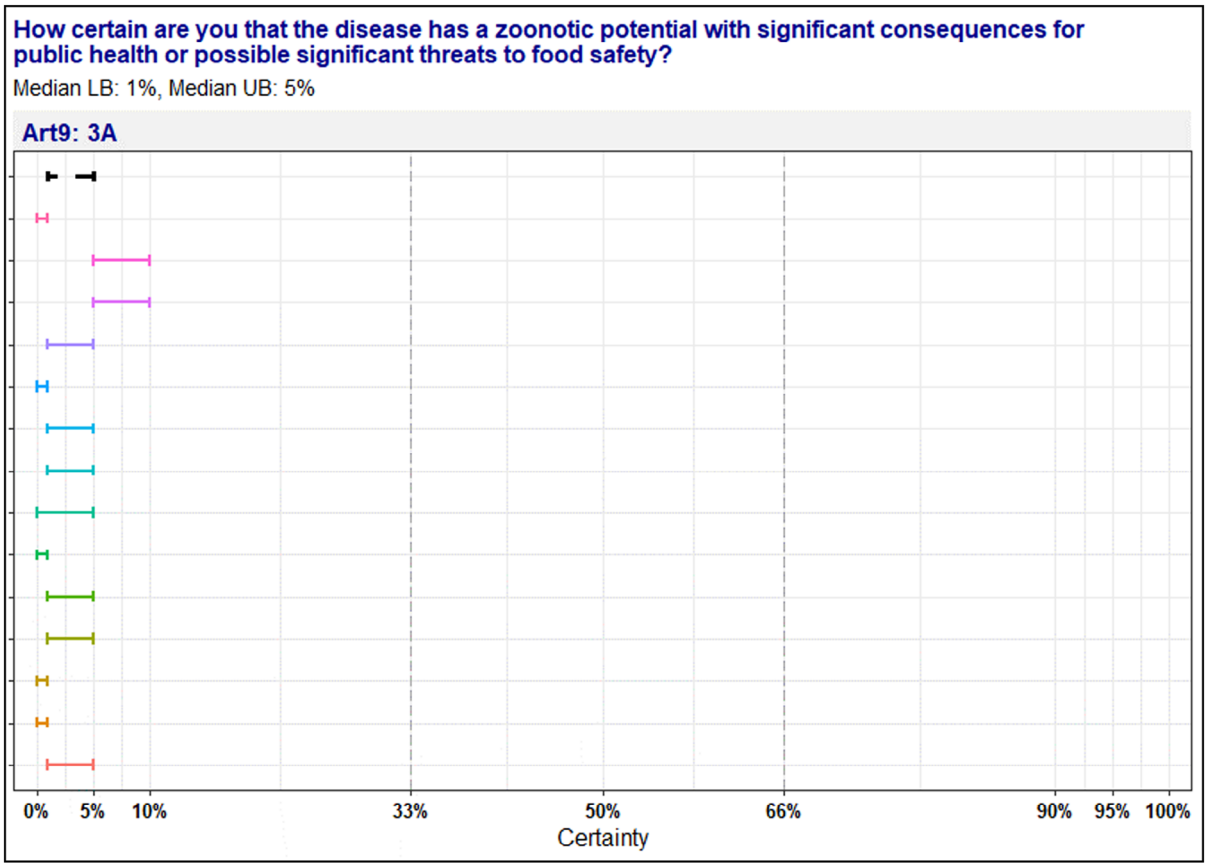


Figure A.23: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 3A (the disease has a zoonotic potential with significant consequences for public health, including epidemic or pandemic potential or possible significant threats to food safety). The black dotted line on the top indicates the median

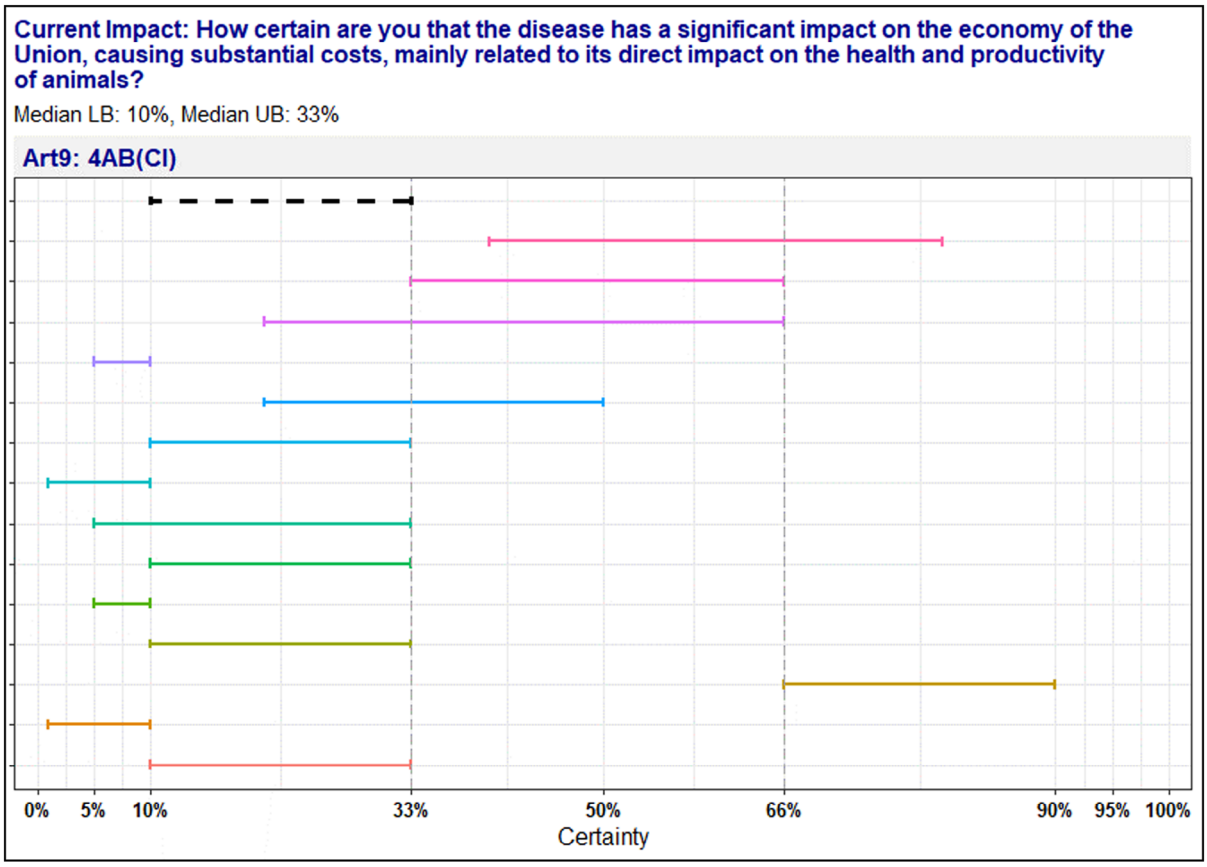


Figure A.24: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 4AB (current impact) (the disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals). The black dotted line on the top indicates the median

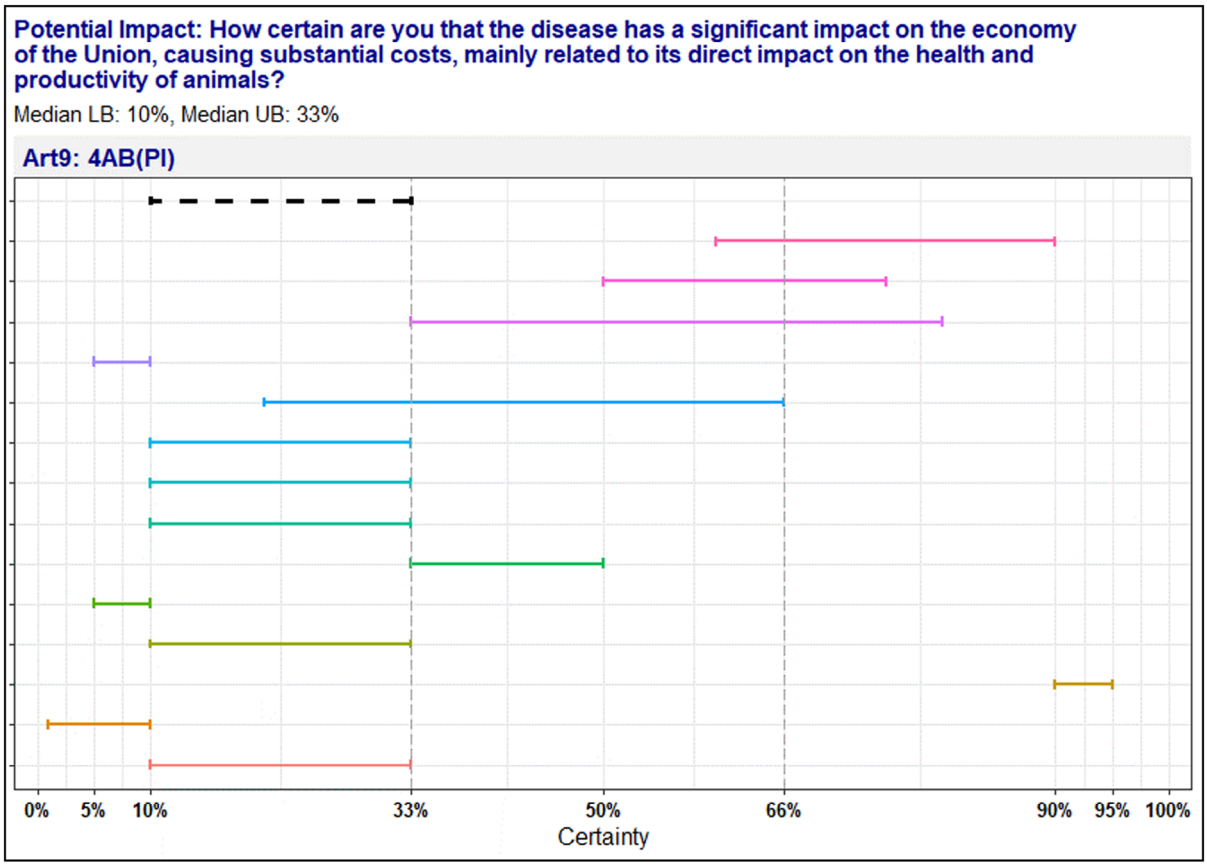


Figure A.25: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 4AB (potential impact) (the disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals). The black dotted line on the top indicates the median

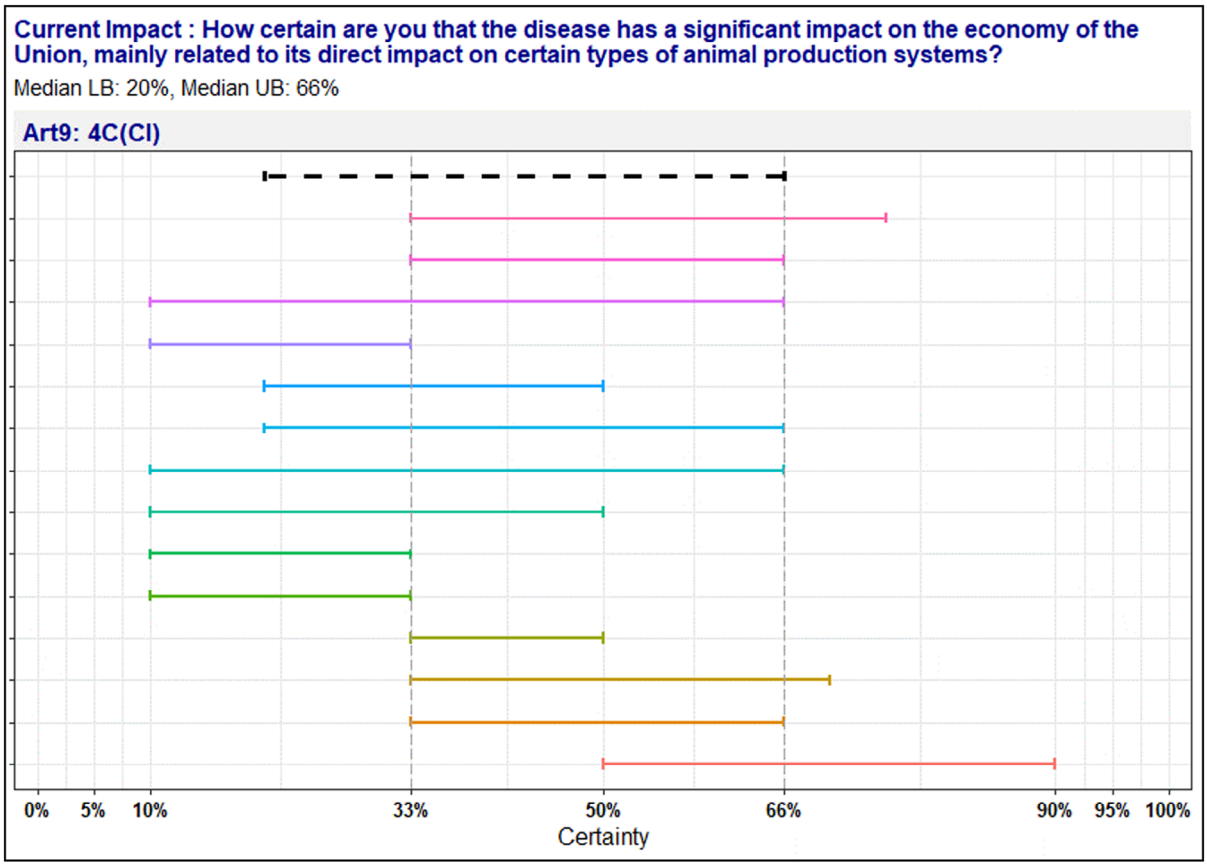


Figure A.26: Individual probability ranges, after the collective judgement, reflecting the uncertain outcome of the criterion 4C (current impact) (the disease has a significant impact on the economy of the Union, mainly related to its direct impact on certain types of animal production systems). The black dotted line on the top indicates the median

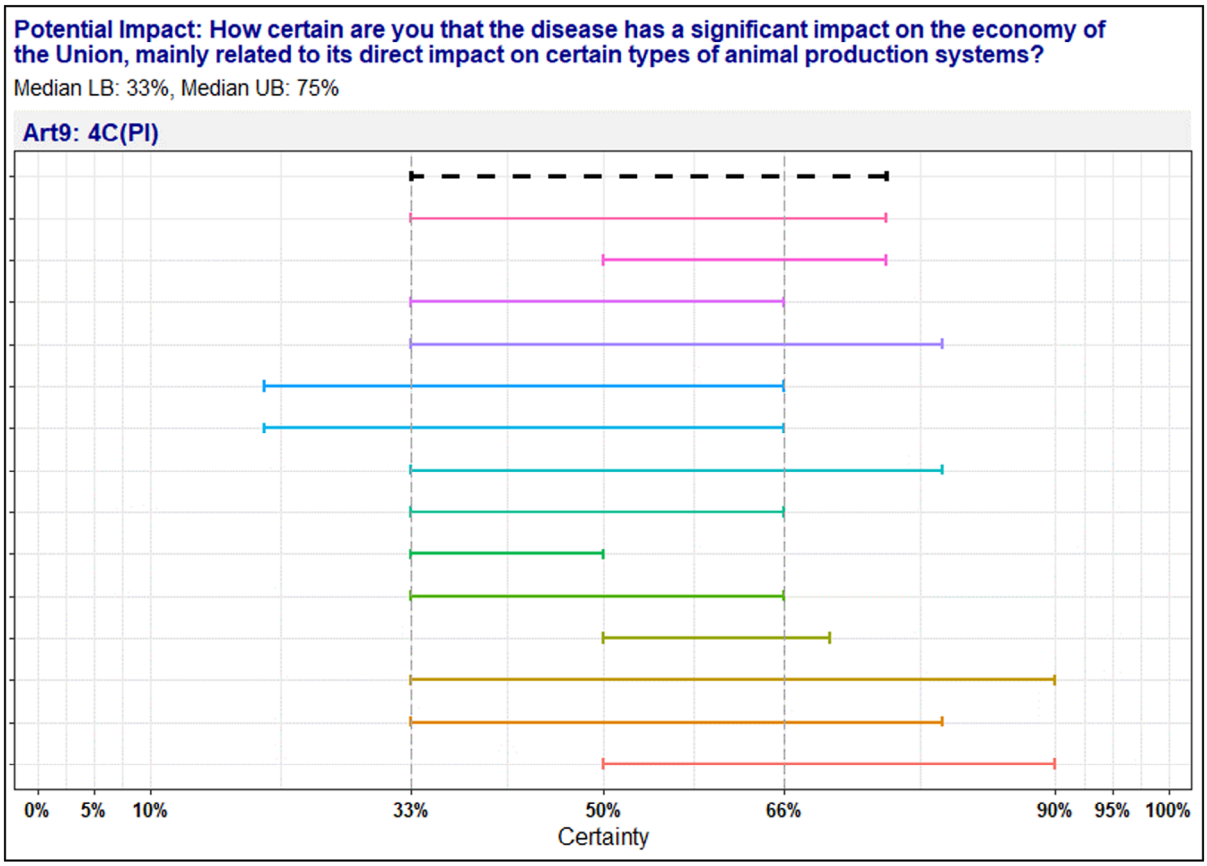


Figure A.27: Individual probability ranges, after the collective judgement, reflecting the uncertain outcome of the criterion 4C (potential impact) (the disease has a significant impact on the economy of the Union, mainly related to its direct impact on certain types of animal production systems). The black dotted line on the top indicates the median

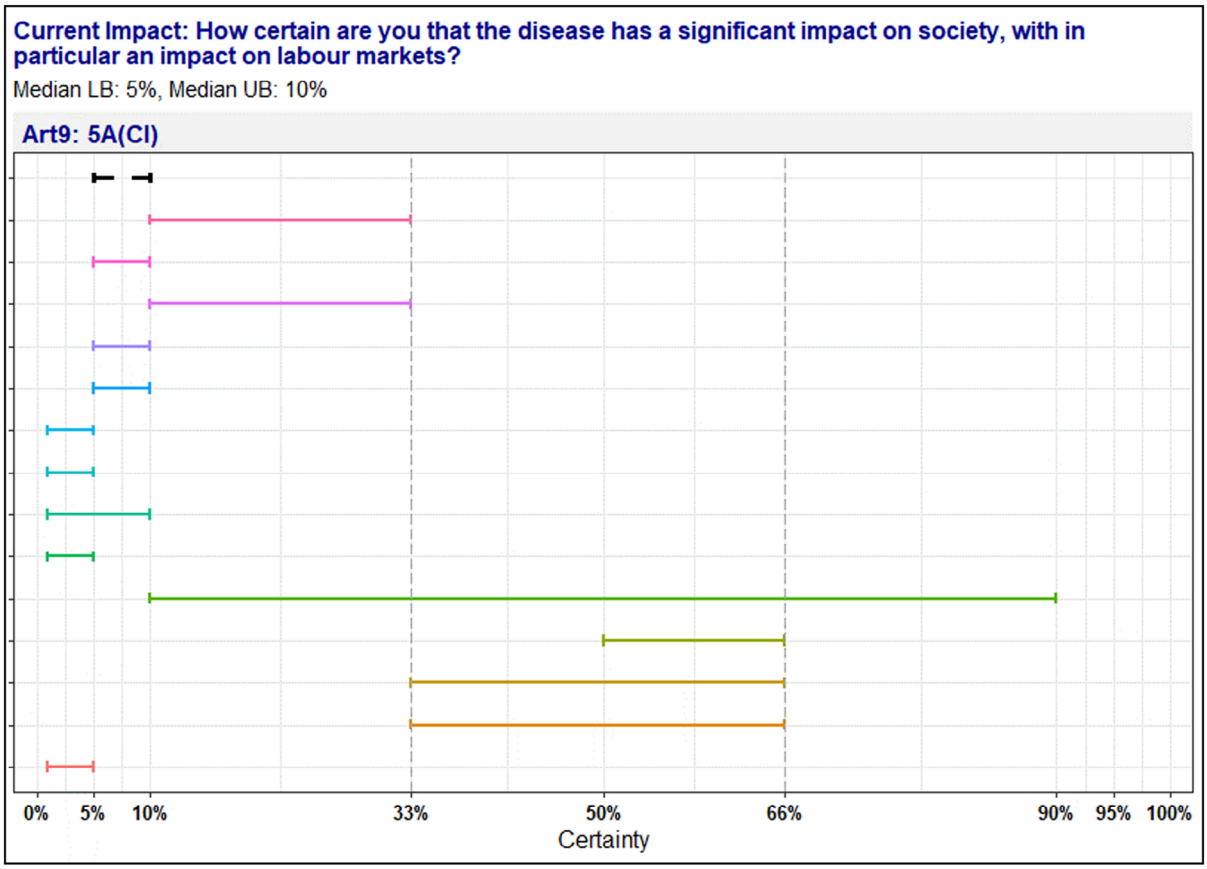


Figure A.28: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 5A (current impact) (the disease has a significant impact on society, with in particular an impact on labour markets). The black dotted line on the top indicates the median

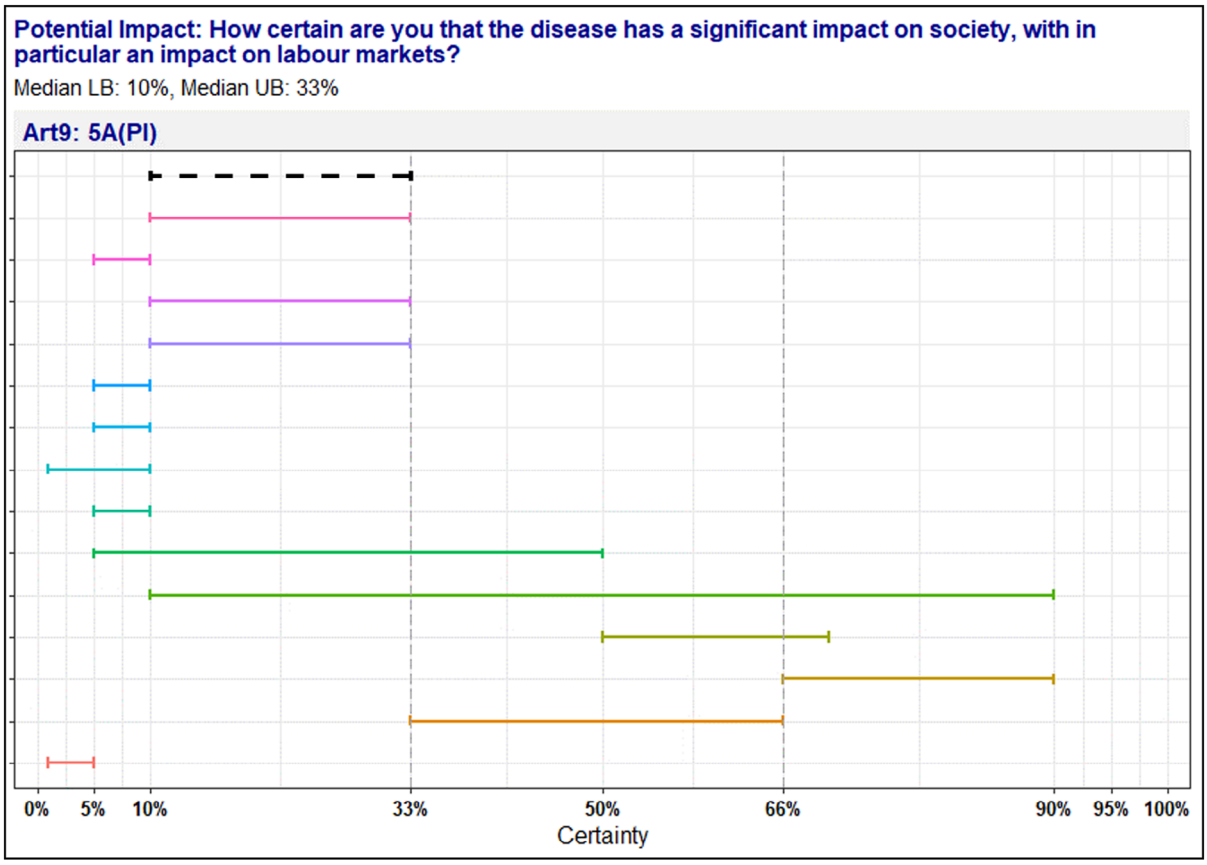


Figure A.29: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 5A (potential impact) (the disease has a significant impact on society, with in particular an impact on labour markets). The black dotted line on the top indicates the median

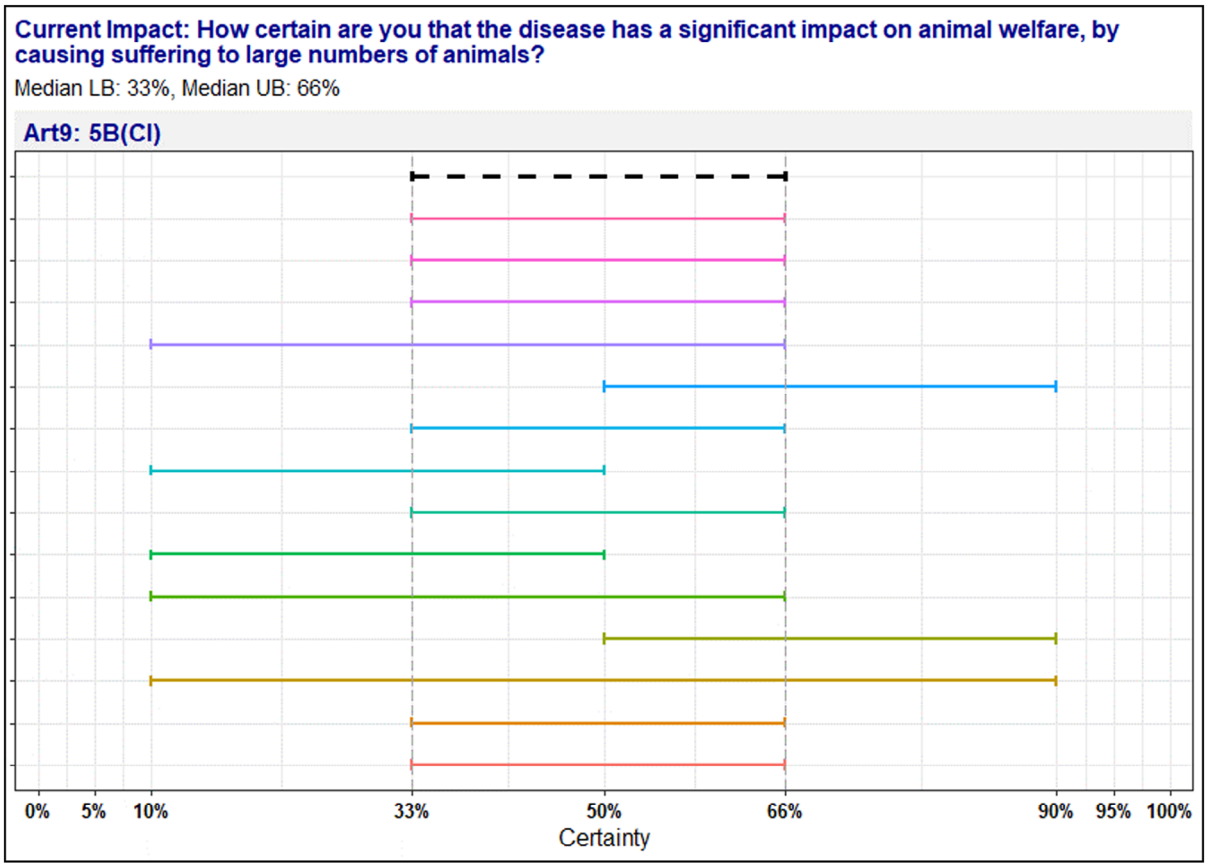


Figure A.30: Individual probability ranges, after the collective judgement, reflecting the uncertain outcome of the criterion 5B (current impact) (the disease has a significant impact on animal welfare, by causing suffering of large numbers of animals). The black dotted line on the top indicates the median

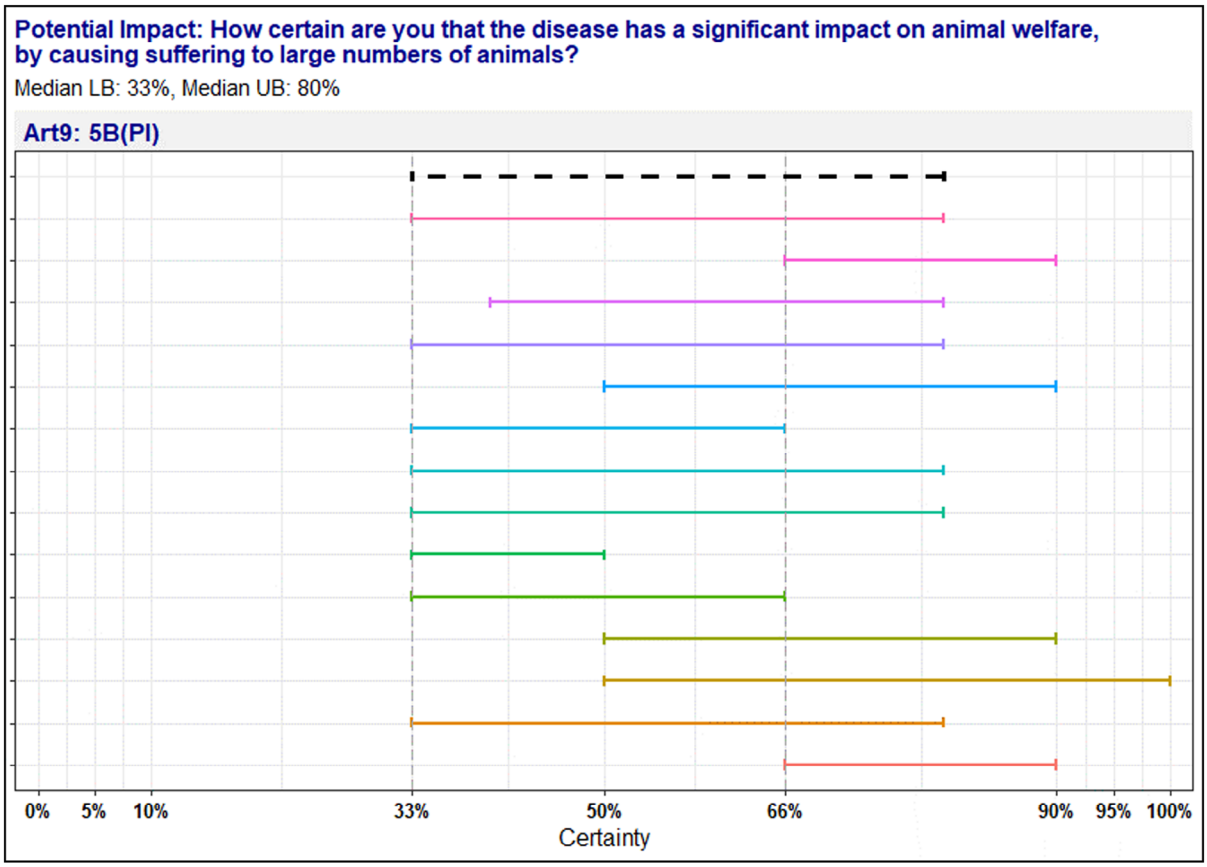


Figure A.31: Individual probability ranges, after the collective judgement, reflecting the uncertain outcome of the criterion 5B (potential impact) (the disease has a significant impact on animal welfare, by causing suffering of large numbers of animals). The black dotted line on the top indicates the median

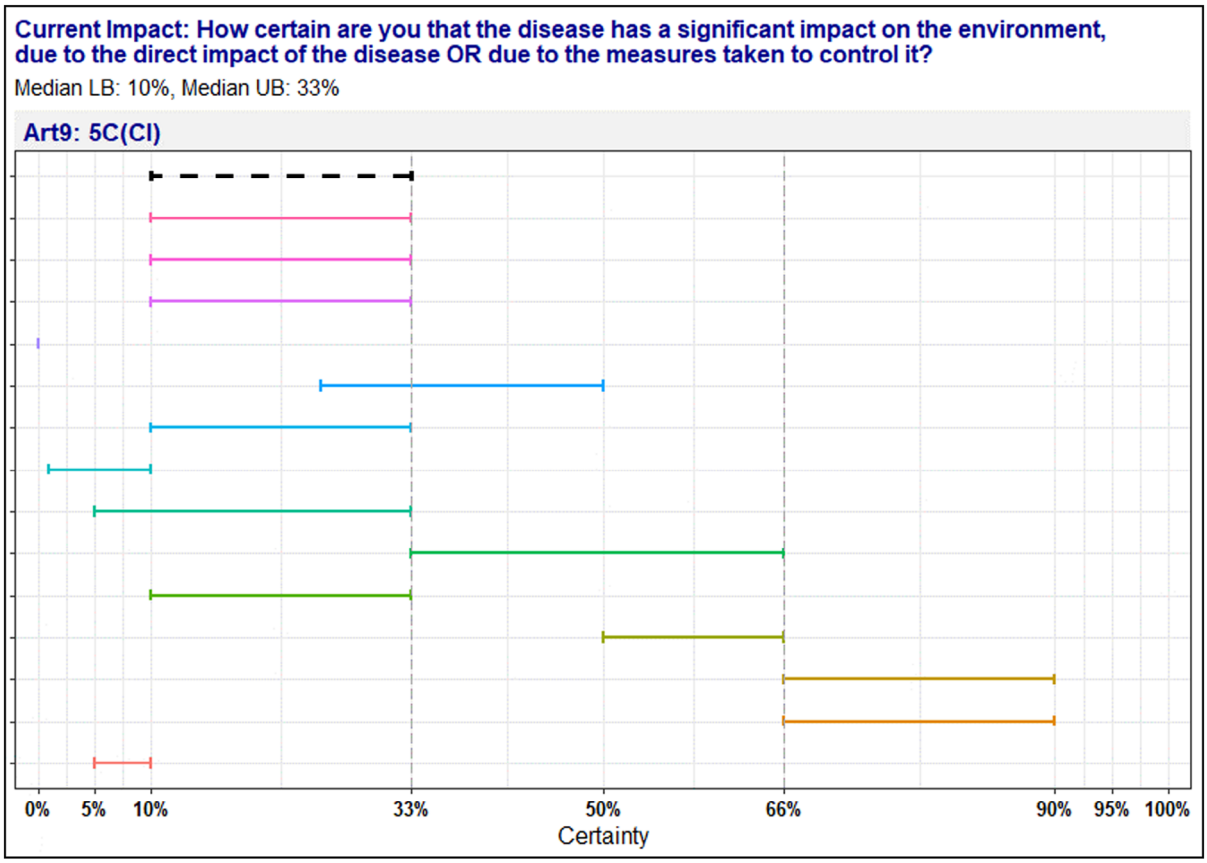


Figure A.32: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 5C (current impact) (the disease has a significant impact on the environment, due to the direct impact of the disease or due to the measures taken to control it). The black dotted line on the top indicates the median

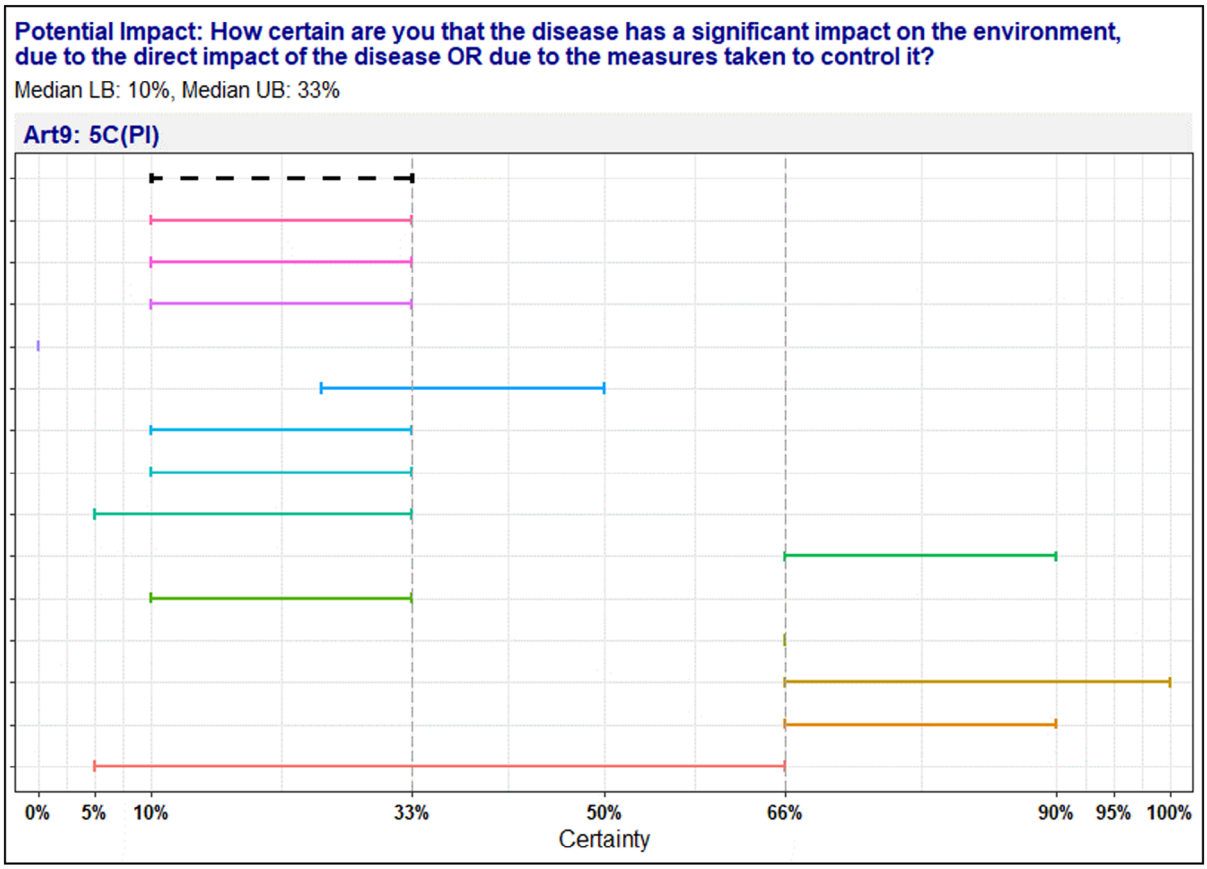


Figure A.33: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 5C (potential impact) (the disease has a significant impact on the environment, due to the direct impact of the disease or due to the measures taken to control it). The black dotted line on the top indicates the median

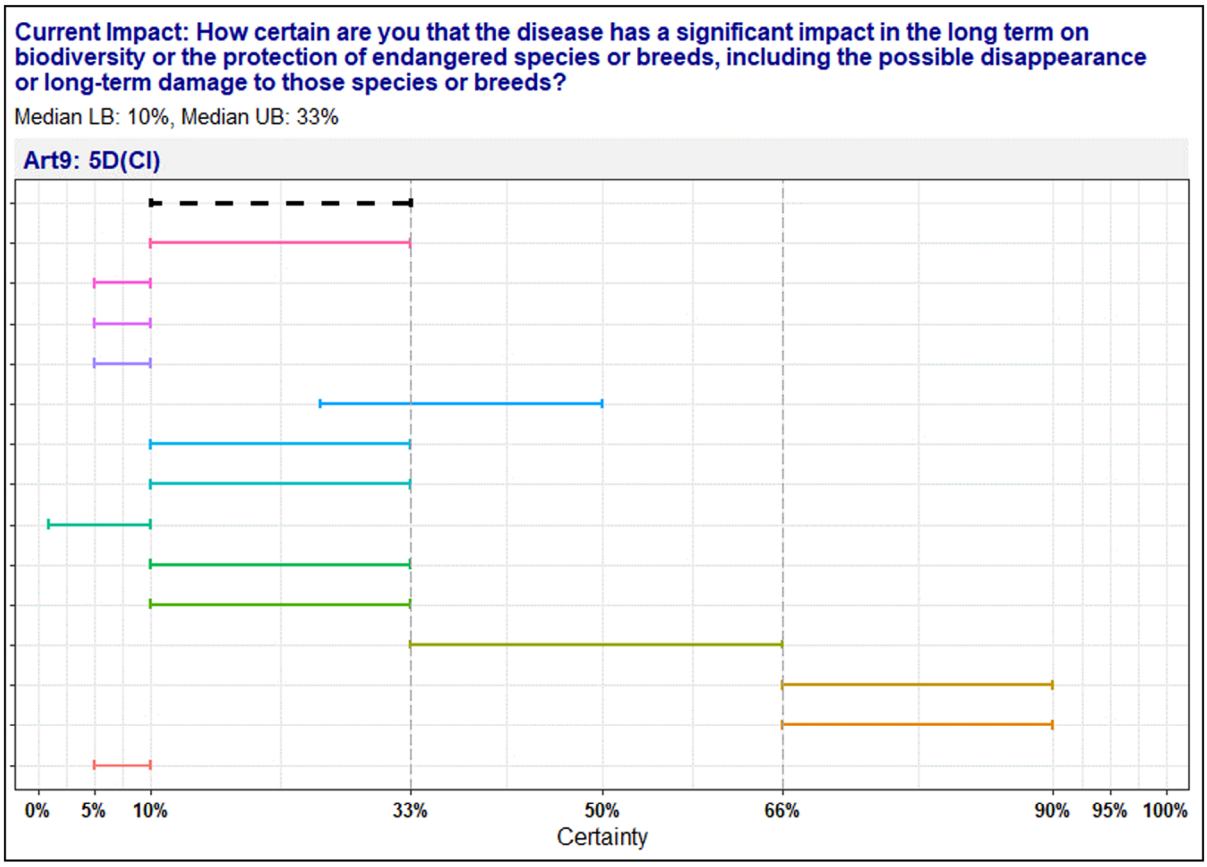


Figure A.34: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 5D (current impact) (the disease has a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds). The black dotted line on the top indicates the median

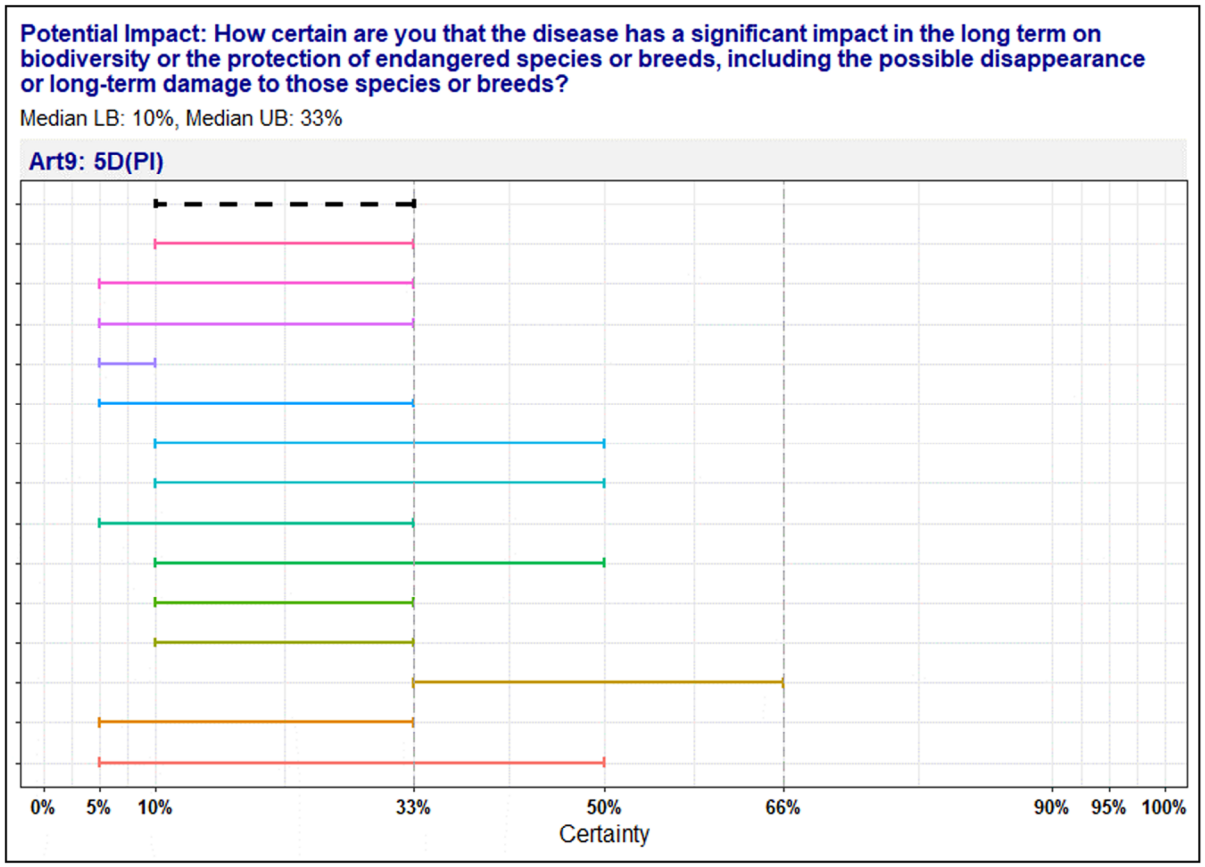


Figure A.35: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 5D (potential impact) (the disease has a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds). The black dotted line on the top indicates the median

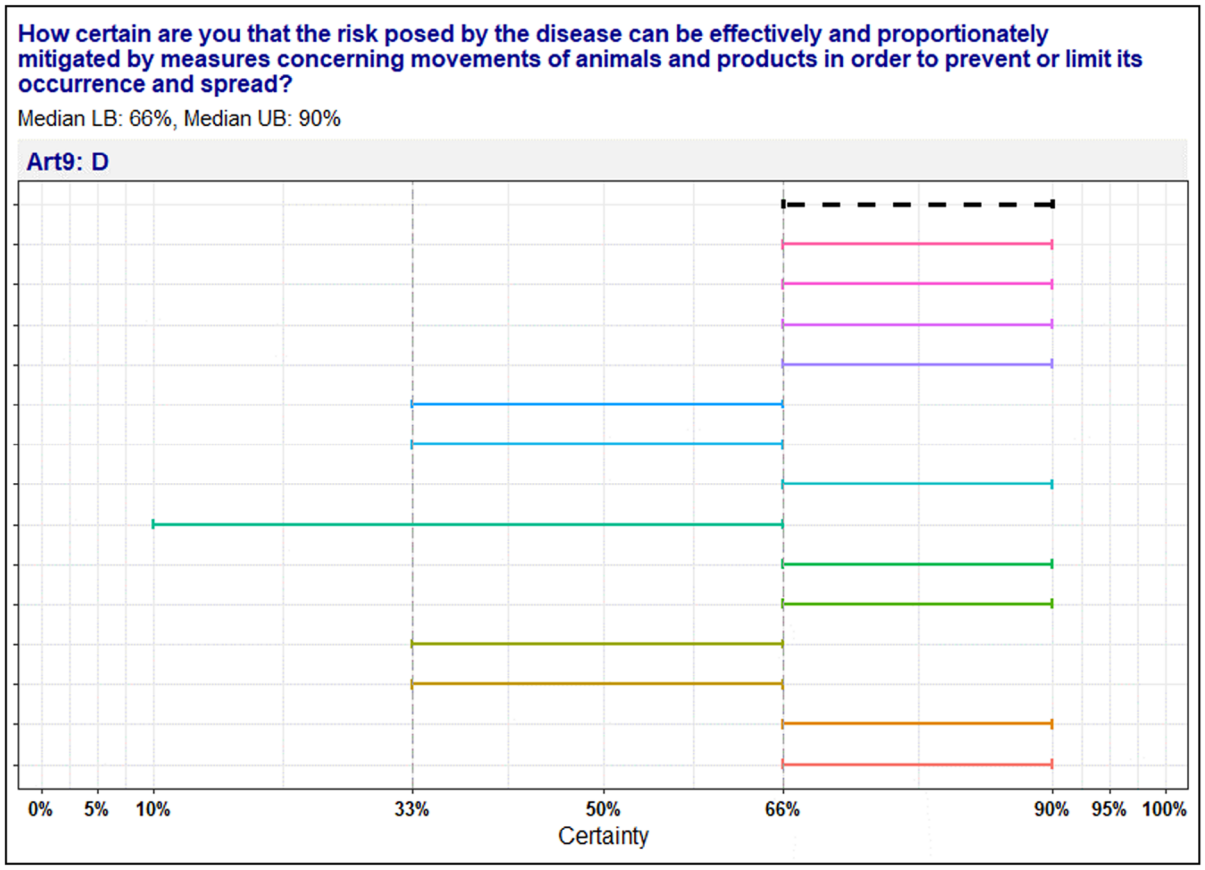


Figure A.36: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion D (the risk posed by the disease can be effectively and proportionately mitigated by measures concerning movements of animals and products in order to prevent or limit its occurrence and spread). The black dotted line on the top indicates the median

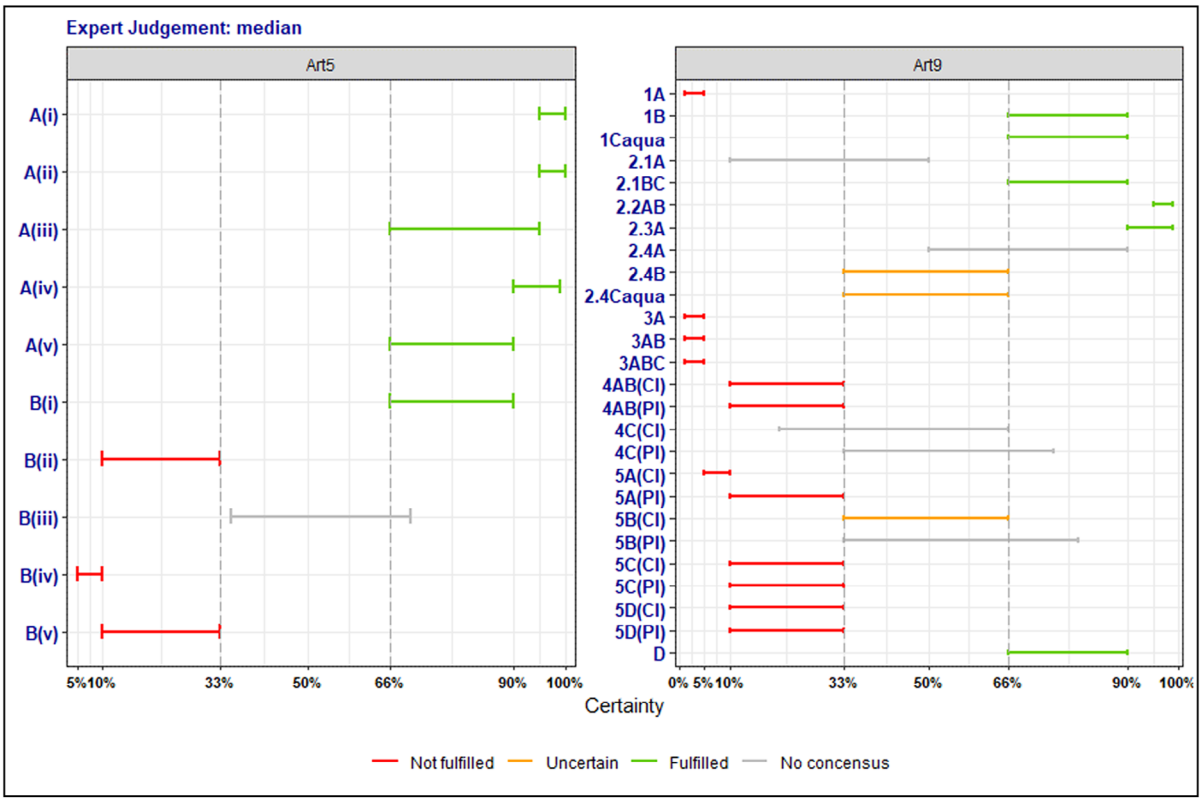


Figure A.37: Medians of the judgement replies in questions related to article 5 (left side) and article 9 (right side)