SCIENTIFIC OPINION

efsa JOURNAL

ADOPTED: 27 September 2023

doi: 10.2903/j.efsa.2023.8327

Assessment of listing and categorisation of animal diseases within the framework of the Animal Health Law (Regulation (EU)2016/429): Infection with salmonid alphavirus (SAV)

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Abstract

Infection with salmonid alphavirus (SAV) 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 infection with SAV. 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 the assessment, it was uncertain whether infection with salmonid alphavirus can be considered eligible to be listed for Union intervention according to Article 5 of the AHL (50–80% 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 infection with salmonid alphavirus does not meet the criteria in Section 1 (Category A; 5–10% probability of meeting the criteria) and it is uncertain whether it meets the criteria in Sections 2, 3, 4 and 5 (Categories B, C, D and E; 50–90%, probability of meeting the criteria). The animal species to be listed for infection with SAV according to Article 8 criteria are provided.

Keywords: aquatic animals, animal health law, salmonid alphavirus, listing, categorisation, impact

Requestor: European Commission

Question number: EFSA-Q-2023-00065

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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 Estelle Méroc selected through the Individual Scientific Advisor schema (ISA expert; EOI/EFSA/SCIENCE/2022/01 – CT 05 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 FEEDAP 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, B., 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): Infection with salmonid alphavirus (SAV). *EFSA Journal*, *21*(10), 1–80. https://doi.org/10.2903/j.efsa.2023.8327

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.

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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

[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.

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.

(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 terms of reference (ToRs) 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, 2017a).

The present document reports the results of the assessment on the infection with salmonid alphavirus (SAV) according to the criteria of the AHL articles as follows:

- Article 7: infection with SAV profile and impact;
- Article 5: eligibility of infection with SAV to be listed;
- Article 9: categorisation of infection with SAV 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 they 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 infection with SAV.

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, 2017a). This ad hoc methodology has been used for assessing any animal disease 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, 2017a) 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, 2017a), five experts from the EFSA WG with expertise in aquatic animal diseases participated in the judgement.

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

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

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

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 05 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 infection with SAV 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, 2017a). 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

Salmonid alphavirus is a single-stranded RNA virus, which belongs to the genus *Alphavirus* within the family *Togaviridae,* and is a pathogen of salmonid aquaculture (Snow et al., 2010). So far, seven genotypes of SAV (SAV1–7) have been identified based on sequence analysis: SAV1,3,4,5,6 typically cause pancreas disease (PD) in seawater Atlantic salmon (*Salmo salar*). SAV2 is divided into two variants: the freshwater variant (SAV2 FW) which is responsible for sleeping disease (SD) in freshwater rainbow trout (*Oncorhynchus mykiss*) and the marine variant (SAV2 MW) which causes PD and has been isolated from diseased Atlantic salmon in Scotland and Norway. The seventh genotype has been detected in ballan wrasse (*Labrus bergylta*) but has not been shown to cause PD in salmonids so far (Tighe et al., 2020). These genotypes all belong to the same virus species, abbreviated as salmon pancreas disease virus (SPDV) by the International Committee on Taxonomy of Viruses (ICTV) (Chen et al., 2018). The primary target organs for SAV are the heart and the pancreas, and it is considered likely that fish become infected through the gills, skin and intestine (Jansen et al., 2017). Clinical signs associated with PD include sudden inappetence, lethargy and an increased number of faecal casts in the cages, as well as mortality. SD is an infectious disease similar to PD, which represents an increasing problem throughout Europe, causing high mortality and growth retardation of fish (Graham et al., 2007a; McLoughlin and Graham, 2007; Deperasińska et al., 2018). Lesions of PD and SD include necrosis of the pancreatic tissue as well as alterations in the heart and the skeletal muscle. In 2014, SAV was listed by the World Organisation for Animal Health (WOAH) (WOAH, 2021; Baumgartner et al., 2022).

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

Susceptible animal species

Note: Farmed and wild aquatic animals cannot be easily distinguished.

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

The species naturally susceptible to SAV are listed in Table 2. Atlantic salmon and rainbow trout are the species with the highest likelihood of infection with SAV, and fish in all life stages are susceptible. Additionally, species for which there is incomplete evidence for susceptibility according to the WOAH include long rough dab (*Hippoglossoides platessoides*), plaice (*Pleuronectes platessa*) and ballan wrasse (*Labrus bergylta*) (WOAH, 2021).

Table 2: Naturally susceptible fish species

Fish species (*Scientific Name*)	Genotype	Reference
Arctic charr (*Salvelinus alpinus*)	SAV2	Lewisch et al. (2018), World Organisation for Animal Health (2022b)
Atlantic salmon (*Salmo salar*)	SAV1-2-3-4-5-6	WOAH (2022a,b)
Common dab (*Limanda limanda)*	SAV5	Snow et al. (2010), Andersen and Blindheim (2022), World Organisation for Animal Health (2022b)
Rainbow trout (*Oncorhynchus mykiss*)	SAV1-2-3	Fringuelli et al. (2008), WOAH (2022a,b)

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

The species naturally susceptible to SAV are listed in Table 2. Atlantic salmon and rainbow trout are the species with the highest likelihood of infection with SAV, and all life stages are susceptible.

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

Wild fish species that were found to be experimentally susceptible to SAV and that are not already mentioned in the list of naturally susceptible fish species in Table 2 are reported in Table 3.

Table 3: Experimentally susceptible fish species

Fish species	Genotype	Experiment setting	Reference
Brown trout (*Salmo trutta*)	Not reported	Infected intra-peritoneally	Boucher et al. (1995)

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

Domestic/farmed fish species that were found to be experimentally susceptible to SAV and that are not already mentioned in the list of naturally susceptible fish species in Table 2 are reported in Table 3.

Reservoir animal species

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

The presence of SAV has been detected by RT-PCR in several species of pleuronectids through survey studies conducted in Ireland and Scotland; SAV RNA was retrieved in heart tissue from common dab (Table 2), European plaice and long rough dab (Snow et al., 2010; Bruno et al., 2014; McCleary et al., 2014; Simons et al., 2016). However, the results of an experimental challenge trial conducted by Andersen and Blindheim (2022) indicated that pleuronectids carrying SAV do not transmit the virus to salmon. Recently, SAV was isolated from a pooled sample of asymptomatic ballan wrasse caught in Ireland (Ruane et al., 2018).

The WOAH has also reported that SAV has been detected by RT-PCR in tissues from the following fish species with no sign of active infection: herring (*Clupea harengus*), longhorn sculpin (*Myoxocephalus octodecemspinosus*), haddock (*Melanogrammus aeglefinus*), Norway pout (*Trisopterus esmarkii*), saithe (*Pollachius virens*), whiting (*Merlangius merlangus*), Atlantic cod (*Gadus morhua*), Argentine hake (*Merluccius hubbsi*), European flounder (*Platichthys flesus*) and brown trout (*Salmo trutta*) (WOAH, 2021). In addition, SAV-neutralising antibodies have been detected in the serum of saithe (*Gadus virens*) sampled from Atlantic salmon cages with SAV-infected fish (Graham et al., 2006).

Additionally, species for which there is incomplete evidence for susceptibility according to the WOAH include long rough dab (*Hippoglossoides platessoides*), plaice (*Pleuronectes platessa*) and ballan wrasse (*Labrus bergylta*) (WOAH, 2021).

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

There is evidence suggesting that some susceptible species that survive outbreaks will become long-term carriers of the virus (Graham et al., 2010), and, in consequence, farmed Atlantic salmon and rainbow trout can be considered the main reservoir species of SAV (Taksdal and Sindre, 2016). In addition, some of the wild reservoir species mentioned in Parameter 5 may also be farmed, for instance Atlantic cod (*Gadus morhua*) and ballan wrasse (*Labrus bergylta*) and could be possible reservoirs.

Vector animal species

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

Unlike other alphaviruses, which typically require an arthropod vector to complete their life cycle, SAV is known to be transmitted directly from one primary host to another host (McLoughlin et al., 1996). However, Petterson et al. (2009) reported the presence of SAV3 RNA in salmon sea louse (*Lepeophtheirus salmonis*) in Norway. Nonetheless, active replication in the lice has not been demonstrated nor has it been possible to infect *L. salmonis* in the laboratory (Karlsen et al., 2015; Karlsen and Johansen, 2017).

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

No domestic/farmed species have been identified as vectors of SAV.

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

The prevalence during SAV outbreaks in farmed Atlantic salmon is variable but usually high (> 70%). The prevalence in wild fish is largely unknown (WOAH, 2021). A few examples of (sero-) prevalence and incidence estimates are described in Table 4.

Table 4: Measures of SAV prevalence and incidence in wild and farmed fish

Country	Time period	Indicator	Study population	Value	Reference
Ireland	2006–2008	Within-farm prevalence	Farmed Atlantic salmon	Range: 80–100%	Graham et al. (2010)
		Within-farm seroprevalence		Range: 63–90%	
Ireland	1990–2007	Yearly farm-level incidence rate	Farmed Atlantic salmon	Range: 59% (2002) to 91% (2007)	McLoughlin et al. (2003), Ruane et al. (2008)
Norway	2013–2021	Yearly farm-level incidence	Farmed Atlantic salmon	100 farms (2013 and 2021)	Sommerset et al. (2022)
			Rainbow trout	176 farms (2017)	
Norway	2012	Animal-level prevalence	Wild Atlantic salmon	< 0.89%	Madhun et al. (2018)
Norway	2008–2011	Yearly farm-level incidence	Farmed Atlantic salmon	Range: 75 farms (2009)-105 farms (2008)	Bang Jensen et al. (2012)
			Rainbow trout		
Norway	2006–2008	Farm-level prevalence	Farmed Atlantic salmon	63.9% (95% CI: 46.2–78.7)	Jansen et al. (2010a)
Norway	1998–2007	Yearly farm-level incidence	Farmed Atlantic salmon	Range: 7 farms (1998) –98 farms (2007)	Ruane et al. (2008)
Norway	1996–2004	Animal-level seroprevalence	Farmed Atlantic salmon and rainbow trout	70%	Taksdal et al. (2007)
		Animal-level prevalence		90%	
UK	2004	Animal-level seroprevalence	Farmed rainbow trout	29%	Graham et al. (2007b)
		Animal-level prevalence		58%	
UK	2002	Within-farm seroprevalence	Farmed Atlantic salmon	90%–100%	Graham et al. (2005)
UK (Scotland)	2006–2007	Farm-level prevalence	Farmed Atlantic salmon	16%	Lester et al. (2011)
			Farmed rainbow trout	25%	

PD: Pancreas disease; SAV: Salmonid alphavirus; UK: United Kingdom.

Parameter 2 – Case-morbidity rate (% of infected animals that show clinical disease)

Graham et al. (2006) conducted a prospective longitudinal study of SAV infections in farmed Atlantic salmon and described cases of subclinical infection (Graham et al., 2006). A Norwegian field study detected SAV-RNA in fish up to 71 weeks prior to the outbreak of clinical disease at the site (Jansen et al., 2010a). Aldrin et al. (2015) reported that up to one-third of SAV-infected salmon populations do not develop clinical PD. In Norway, infections with marine SAV2 are reported to generate a higher proportion of subclinical cases than SAV3 infections (Jansen et al., 2015, 2017). Differences in susceptibility between salmon families have also been reported (McLoughlin et al., 2006).

Parameter 3 – Case-fatality rate (% of infected animals that die from the disease)

The cumulative mortality of PD at the farm level varies widely from very low to over 50% in severe cases (Graham et al., 2003). For instance, in Ireland, annual mortality from 2000 to 2010 ranged between 14% and 18%, reaching 40% in badly affected cages (McCleary et al., 2014). Examples of farm-level mortality estimates obtained during field outbreaks are described in the following Table 5.

Table 5: Mortality estimates observed during field outbreaks in European countries

Country	Study period	Indicator	Study population	Values (n = number of estimates)	Reference
Ireland	2006–2008	PD-related mortality	Farmed Atlantic salmon	(n = 2): 10.9% and 30%	Graham et al. (2010)
Ireland	2003–2004	PD-related mortality	Farmed Atlantic salmon	Mean (n = 13): 18.8% (range: 2–27%)	Rodger and Mitchell (2007)
Ireland	2001–2003	PD-related mortality	Farmed Atlantic salmon	Mean (n = 13): 12% (range: 1–42%)	McLoughlin et al. (2003)
Ireland	1990–2007	PD-related mortality	Farmed Atlantic salmon	Range of yearly means (n: each year between 59% and 91% of Irish marine salmon sites): 4% (1993)–23% (2007)	Crockford et al. (1999), McLoughlin et al. (2003), Ruane et al. (2008)
Norway	2003–2007	PD-related mortality	Farmed salmonids	Mean range (n = 150): 4% (2006), 11% (2003)	Stormoen et al. (2013)
Norway	2007–2009	PD-related cumulative mortality	Farmed Atlantic salmon	Mean (n = 52): 22.6% (SD = 13.2)	Bang Jensen et al. (2012)
Norway	2006–2008	PD-related mortality	Farmed Atlantic salmon	Mean (n = 20): 6.9% (range: 0.7–26.9%)	Jansen et al. (2010a)
Norway	1996–2004	PD-related mortality	Farmed Atlantic salmon and rainbow trout	Range (n = 31): 3–20%	Taksdal et al. (2007)
Norway	2006–2011	PD-related mortality	Farmed Atlantic salmon	Mean (n = 28): 21.6% (range: 6.1–68.6%)	Stene et al. (2014a)
Switzerland	2013	SD-related mortality	Farmed rainbow trout	Range (n = 3): 2–8%	Schmidt-Posthaus et al. (2014)

n: number of outbreaks.

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 indicating that SAV can infect 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

Not applicable. No effective treatment for SAV is currently available.

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

In order to study PD transmission dynamics among salmon farms in Norway, Stene et al. (2014b) assumed that the infectious period lasted until the infected cohort was harvested. Indeed, a previous prospective longitudinal study observed that once SAV RNA was detected by RT-PCR at a site, it was persistently found until the end of the study period, up to 19 months after the first detection (Jansen et al., 2010b).

In a cohabitant trial conducted in Atlantic salmon, the testing of faeces from the SAV genotypes 1, 3 and 6 challenge groups found positive results in each group, beginning at 1–3 weeks post-challenge (wpc) and remaining detectable for a further 2–3 weeks. Parallel testing of mucus samples found these positive at 2–3 wpc and they remained positive for a further 1–3 weeks (Graham et al., 2011).

In the context of a prospective longitudinal study of SAV infection in farmed Atlantic salmon, which aimed to gain a better understanding of the epidemiology of a natural outbreak of PD, the first evidence of infection was detected on day 146 when four of 20 fish were found to be viraemic by inoculating sera onto chinook salmon embryo-214 cells and staining after 3 days, and 1 out of 20 to be antibody positive. At the following sampling on day 153, only two of 20 fish were viraemic and 1 antibody positive. At the next sampling (day 158), no viraemic or antibody positive fish were detected. However, throughout the study period, there were no clinical signs of PD and no significant mortality attributed to PD (Graham et al., 2006).

Parameter 2 – Presence and duration of latent infection period

Desvignes et al. (2002) detected SAV by 2 days post-challenge in all experimentally infected Atlantic salmon parr, and the peak value of viraemia was reached 4 days after the challenge.

Based on analyses of antibody production during cohabitation trials, the incubation period of PD has been estimated to be 7–10 days at a water temperature of 12–15°C (McLoughlin and Graham, 2007). From field data, survival analysis demonstrated that cohorts exposed to the virus at decreasing sea temperature had a significantly longer incubation period than cohorts infected when the sea temperature was increasing (Stene et al., 2014a).

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

Prolonged persistence of a positive PCR signal by real-time RT-PCR can be found in infected populations, with the majority of populations remaining PCR positive until slaughter even when infected early during the seawater phase (Graham et al., 2010; Jansen et al., 2010a; Jansen et al., 2017). SAV has been grown in cell culture from tissues of infected fish at least 4–6 months after the initial SAV detection at a site (Jansen et al., 2010b).

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)

SAV has re-emerged at some farms following restocking, and the persistence of the virus in sediments may serve as a source of infection (Jones et al., 2015). SAV can remain infectious under experimental conditions for a long period in sterile seawater (McLoughlin and Graham, 2007). Testing was conducted under sterile conditions in seawater, half-strength seawater and fresh (hard) water, both in the absence and presence of added organic matter. SAV survival was shown to be inversely related to temperature and to be reduced by the presence of organic matter, with half-lives ranging from 1.5 to 61 days (Graham et al., 2007c). Skjold (2014) observed that SAV survive less than 72 hours in the natural environment, given a seawater temperature of around 10°C.

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)

The main transmission route of SAV appears to be horizontal and via water contact. This has been supported by both experimental trials and field observations (Deperasińska et al., 2018; WOAH, 2021). Virus excretion is believed to be through natural excretion/secretion, which is supported by the detection of SAV-RNA in faeces and mucus from SAV-infected fish, as well as in the lipid surface layer around SAV-infected cages (Graham et al., 2012; Stene et al., 2016; Jansen et al., 2017).

The Norwegian Scientific Committee for Food Safety carried out a risk assessment and concluded that the risk of vertical transmission of SAV is negligible (Rimstad et al., 1991; Jansen et al., 2017; WOAH, 2021).

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

There is no evidence of SAV transmission between animals and humans.

Speed of transmission

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

Data on the incidence of SAV in fish have been described previously (see Section 1.2 Morbidity – Parameter 1).

There is no evidence of SAV transmission between animals and humans.

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

Three studies reported relevant epidemiological characteristics: One study reported transmission rate for SAV and two studies reported basic reproduction number (Table 6):

Table 6: Transmission rate (beta) and basic reproduction number (R_0) for infection with salmonid alphavirus

Country	Indicator	Study population	Value	Reference
United Kingdom	Basic reproduction number PD	Farmed Atlantic salmon	~ 1.0	Graham et al. (2006)
Norway	Basic reproduction number PD	Farmed Atlantic salmon	Range:1.0 and 2.9	Tavornpanich et al. (2013)
Norway	Transmission rate PD (time unit = monthly)	Marine farmed salmonids	Range: ~ 0 (September) to ~ 3 (June)	Aldrin et al. (2015)

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 reported to be present in EU

The following map displays EU World Animal Health Information System (WOAH-WAHIS) data reflecting the epidemiological situation of SAV outbreaks as reported by veterinary authorities from Member States (MSs) (Figure 1):

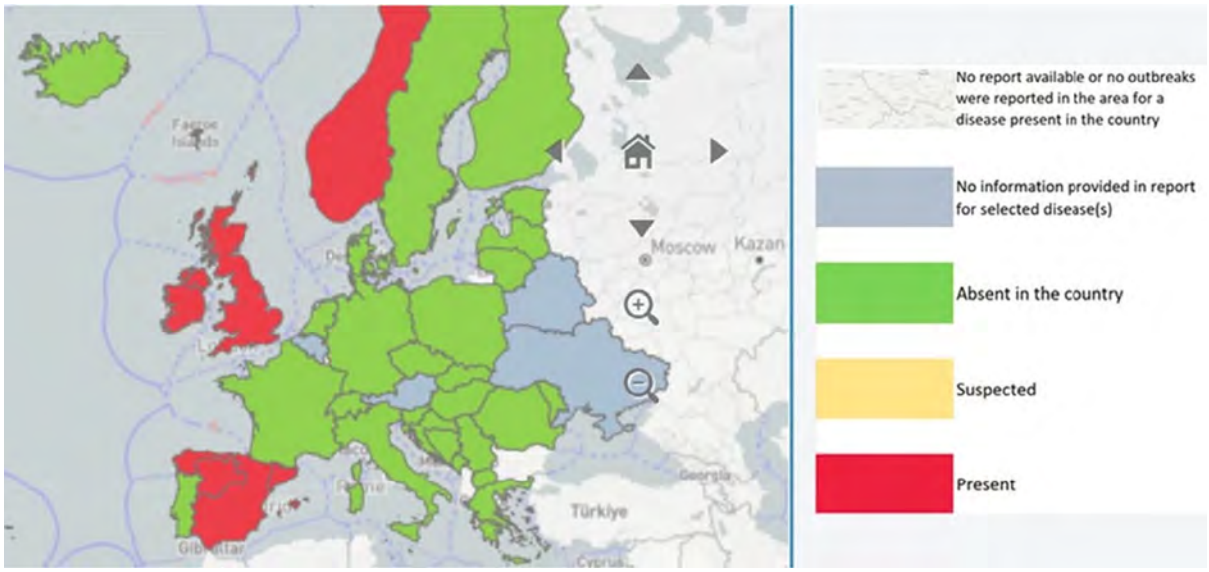


Figure 1: SAV outbreaks in Europe as reported by Veterinary Authorities to WOAH from 2018 to 2022; Source of the map: WOAH-WAHIS[3]

[3] https://wahis.woah.org/#/dashboards/country-or-disease-dashboard

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

Jansen et al. (2017) described the distribution of PD in Europe. The authors reported that 62% and 86% of salmonid sites in Ireland were affected by PD, in 2003 and 2004, respectively. In 2007, a large part of Western Norway became defined as a SAV3 zone, where PD was considered endemic. Sporadic outbreaks of PD north of the endemic zones have been controlled up to 2017 by depopulation. Rodger and Mitchell (2007) reported that PD was endemic in most salmon marine sites in Ireland and in historically infected sites in other countries; and that the disease tended to recur in each successive generation of fish introduced onto the site irrespective of the duration of the fallowing period (McLoughlin and Graham, 2007).

Risk of introduction

Parameter 3 – Routes of possible introduction

Not applicable. SAV has already been introduced in several EU countries.

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

Not applicable. SAV has already been introduced in several EU countries.

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

Not applicable. SAV has already been introduced in several EU countries.

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

Not applicable. SAV has already been introduced in several EU countries.

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

Not applicable. SAV has already been introduced in several EU countries.

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

Not applicable. SAV has already been introduced in several EU countries.

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

Diagnostic tools

Parameter 1 – Existence of diagnostic tools

A preliminary and indirect diagnosis can be based on gross clinical signs and histopathology, but because other pathogens may produce similar signs, the identification of viral molecules is required to confirm SAV infection (Karlsen and Johansen, 2017). The diagnosis of SAV is currently based on a combination of histopathological examination, antibody detection, virus culture and PCR technique (Deperasińska et al., 2018). The WOAH recommends the following: 1. Real-time RT-PCR for the surveillance of apparently healthy animals and for the presumptive diagnosis of clinically affected animals; and 2. amplicon sequencing for the confirmation of a suspect result from surveillance or presumptive diagnosis (WOAH, 2021).

Control tools

Parameter 2 – Existence of control tools

Different tools, including biosecurity measures, vaccination, movement restrictions and selective breeding of resistant strains, are currently available in order to control SAV (Deperasińska et al., 2018).

The disease is managed as an endemic disease in Ireland and Scotland. It is managed as an endemic disease in western to mid-Norway, but in Northern parts of Norway, which are considered free of the disease, is treated as an exotic disease and emergency measures should be implemented. In 2006, the regional industry established the 'Hustadvika barrier', a 15–20 km zone with no farming activities in mid-Norway, on the frontier between the endemic and non-endemic areas, with the purpose of preventing disease dissemination into the densely farmed areas further north in mid-Norway. Government regulations have been in place since 2007 requiring the depopulation of infected sites in disease-free areas and alterations to management practices in the endemic area (Pettersen et al., 2015b). In a new regulation from 2017, a PD endemic zone was defined from Jæren in the south to the mid-Trøndelag. The areas south and north of this zone were defined as PD-free

surveillance zones (Norwegian Veterinary Institute, 2022). Mandatory screening of all seawater production sites was also introduced at this time. There has been a significant decline in clinical SAV cases in the SAV3 endemic area at the west coast. The cause of this decline has yet to be investigated, but may be an effect of increased biosecurity measures, vaccination or a combination of these and other unknown factors (Sommerset et al., 2022).

Jansen et al. (2017) highlighted that, except for vaccination, there is currently very limited scientific knowledge regarding the impact of other management strategies for SAV, and the authors suggested further investigations be conducted.

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 notification and reporting of SAV is not mandatory at the EU level (cf. Article 5 of Regulation (EU) 2016/429). According to the European Union Reference Laboratory (EURL) for Fish and Crustacean Diseases,[4] between 2014 and 2021 SAV was detected in Austria, France, Germany, Ireland, Norway*, Poland, Serbia, Spain, Switzerland* and the United Kingdom (Scotland)*. As set out in Annexes I and II of the Commission Implementing Decision (EU)2021/260, the continental parts of Finland are currently regarded as being free of SAV.

*Not part of the European Union, but important considerations in the region.

The loss of production of the disease

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

Biomass lost through mortalities contributes to one part of the loss, but poor growth and a reduction in fillet quality are also major consequences of infection (Karlsen and Johansen, 2017).

A review of farm records from one of Scotland's largest salmon producers revealed that from 2000 to 2009 PD accounted for the loss of 8.6% of total salmon biomass (Kilburn et al., 2012).

An 11.4% loss in growth over a 2-year period (2003 and 2004) has been associated with PD outbreaks in Ireland (Rodger and Mitchell, 2007).

Similarly, Norwegian field data have shown PD-affected fish groups have reduced growth rates compared to unaffected fish groups (Bang Jensen et al., 2012). In Norwegian SAV-infected Atlantic salmon farms, the production was reduced to 70% (P5:57% and P95:81%) of saleable biomass (Aunsmo et al., 2010).

A study concluded that the most important consequences of PD caused by SAV2 infection is reduced growth and feed conversion in large Atlantic salmon; the estimated impact corresponded to a growth reduction of 0.7 kg and 0.07 points increase in feed conversion ratio (Røsæg et al., 2019).

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

Transmissibility between animals and humans

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

There is no evidence in the literature that SAV infects humans.

Parameter 2 – Incidence of zoonotic cases

There is no evidence in the literature that SAV infects humans.

Transmissibility between humans

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

There is no evidence in the literature that SAV infects humans.

[4] https://www.eurl-fish-crustacean.eu/fish/survey-and-diagnosis

Parameter 4 – Sporadic, endemic, epidemic or pandemic potential.

There is no evidence in the literature that SAV infects humans.

Parameter 5 – Disability-adjusted life year (DALY)

There is no evidence in the literature that SAV infects humans.

The availability of effective prevention or medical treatment in humans

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

There is no evidence in the literature that SAV infects humans.

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

There is no evidence in the literature that SAV infects humans.

3.1.2.3. Article 7(b)(iii) The impact of the disease on animal welfare

Parameter 1 – Severity of clinical signs at case level and related level and duration of impairment

The clinical progression of natural PD infection occurring in the seawater phase of the production cycle is typically characterised by three histologically distinct phases. The initial acute phase lasts for up to 10 days at 2–14°C, during which time infected fish may exhibit external signs such as lethargy, inappetence and production of yellow faecal casts due to lack of feeding. During this phase, inflammation in the pancreas and heart are also histologically detectable. The subacute phase lasts around 10–21 days from the onset of clinical signs and is characterised by histological lesions in pancreatic tissue, heart and skeletal muscle. Skeletal muscle lesions are the predominant histological feature observed in the chronic stages of infection, usually lasting for up to 42 days (Herath et al., 2017).

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

Biodiversity

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

The long rough dab, one of the species with incomplete evidence for susceptibility according to the WOAH (Section 3.1.1.1 *Susceptible animal species*) is listed as 'Endangered' in the IUCN list.

Parameter 2 – Mortality in wild species

No information was found in the literature. However, in a Norwegian surveillance programme conducted among 453 wild Atlantic salmon and 100 wild sea trout caught in areas where SAV3 is endemic with frequent outbreaks of PD, only one released Atlantic salmon smolt tested positive for SAV3. In conclusion, it appears that while SAV is highly prevalent within the Norwegian aquaculture industry, it is found only at a low prevalence in wild brood fish (Biering et al., 2013). Similarly, no SAV antibodies were found in serum from wild salmonids in river systems in Northern Ireland, despite their proximity to SAV-infected aquaculture sites (Graham et al., 2003; Jansen et al., 2017). SAV infection seems to occur at low levels in wild salmonid and non-salmonid fish and there is no evidence that infections are associated with disease.

Environment

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

As discussed previously (Section 3.1.1.5 Parameter 4 Persistence of the disease in an animal population or the environment), SAV may also survive in the environment such as in the water. Nevertheless, it does not seem to cause mortality in wild susceptible species (Section 3.1.2.4 Parameter 2 mortality in wild species).

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

SAV is not listed by the Center for Food Security and Public Health (CFSPH).[5]
SAV is listed as a notifiable disease by WOAH.[6]

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

SAV 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

SAV is not listed as a potential bio–agro-terrorism agent.

3.1.4. Article 7(d) The feasibility, availability and effectiveness of the following disease prevention and control measures

3.1.4.1. Article 7(d)(i) Diagnostic tools and capacities

Availability

Parameter 1 – Officially/internationally recognised diagnostic tool, WOAH certified

See Section 3.1.1.8 Diagnostic tools.

Effectiveness

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

The sensitivity and specificity of the tests available for SAV diagnosis are described in Table 7 (WOAH, 2021).

Table 7: Tests available for the diagnosis of SAV in Atlantic Salmon, and their reported sensitivity and specificity. Source: summarised from WOAH (2021)

Test	Species	Se	Sp	Reference
Real-time PCR	Atlantic salmon	0.39	0.83	Hall et al. (2014), Jansen et al. (2019)
		0.98	> 0.99	Jansen et al. (2019)
Isolation of SAV in cell culture	Atlantic salmon	0.5	0.99	Hall et al. (2014), Jansen et al. (2019)
		0.95	> 0.99	Jansen et al. (2019)
Detection of neutralising activity against SAV	Atlantic salmon	0.085	0.74	Jansen et al. (2019)
Histopathology	Atlantic salmon	0.637	0.967	Jansen et al. (2019)

Se: sensitivity; Sp: specificity.

Feasibility

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

The type of samples to be tested for SAV diagnostic are described in Table 8 summarised from the WOAH (2021):

Table 8: Types of tissues and samples to be tested for SAV diagnosis in Atlantic salmon. Source: summarised from WOAH (2021)

Test	Species	Tissue or sample type	Reference
Real-time PCR	Atlantic salmon	Kidney Heart and mid-kidney	Hall et al. (2014), Jansen et al. (2019)

[5] https://www.cfsph.iastate.edu/diseaseinfo/
[6] https://www.woah.org/en/what-we-do/animal-health-and-welfare/animal-diseases/
[7] http://www.australiagroup.net/en/human_animal_pathogens.html

Test	Species	Tissue or sample type	Reference
Isolation of SAV in cell culture	Atlantic salmon	Heart ventricle and head-kidney	Hall et al. (2014), Jansen et al. (2019)
Detection of neutralising activity against SAV	Atlantic salmon	Serum or plasma	Jansen et al. (2019)
Histopathology	Atlantic salmon	Heart and mid-kidney	Jansen 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.)

DNA-based and cell-culture-based virus-inactivated vaccines against PD in Atlantic salmon (*Salmo salar*) are both commercially available (WOAH, 2021). In 2017, the European Medicines Agency (EMA)[8] issued a marketing authorisation for a DNA vaccine against PD in Atlantic salmon (CLYNAV™, Elanco GmbH) for all EU Countries. The commercially available vaccines in different countries in Europe found in the literature are provided in Table 9. Vaccines against SD in trout populations are not yet available.

Table 9: Vaccines against PD in Atlantic salmon (*Salmo salar*) commercially available in Europe

Vaccine name	Company	Countries	Type	Administration	Duration of protection
ALPHA JECT® micro 1 PD	Pharmaq AS, (now part of Zoetis)	Ireland, Norway, UK	Inactivated SAV3 (strain ALV 405)	Intraperitoneal injection	At least 12 months
AQUAVAC® PD3 (Trivalent vaccine)	Intervet/MSD Animal Health Ireland (former Intervet)	Ireland, UK	Inactivated for SAV1 (strain F93-125), IPNV and Aeromonas salmonicida	Intraperitoneal injection	15 months
AQUAVAC® PD7 (Heptavalent vaccine)	Intervet/MSD Animal Health	Norway	Inactivated for SAV1 (strain F93-125), IPN, *Aeromonas salmonicida, Aliivibrio salmonicida, Vibrio salmonicida, Vibrio anguillarum (O1, O2a), Moritella viscosa*	Intraperitoneal injection	At least 16 months
Norvax® Compact PD	Intervet/MSD Animal Health (former Intervet)	Ireland, Norway, UK	Inactivated SAV1 (strain F93-125)	Intraperitoneal injection	12–18 months
CLYNAV™	Elanco GmbH Animal Health	EU (authorisation by EMA), Norway	Recombinant DNA plasmid of SAV3 virus	Intramuscular injection	9.5–12 months

Bang Jensen et al. (2012), Deperasińska et al. (2018).
Summary of Product Characteristics (SPC): ALPHA JECT micro 1 PD (HPRA, 2015b), AQUAVAC® PD3 (HPRA, 2015a), AQUAVAC® PD7 (The Norwegian Medicines Agency, 2015), Norvax® Compact PD:(HPRA, 2015a), CLYNAV™ (EMA, 2017).

Parameter 2 – Availability/production capacity (per year)

No data were found in the literature about the availability and the production capacity of the vaccines.

Effectiveness

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

The Norvax® Compact PD vaccine demonstrated a reduction in mortality of at least 50% in vaccinated fish compared with unvaccinated fish at the same farm. Vaccination with Norvax® Compact

[8] European Medicines Agency: https://www.ema.europa.eu/en

PD has been used in the Norwegian aquaculture of salmon since 2007, and has reduced the number of outbreaks in Norwegian salmon farms, the cumulative mortality and the number of discarded fish at slaughter as well as increased the growth rate compared to non-vaccinated farms (Bang Jensen et al., 2012; Deperasińska et al., 2018).

In two controlled field studies, the efficacy of three commercially SAV vaccines available in Norway was compared by measuring mortality and growth in farmed Atlantic salmon experiencing natural SAV2 and SAV3 outbreaks. Only the group immunised with the Clm6 vaccine (DNA-based vaccine CLYNAV™) provided protection against mortality compared with the control group, (reduction in mortality of 1.31% [CI 95: 0.8–1.8]). Significant protection against PD-induced loss of growth was similarly only found in the Clm6 group, with increased harvest weight estimated at 0.43 and 0.51 kg compared with the control group of the two controlled field studies (Røsaeg et al., 2021).

In the context of a survey carried out in 2021 among fish health personnel and inspectors at the Norwegian Food Safety Authority, it was reported that of the respondents with experience with vaccination against PD (N = 43), approximately 50% stated that they have not observed PD disease after vaccination. A further 37% reported that there was less disease in vaccinated than in non-vaccinated fish. Some of the respondents linked this to vaccination with the DNA vaccine (Sommerset et al., 2022). In addition, vaccination results in reduced viral shedding from infected fish (Skjold et al., 2016; Sommerset et al., 2022).

Parameter 4 – Duration of protection

According to the SPCs of the vaccines, the duration of immunity able to protect fish against SAV varies per vaccine: (i) at least 12 months for ALPHA JECT® micro 1 PD vaccine, (ii) 15 months for AQUAVAC® PD3, (iii) at least 16 months for AQUAVAC® PD7, (iv) at least 12 months for reduction of heart lesions and 18 months for reduction of mortality and weight loss for Norvax® Compact PD, (v) 1 year for reduction in impaired daily weight gain, and cardiac, pancreatic and skeletal muscle lesions and 9.5 months for reduction of mortality (demonstrated in a laboratory efficacy study in saltwater conditions using a cohabitation challenge model) for CLYNAV™.

Feasibility

Parameter 5 – Way of administration

Vaccines against SAV are usually administered by intraperitoneal injection (Gomez-Casado et al., 2011).

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

Availability

Parameter 1 – Types of drugs available on the market

No effective treatment for SAV is currently available.

Parameter 2 – Availability/production capacity (per year)

As currently there is no treatment available for SAV, Parameter 2 is not applicable for the assessment.

Parameter 3 – Therapeutic effect in the field (effectiveness)

As currently there is no treatment available for SAV, Parameter 2 is not applicable for the assessment.

Feasibility

Parameter 4 – Way of administration

As currently there is no treatment available for SAV, Parameter 4 is not applicable for the assessment.

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

Availability

Parameter 1 – Available biosecurity measures

To avoid infection with SAV good husbandry practices are recommended, such as the use of appropriate sites for farming, segregation of generations, stocking with good quality fish, removal of dead fish, regular cleaning of tanks and pens and control of parasites and other pathogens, as well as careful handling of fish. Once an outbreak has started, mortality may be reduced by minimising handling and ceasing feeding (WOAH, 2021).

Ruane et al. (2008) recommended to maintain a high level of site biosecurity with emphasis on: (i) biosecurity measures for personnel, visitors and equipment, (ii) using a single bay management strategy, (iii) fast fish for 5–10 days on a pen-by-pen basis if pancreas disease is detected at an early stage and (iii) removing dead fish from the pens frequently.

SAV is rapidly inactivated at pH 4 and pH 12, after heating 1 h to 60°C, as well as by UV light. Commercially available disinfectants have been tested for efficacy against SAV under different conditions, all being found to be effective under at least some of the conditions tested (Graham et al., 2007a). Therefore, treatment and disposal of dead fish during an outbreak using the common practices of ensiling (low pH), alkaline hydrolysis (high pH) or composting (high temperatures) can effectively inactivate the virus (Ruane et al., 2008). Standard disinfection procedures are considered sufficient to prevent surface contamination of eggs by SAV (WOAH, 2021).

Proper boat and transporter cleaning and disinfection are also critical to control the spread of all infectious agents. The efficient removal and safe disposal of dead fish may reduce the viral challenge. Biosecure killing methods and safe disposal of offal and effluent are also key to minimising the risk from these processes. Good sea lice control is desirable as sea lice may act as reservoirs or vectors of SAV even though there is no evidence that they can transmit SAV to the susceptible species (McLoughlin and Graham, 2007).

Fallowing of farm sites reduces or limits the build-up of SAV, a practice that is required in many countries (Jones et al., 2015).

Effectiveness

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

In 2007, the Norwegian aquaculture industry instigated the 'PD-free' project to control PD and reduce the losses through several mitigation measures including better utilisation of suitable sites, closure of poor sites, grouping sites with a single year class, etc. The project evaluation showed a 24% reduction in PD outbreaks in the first 2 years of implementation (2007–2009), and a 10% reduction of the overall losses from 2007 to 2010 (Jansen et al., 2017).

Feasibility

Parameter 3 – Feasibility of biosecurity measure

Holding fish while awaiting test results relies on having suitable biosecurity systems to hold the fish in a sustainable manner. Such systems must have sufficient space to hold the stock, have the ability to feed the fish and maintain the environmental quality of the water they are held in (Depner, 2017).

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

Availability

Parameter 1 – Available movement restriction measures

Since 2007, restrictions have been applied in Norway for the movement of infected fish to avoid the spread of SAV (Aslam et al., 2020). The Norwegian coastline is divided into one endemic and two non-endemic zones and SAV is notifiable in all zones. In the endemic zone, restrictions on the movement of fish are imposed on farms with either a suspicion or a confirmed diagnosis of SAV. In the non-endemic zones, SAV is as a general rule controlled by stamping-out farms with a confirmed diagnosis of SAV unless the risk of disease transmission is considered low (Bang Jensen et al., 2021).

Since 2014, SAV has been included in the list of infectious fish diseases at WOAH. As a consequence, countries that can document freedom from this disease are allowed to refuse to import salmonids from SAV-affected areas.

Effectiveness

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

No information was found in the literature.

Feasibility

Parameter 3 – Feasibility of restriction of animal movement

No information was found in the literature.

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

Availability

Parameter 1 – Available methods for killing animals

Norway aims to control the spread of SAV beyond the endemic zones by depopulation. Sites within a 10 km radius of a depopulated site are sampled monthly over an extended period, defined by the Norwegian Food Safety Authority, to ensure that no local spread occurs (Jansen et al., 2017).

As described in the Aquatic Code of the World Organisation for Animal Health (Chapters 7.3 and 7.4) (WOAH, 2022a,b) several killing methods exist, such as using an overdose of an anaesthetic agent or mechanical killing methods. The killing method should be selected taking into consideration fish welfare and biosecurity requirements, as well as the safety of the personnel. EFSA (2009) reported the following methods used for emergency killing: pharmacological, electrical and maceration. Broodstock is usually killed by the application of pharmacological methods before destruction.

Effectiveness

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

A Norwegian study was conducted to evaluate the economic effects of different control strategies towards SAV in a PD-endemic area. In this study, a scenario where all farms were stamped out within 30 days of virus detection reduced the expected aggregated number of PD outbreaks from 162 to six. A scenario where all farms were stamped out only after a clinical outbreak led to a reduction from 162 to 103 thus supporting the efficacy of immediate measures (Pettersen et al., 2016; Bang Jensen et al., 2021).

Feasibility

Parameter 3 – Feasibility of killing animals

Killing using an overdose of an anaesthetic (e.g. MS222) administered to fish kept in small volumes of water is the most feasible method available. Detailed protocols setting tank sizes and dosing per biomass of fish are not publicly available. Percussion stunning using a 'priest' followed by exsanguination or evisceration is most suitable for small numbers of fish. Electrical stunning is feasible if the appropriate equipment is available, but they are not widely used. Studies that address fish welfare before slaughter have concluded that many of the traditional systems used to stun fish including CO_2 narcosis are unacceptable as they cause avoidable stress before death. Exposure to water saturated with CO_2 triggers aversive struggling and escape responses for several minutes before immobilisation, whereas in fish exposed to an electric current, immobilisation is close to instant (Gräns et al., 2016). A knowledge gap exists as there are no published data comparing rates of killing by different methods (Depner, 2017).

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

Availability

Parameter 1 – Available disposal option

Assuming that dead fish shed SAV, then the prompt removal and safe disposal of dead animals is a simple husbandry measure that can help prevent the spread of disease. Measures will include the daily inspection of tanks and cages for evidence of dead or moribund fish and the use of systems for removing dead fish from fish farm tanks and cages and their safe disposal (e.g. by composting or ensiling).

Carcasses from fish killed or found dead due to SAV infection belong to Category II materials and should be disposed of and destroyed according to the rules outlined in EC Regulation 1069/2009[9] and EC Regulation 142/2011[10]. The carcases and any relevant by-product must be transported in a sealed container, recorded on both arrival and departure of any site and should be disposed of and processed at an approved establishment. A list of premises approved by EU MSs can be found on the European Commission webpage.[11]

Effectiveness

Parameter 2 – Effectiveness of disposal options

As with other infectious diseases, the efficient removal and safe disposal of carcasses and other animal by-products reduces the viral challenge. Biosecure killing methods and safe disposal of offal and effluent are also key to minimising the risk from these processes (McLoughlin and Graham, 2007).

Feasibility

Parameter 3 – Feasibility of disposal option

An alkaline hydrolysis method in which macerated fish are exposed to high pH (> 13) for 7 days inactivates high titres of virus and is recommended as a biosecurity treatment method for fish by-products that contain fish pathogens (Dixon et al., 2012). However, ensiling (a method of carcass disposal that involves lowering the pH to < 4) was determined as an infective method, in terms of biosecurity, for the disposal of dead fish (Smail et al., 1993; Dixon et al., 2012). Incineration or rendering is feasible where biosecurity measures can be implemented during the transport and an approved establishment is near the farm to process the carcasses (EFSA AHAW Panel, 2017b).

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

Availability

Parameter 1 – Available breeds resistant to the pathogen

Differences in susceptibility towards SAV among different family groups of Atlantic salmon have been observed in both challenge experiments and in the field, indicating the potential for breeding for resistance (WOAH, 2021). Resistance to PD in Atlantic salmon has been shown to be moderate to highly heritable, with estimates ranging from 0.21 to 0.54 depending on the population used and the model of analysis applied (Norris et al., 2008; Gonen et al., 2015; Aslam et al., 2020).

Since the 1990s, Norwegian-owned Scotland farm has been involved in genetic improvement programmes aiming at targeting disease resistance traits in farmed salmon stocks in the United Kingdom and globally, including PD (Gonen et al., 2015; Regan et al., 2021). Commercial breeding programmes to increase resistance towards SAV are implemented in Ireland and Norway (WOAH, 2021).

Effectiveness

Parameter 2 – Effectiveness of having resistant breeds

Breeding programmes in Ireland and Norway have successfully produced fish with increased resistance to disease caused by SAV (WOAH, 2021).

Feasibility

Parameter 3 – Feasibility of having resistant breeds

No information was found in the literature.

[9] 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

[10] 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

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

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)

A Norwegian study estimated the SAV prevention costs (functional feed, improved nets, additional staff, wellboat costs, new sites, boats and land bases) for an Atlantic salmon site with 500,000 smolts at 0.8 (0.7, 1.0) million NOK (1 NOK ~ 0.13 EUR in 2013). However, the authors pinpointed that costs associated with the prevention of disease may be difficult to quantify since many of the preventive measures, such as reducing fish density, site isolation and establishing new sites are not disease-specific (Aunsmo et al., 2010).

An inactivated whole-virus vaccine has been commercially available in Ireland and in Norway since 2003 and in the United Kingdom since 2005. This vaccine has been used extensively in geographical regions where PD is common (Karlsen and Johansen, 2017). Ruane et al. (2007) pinpointed that the smaller market for aquatic animals compared with the much larger terrestrial animal market means that the costs of producing inactivated viral vaccines are relatively high. In addition to this, oral vaccines against fish viral diseases, which would provide a stress-free method of vaccinating fish of any age, are rare as high costs are associated with developing carrier compounds to protect the vaccine against the digestive system.

Parameter 2 – Cost of eradication (culling, compensation)

A cost–benefit analysis conducted in 2012 showed that depopulation was cost-effective for a scenario where 10% of sites had to be depopulated compared to a no-depopulation scenario where 50% of sites developed PD (Jansen et al., 2017).

Parameter 3 – Cost of surveillance and monitoring

No information was found in the literature.

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

No information was found in the literature.

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

In Ireland, the industry estimated a €35 million loss of turnover due to SAV and a €12 million loss of profit for the 2003–2004 production period (Ruane et al., 2008).

Another project carried out in Ireland examined the financial losses due to infectious diseases in fish which went to sea between 2004 and 2008, and identified PD as one of the three most economically significant diseases on marine based fish farms (Ruane et al., 2015).

A Norwegian study estimated production costs due to PD for a site with 500 000 smolts to be increased by €0.75 per kg of fish due to mortality, extra management costs, treatment, prevention and reduced fish meat quality (Aunsmo et al., 2010).

The direct costs from a SAV outbreak in farmed Atlantic salmon from Norway were estimated on average at NOK55.4 million (5%, 50% and 90% percentile: 38.0, 55.8 and 72.4) (1 NOK ~ 0.13 € in 2013) (Pettersen et al., 2015b). These numbers should not be taken as representative of SAV2 epidemics in the rainbow trout industry, where outbreaks affect smaller fish. Because outbreaks of SD are not reported on a regular basis, the cost due to SAV in rainbow trout is difficult to estimate (Karlsen and Johansen, 2017).

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

In Norway, one of the challenges in operating the Hustadvika barrier (Section 1.8 Parameter 2) was the huge cost resulting from depopulation of infected sites just north of the barrier, with such costs imposed on only a small number of salmon producers. Producers just north of the barrier and in close contact with the endemic zone via coastal currents paid the costs of control by depopulating infected sites, while farmers further north only experienced the benefits of being PD-free. The motivation among producers to maintain the barrier was thus highly correlated with the number of outbreaks north of the barrier, and an increase in outbreaks led to more political pressure to abolish or move the

barrier. Identifying appropriate cost-sharing mechanisms is therefore essential (Pettersen et al., 2015a).

Contrarily to chemotherapeutics that may involve safety concerns, vaccination contributes to environmental, social and economic sustainability in global aquaculture, and is therefore generally well accepted as an effective method for preventing infectious diseases such as SAV (Ma et al., 2019). On the other hand, the use of selective breeding and genome-editing approaches to enhance infectious disease resistance in aquaculture may raise safety and ethical concerns. However, a recent survey found that the majority of Norwegian consumers were positive about using gene-editing in Norwegian agriculture and aquaculture for purposes that are perceived to promote societal benefit and sustainability, such as improving animal health (Board of Norwegian Biotechnology Advisory, 2020).

3.1.5.3. Article 7(e)(iii) The welfare of affected subpopulations of kept and wild animals

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

Oil-adjuvanted vaccines delivered by intraperitoneal injection may have side effects on fish welfare such as appetite loss, tissue adhesions around the injection site, pigmentation and intraperitoneum granuloma (Maria Poli, 2009).

In addition, handling and transporting fish for the purpose of testing, quarantine or while awaiting test results, are often stressful events and require the availability of suitable biosecurity systems to hold the fish in a sustainable manner. Such systems must have sufficient space to hold the stock, have the ability to feed the fish and maintain the environmental quality of the water they are held in (Depner, 2017).

EFSA (2009) assessed the welfare aspects of killing farmed Atlantic salmon and reported that crowding and pumping pre-slaughter will subject the fish to metabolic and handling stress. There is also always a certain risk of poor welfare involved when live fish are transported to slaughter; however, if fish are transported under good conditions (open transport), then the fish may recover from crowding and handling during the transport and thus the transport will not affect the fish welfare at slaughter. As the fish are supplied to the stunning or killing unit operation, there is a high risk that salmon are subjected to metabolic stress, handling stress and poor welfare (exhaustion) prior to slaughter. There is some risk of poor welfare when applying electrical stunning in a water (batch) system mainly due to mis-stunning or electrical exhaustion. There is a high risk of poor welfare when benzocaine and metacaine are used in seawater to kill salmon. When using mills for maceration fish should be previously stunned and then be instantaneously killed.

Parameter 2 – Wildlife depopulation as control measure

Wild fish do not seem to play a major role in the epidemiology of SAV. SAV occurs at low levels in wild salmonid and non-salmonid fish (Section 3.1.2.4 Parameter 2). Overall, the conditions that promote epidemics and disease occurrence in aquaculture may not occur for wild fish, thus limiting the occurrence of clinical disease and its effects on wild fish (Jones et al., 2015; Wallace et al., 2017).

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

Environment

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

The use of pharmacological products in the context of fish emergency killing such as anaesthetics might affect the environment if discharged to surrounding water bodies. Yet, the use of anaesthetics in the context of aquaculture is generally considered to be of little risk to the environment, since these products are used infrequently and in low doses, thus limiting the potential for environmental damage (Burridge et al., 2010).

Biodiversity

Parameter 2 – Mortality in wild species

See Section 3.1.2.4 Impact of the disease on biodiversity and the environment – Parameter 2.

3.2. Assessment of infection with salmonid alphavirus according to Article 5 criteria of AHL on its eligibility to be listed

3.2.1. Detailed outcome on Article 5 criteria

The results of the collective expert judgement on the criteria of Article 5 of the AHL for infection with salmonid alphavirus are presented in Table 10 and Figure 2.

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

Table 10: 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	13
A(ii)	Animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union	95–100	Fulfilled	0	13
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	13
A(iv)	Diagnostic tools are available for the disease	90–99	Fulfilled	0	13
A(v)	Risk-mitigating measures and, where relevant, surveillance of the disease are effective and proportionate to the risks posed by the disease in the Union	66–90	Fulfilled	0	13
At least one criterion to be met by the disease: In addition to the criteria set out above at point A(i)–A(v), the disease needs to fulfil at least one of the following criteria					
B(i)	The disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic character	50–66	Uncertain	0	13
B(ii)	The disease agent has developed resistance to treatments which poses a significant danger to public and/or animal health in the Union	NA	NA	13	13
B(iii)	The disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union	50–80	Uncertain	0	13
B(iv)	The disease has the potential to generate a crisis, or the disease agent could be used for the purpose of bioterrorism	1–10	Not fulfilled	0	13
B(v)	The disease has or could have a significant negative impact on the environment, including biodiversity, of the Union	10–33	Not fulfilled	0	13

NA: not applicable.

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

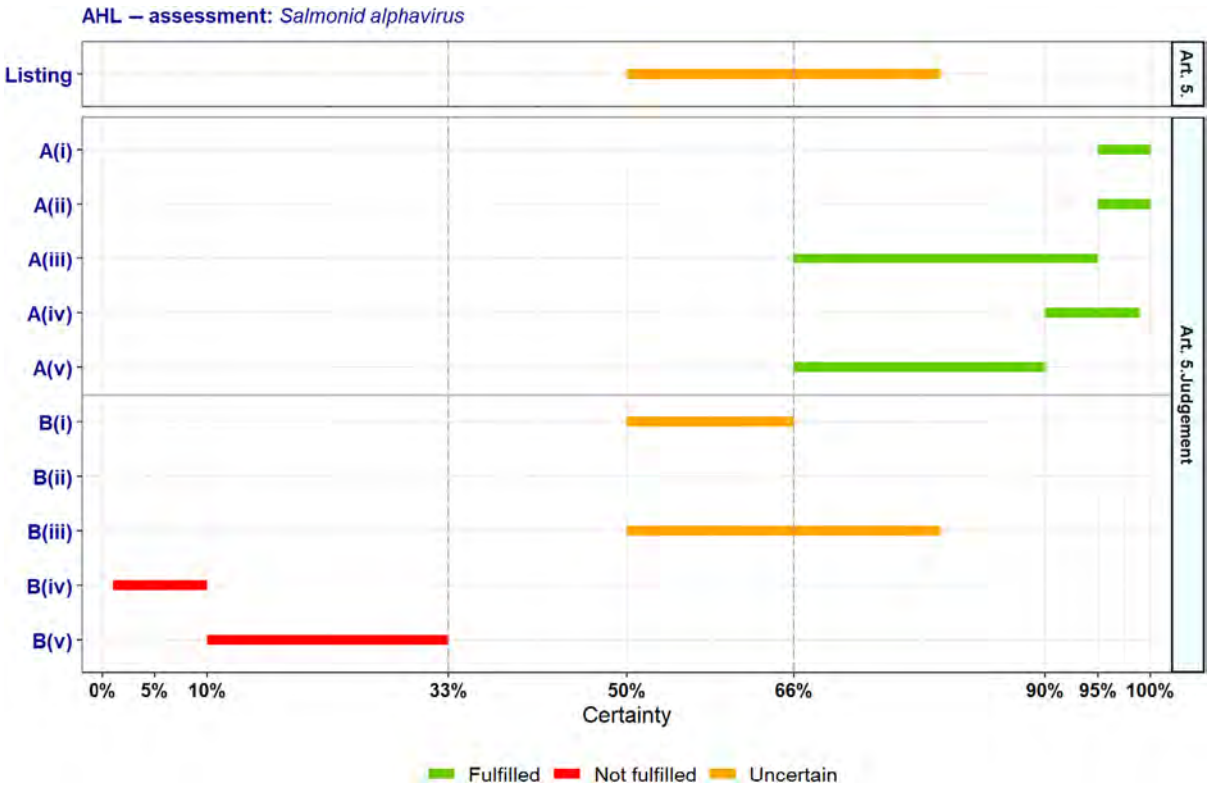


Figure 2: Outcome of the expert judgement on Article 5 criteria of AHL and overall probability of Infection with Salmonid alphavirus on eligibility to be listed

3.2.2. Reasoning for uncertain outcome on Article 5 criteria

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 impact of SAV varies a lot since the clinical manifestation and the severity of the clinical signs are different in different species. In seawater Atlantic salmon (*Salmo salar*) SAV causes pancreas disease (PD) and the impact is higher compared to sleeping disease (SD) in freshwater rainbow trout (*Oncorhynchus mykiss*).
- There are not enough available data on the prevalence. Prevalence during SAV outbreaks in farmed Atlantic salmon varies but is usually high (> 70%).
- SAV2 is present in a large part of the continental EU without causing significant negative effects. SAV1, SAV2, SAV3 and SAV5 have significant negative effects on farmed salmon populations in Norway and/or UK connected to PD outbreaks, but neither of these countries are EU MSs. On the other hand, SAV1 SAV4 and SAV 6 cause serious negative effects on Atlantic salmon in Ireland.
- The disease has a high potential to spread within aquaculture systems and quickly became endemic in Norway following the initial introduction. However, introduction from wild reservoirs seems rare.
- The disease seems to have limited effects in EU MSs, although this may be due to underreporting since one of its main effects is poor appetite and production losses, which are difficult to precisely quantify without proper surveillance activities. In addition, it is uncertain how this situation may evolve if a more virulent SAV3-variant is introduced to the EU or if the importance of salmon aquaculture increases in the future
- SAV is not a zoonotic disease and therefore there is no impact on public health.

Criterion B(iii) *(the disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union):*

- Both the current and the potential impact of SAV have been taken into consideration for the assessment of the economic impact on aquaculture production in Union.

- An 11.4% loss in growth over a 2-year period (2003 and 2004) has been associated with pancreatic disease outbreaks in Ireland.
- It seems to have a major impact on the aquaculture industry in affected countries, though there is uncertainty regarding whether this constitutes a 'significant' impact. In addition, in the EU, Atlantic salmon production is concentrated in Ireland and it is uncertain what will be the potential impact if in the future salmon production is extended to other MSs or if a more virulent strain is introduced in the EU.

3.2.3. 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 10, infection with salmonid alphavirus complies with five criteria of the first set (A(i)–A(v)), but it does not comply with any of the criteria of the second set (B(i) to B(v)). Therefore, it is uncertain whether infection with salmonid alphavirus 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 Infection with salmonid alphavirus being eligible to be listed is 50–80% (see Figure 2).

3.3. Assessment of infection with salmonid alphavirus according to criteria in Annex IV for the purpose of categorisation as in Article 9 of the AHL

In Tables 11–15 and related graphs (Figures 3–5), the results of the expert judgement on infection with salmonid alphavirus 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.

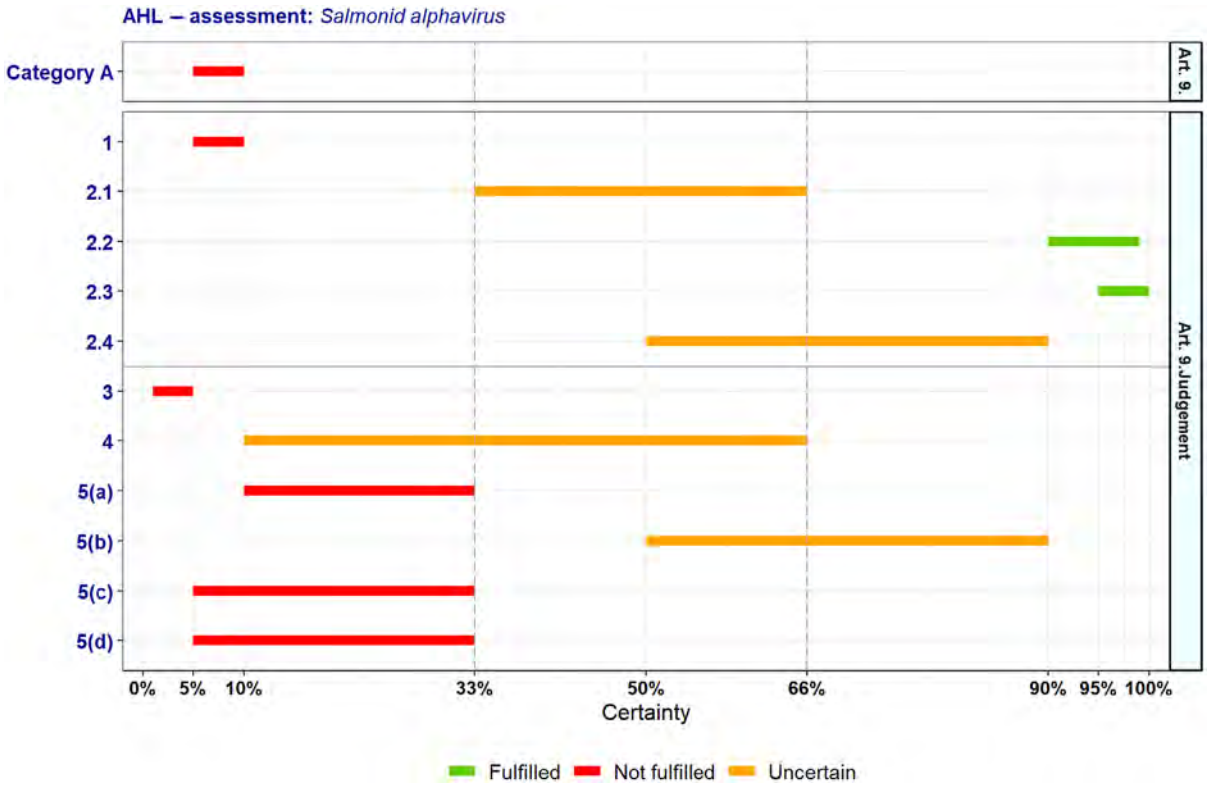
3.3.1. Detailed outcome on category a criteria

Table 11: 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 only in a very limited part of the territory of the Union	5–10	Not fulfilled	0	13
2.1	The disease is highly transmissible	33–66	Uncertain	0	13
2.2	There are possibilities of airborne or waterborne or vector-borne spread	90–99	Fulfilled	0	13
2.3	The disease affects multiple species of kept and wild animals or single species of kept animals of economic importance	95–100	Fulfilled	0	13
2.4	The disease may result in high morbidity and significant mortality rates	50–90	Uncertain	0	13
	At least one criterion to be met by the disease: In addition to the criteria set out above at point 1–2.4, the disease needs to fulfil at least one of the following criteria				
3	The disease has a zoonotic potential with significant consequences for public health, including epidemic or pandemic potential or possible significant threats to food safety	1–5	Not fulfilled	0	13

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
4	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	10–66	Uncertain	0	13
5(a)	The disease has a significant impact on society, with in particular an impact on labour markets	10–33	Not fulfilled	0	13
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	50–90	Uncertain	0	13
5(c)	The disease has a significant impact on the environment, due to the direct impact of the disease or due to the measures taken to control it	5–33	Not fulfilled	0	13
5(d)	The disease has a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	5–33	Not fulfilled	0	13

NA: not applicable.



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

Figure 3: Outcome of the expert judgement on the criteria of Section 1 of Annex IV of AHL and overall probability of Infection with salmonid alphavirus to 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):*

- The disease has a high potential to spread within aquaculture systems and quickly became endemic in Norway following the initial introduction. The spread potential depends on the SAV genotype, the affected fish species and the farming system.

- There are limited data on SAV transmission rates. The information found in the literature shows that the transmission rate in UK and Norway outbreaks ranges from 1 to 3 suggesting a moderate transmission.
- According to the experience from the outbreaks in Norway SAV, especially for the SAV3 genotype, has been shown to be highly transmissible over large distances at sea and with high on-site prevalence.
- Infection with SVA can remain subclinical for a long time and therefore undetected without proper surveillance activities.

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

- Both morbidity and mortality rates vary. The extent and the severity of clinical manifestations are dependent on the genotype of the affected species and the farming systems.
- In Norway, both high and low morbidity and mortality rates were observed, where infections with marine SAV2 are reported to generate a higher proportion of subclinical cases than SAV3 infections.
- Mortality rates may vary from very low to over 50% in severe cases and can increase progressively in affected populations. In Ireland, annual mortality from 2000 to 2010 has ranged between 14% and 18%, reaching 40% in high affected cages.
- The notification and reporting of SAV is not mandatory at the EU level, and therefore, it is likely that the disease is under reported.
- In the absence of control measures and vaccination, the mortality rates can be high.

Criterion 4: *(The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals):*

- Both the current and the potential impact of SAV have been taken into consideration for the assessment of this criterion.
- It seems to have a major impact the aquaculture industry in affected countries, though there is uncertainty regarding whether this constitutes 'significant' impact on the economy of the Union. In addition, in the EU, the Atlantic salmon production is concentrated in Ireland and it is uncertain what will be the potential impact if in the future salmon production is extended to other MSs.
- Production loss is a major observation following SAV infection. An 11.4% loss in growth over a 2-year period (2003 and 2004) has been associated with PD outbreaks in Ireland. A negative impact on the quality of the fish fillet has been observed.
- In Ireland, the industry estimated a €35 million loss of turnover due to SAV and a €12 million loss of profit for the 2003–2004 production period.

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

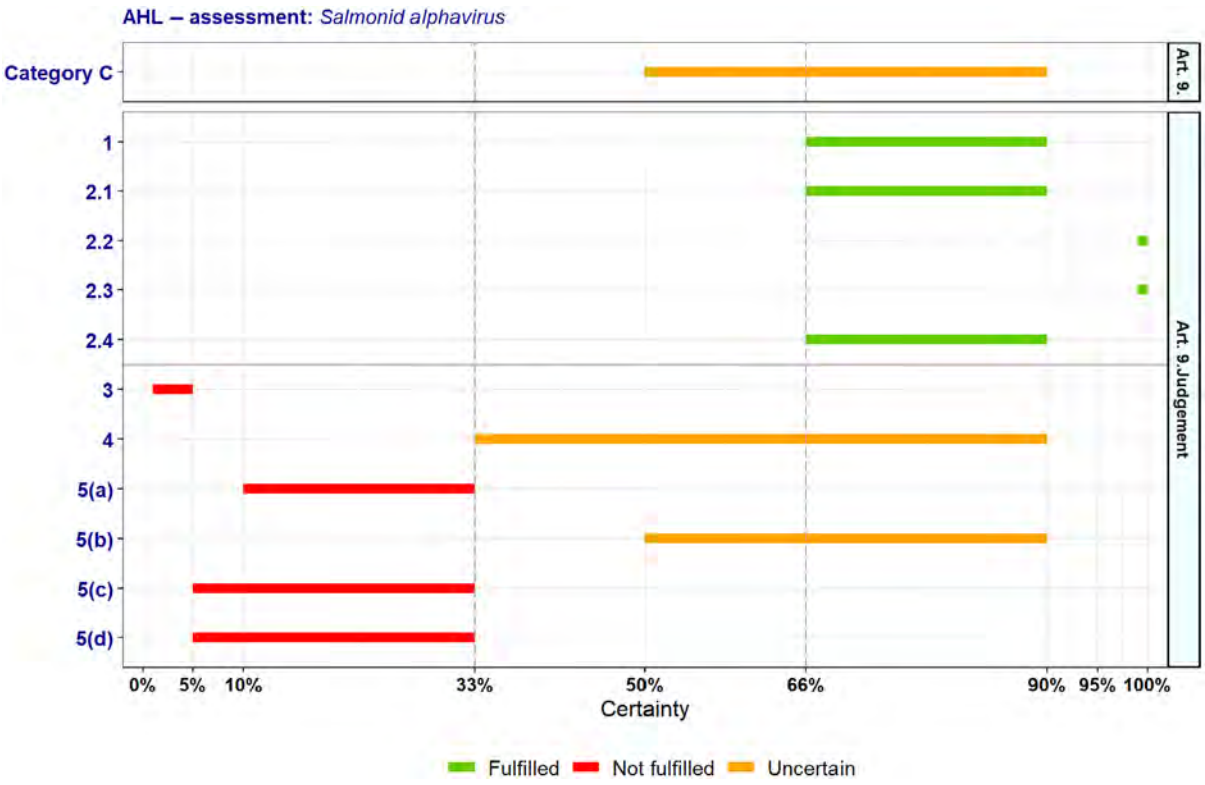
- Both the current and the potential impact of SAV on animal welfare have been taken into consideration for the assessment of this criterion.
- The clinical signs, especially for PD in Atlantic salmon, are severe and cause suffering to animals. The disease significantly affects the health and welfare of large numbers of farmed Atlantic salmon and rainbow trout, and is already endemic in some areas and reported in others. Nevertheless, it is uncertain if the impact on animal welfare can be considered significant.
- There are no studies available to estimate the impact of SAV on animal welfare.

3.3.2. Detailed outcome on category B criteria

Table 12: 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	13
2.1	The disease is moderately to highly transmissible	66–90	Fulfilled	0	13
2.2	There are possibilities of airborne or waterborne or vector-borne spread	90–99	Fulfilled	0	13
2.3	The disease affects single or multiple species[(a)]	–	Fulfilled	0	13
2.4	The disease may result in high morbidity with in general low mortality	66–90	Fulfilled	0	13
At least one criterion to be met by the disease: In addition to the criteria set out above at points 1–2.4, the disease needs to fulfil at least one of the following criteria					
3	The disease has a zoonotic potential with significant consequences for public health, including epidemic potential or possible significant threats to food safety	1–5	Not fulfilled	0	13
4	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	10–66	Uncertain	0	13
5(a)	The disease has a significant impact on society, with in particular an impact on labour markets	10–33	Not fulfilled	0	13
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	50–90	Uncertain	0	13
5(c)	The disease has a significant impact on the environment, due to the direct impact of the disease or due to the measures taken to control it	5–33	Not fulfilled	0	13
5(d)	The disease has a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	5–33	Not fulfilled	0	13

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 Infection with salmonid alphavirus to be fitting in Category B of Article 9 of AHL

3.3.2.1. Reasoning for uncertain outcome on Category B criteria

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

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

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.

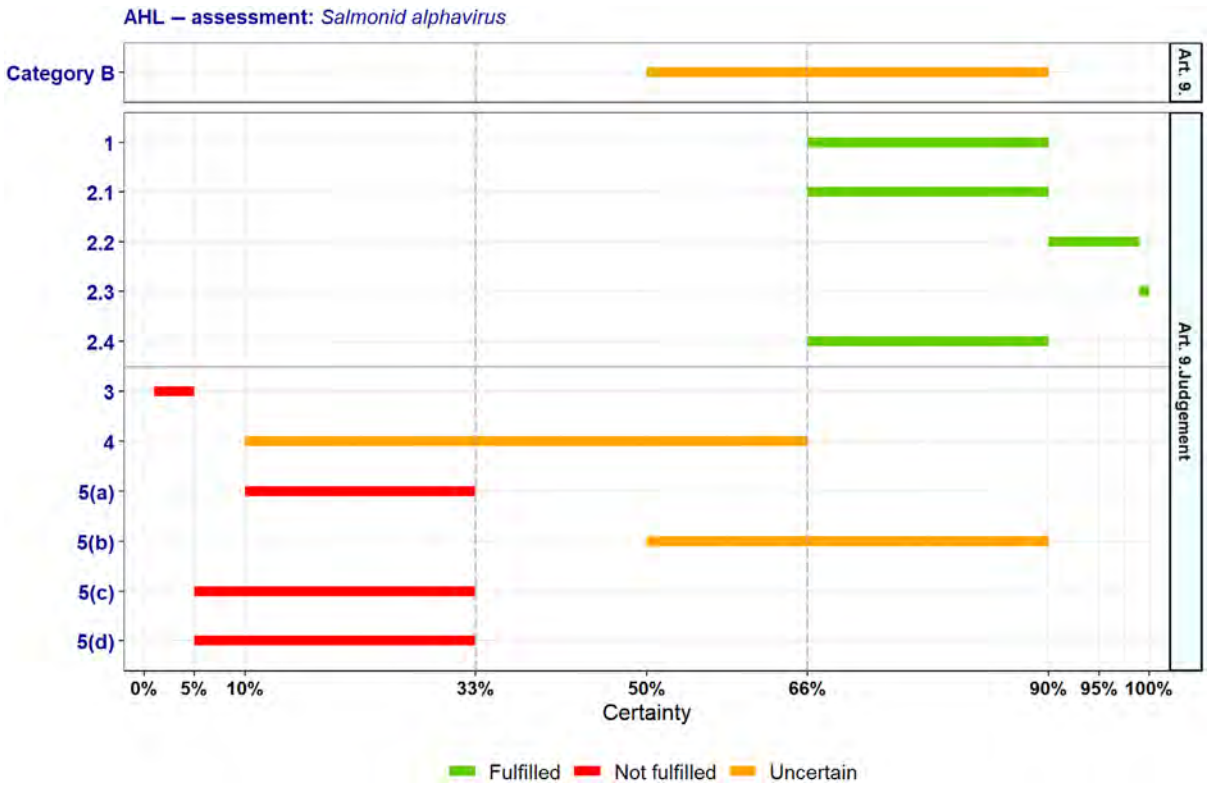
3.3.3. Detailed outcome on Category C criteria

Table 13: 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**
1	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	13
2.1	The disease is moderately to highly transmissible	66–90	Fulfilled	0	13

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
2.2	The disease is transmitted mainly by direct or indirect transmission[(a)]	–	Fulfilled	0	13
2.3	The disease affects single or multiple species[(a)]	–	Fulfilled	0	13
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.	66–90	Fulfilled	0	13
At least one criterion to be met by the disease: In addition to the criteria set out above at points 1–2.4, the disease needs to fulfil at least one of the following criteria					
3	The disease has a zoonotic potential with significant consequences for public health or possible significant threats to food safety	1–5	Not fulfilled	0	13
4	The disease has a significant impact on the economy of the Union, mainly related to its direct impact on certain types of animal production systems	33–90	Uncertain	0	13
5(a)	The disease has a significant impact on society, with in particular an impact on labour markets	10–33	Not fulfilled	0	13
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	50–90	Uncertain	0	13
5(c)	The disease has a significant impact on the environment, due to the direct impact of the disease or due to the measures taken to control it	5–33	Not fulfilled	0	13
5 (d)	The disease has a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	5–33	Not fulfilled	0	13

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 Infection with salmonid alphavirus to be fitting in Category C of Article 9 of AHL

3.3.3.1. Reasoning for uncertain outcome on category C criteria

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 SAV on the economy of the Union have been taken into consideration for the assessment of this criterion.
- It seems to have a major impact on the aquaculture industry in affected countries, though there is uncertainty regarding whether this constitutes a 'significant' impact on the economy of the Union. In addition, in the EU, Atlantic salmon production is concentrated in Ireland and it is uncertain what will be the potential impact if in the future salmon production is extended to other MSs.

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 14: 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	13

NA: not applicable.

3.3.5. Detailed outcome on Category E criteria

Table 15: 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.)	50–90	Uncertain

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

As from the legal text of the AHL, a disease is considered fitting in a certain category (A, B, C, D or E – corresponding to points (a) to (e) of Article 9(1) of the AHL) if it fulfils all criteria of the first set from 1 to 2.4 and at least one of the second set of criteria from 3 to 5(d), as shown in Tables 11–15. 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 Infection with salmonid alphavirus as in Article 9, is presented in Table 16 and Figure 6.

Table 16: 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	Impact on animal welfare	Impact on environment	Impact on biodiversity		
A	5–10	33–66	90–99	95–100	50–90	1–5	10–66	10–33	50–90	5–33	5–33		
B	66–90	66–90	90–99	–[(a)]	66–90	1–5	10–66	10–33	50–90	5–33	5–33		
C	66–90	66–90	–[(b)]	–[(b)]	66–90	1–5	33–90	10–33	50–90	5–33	5–33		
D												66–90	
E													50–90

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

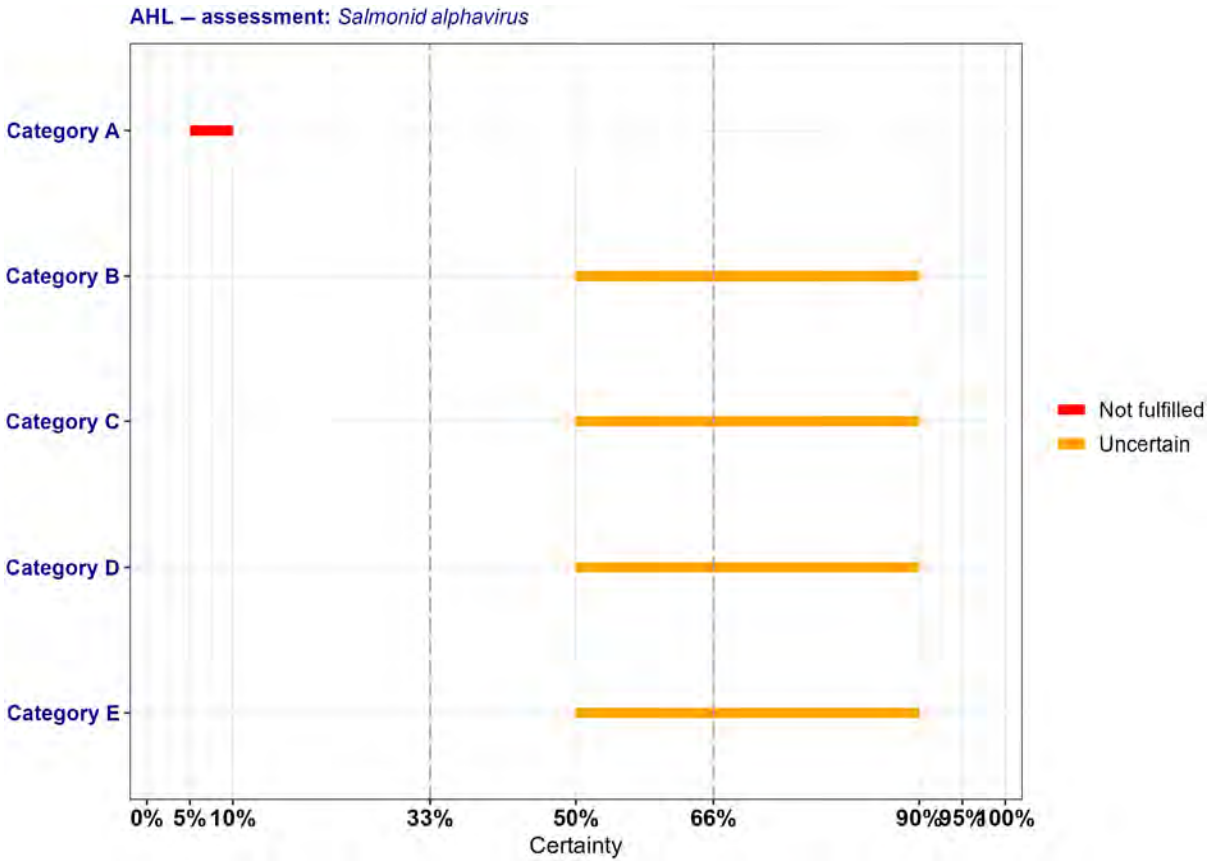


Figure 6: Outcome of the expert judgement on criteria in Annex IV of AHL and overall probabilities for categorisation of infection with salmonid alphavirus in accordance with Article 9 of AHL

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

1) To be assigned to **Category A**, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and, according to the assessment, infection with salmonid alphavirus complies only with two out of five criteria (Sections 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 infection with salmonid alphavirus does not comply with any of those. Overall, it was assessed with **5–10% probability** that infection with salmonid alphavirus may be assigned to Category A according to criteria in Section 1 of Annex IV for the purpose of categorisation as in Article 9 of the AHL.
2) To be assigned to **Category B**, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and, according to the assessment, infection with salmonid alphavirus complies with all five criteria; 1, 2.1, 2.2, 2.3 and 2.4. To be eligible for Category B, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5(a)–(d)) and infection with salmonid alphavirus complies with none of these criteria. Overall, it was assessed with **50–90% probability** that infection with salmonid alphavirus 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, SAV complies with all five criteria; 1, 2.1, 2.2, 2.3 and 2.4). To be eligible for Category C, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5(a)–(d)) and infection with salmonid alphavirus complies with none of these criteria. Overall, it was assessed with **50–90% probability** that infection with salmonid alphavirus 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. SAV does not comply with criteria of Section 1, 2, 3 or 5 of Annex IV of the AHL but complies with **66–90% probability** with criterion D.
5) To be assigned to **Category E**, a disease needs to comply with criteria of Section 1, 2 or 3 of Annex IV of the AHL, and/or the surveillance of the disease is necessary for reasons related to animal health, animal welfare, human health, the economy, society or the environment. The latter is applicable if a disease fulfils the criteria as in Article 5, for which the assessment is uncertain with **50–90% probability**.

3.4. Assessment of infection with salmonid alphavirus 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 infection with salmonid alphavirus 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 also cover 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, 2017a), the animal species to be listed for infection *with Salmonid alphavirus* according to the criteria of Article 8(3) of the AHL are as displayed in Table 17 (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 infection with salmonid alphavirus has been described, but also those animal species from which only the infection with salmonid alphavirus itself has been isolated. The latter makes susceptibility to infection with salmonid alphavirus likely.

Table 17: Animal species to be listed for Infection with Salmonid alphavirus according to the criteria of Article 8 of AHL

Type	Class	Order	Family	*Genus/species*	References
Susceptible	Actinopterygii	Salmoniformes	Salmonidae	*Oncorhynchus mykiss*	Fringuelli et al. (2008), Taksdal and Sindre (2016), WOAH (2022a,b)
				Salmo salar	WOAH (2022a,b)
				Salvelinus alpinus	Lewisch et al. (2018), WOAH (2022a,b)
		Pleuronectiformes	Pleuronectidae	*Limanda*	Snow et al. (2010), Bruno et al. (2014), McCleary et al. (2014), Simons et al. (2016)
Reservoir	Actinopterygii	Clupeiformes	Clupeidae	*Clupea harengus*	WOAH (2021)
		Gadiformes	Gadidae	*Gadus morhua*	WOAH (2021)
				Gadus virens	Graham et al. (2006)
				Melanogrammus aeglefinus	WOAH (2021)
				Merlangius merlangus	WOAH (2021)
				Pollachius virens	WOAH (2021)
				Trisopterus esmarkii	WOAH (2021)
			Merlucciidae	*Merluccius hubbsi*	WOAH (2021)
		Labriformes	Labridae	*Labrus bergylta*	Ruane et al. (2018)
		Pleuronectiformes	Pleuronectidae	*Hippoglossoides platessoides*	Snow et al. (2010), Bruno et al. (2014), McCleary et al. (2014), Simons et al. (2016)
				Platichthys flesus	WOAH (2021)
				Pleuronectes platessa	Snow et al. (2010), Bruno et al. (2014), McCleary et al. (2014), Simons et al. (2016)
		Salmoniformes	Salmonidae	*Salmo trutta*	WOAH (2021)
		Scorpaeniformes	Cottidae	*Myoxocephalus octodecemspinosus*	WOAH (2021)
Vector	There is no evidence in the literature whether other species to those listed as susceptible can transmit the SAV 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), World Register 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 concluded that it is uncertain (**50–80% probability**) whether infection with salmonid alphavirus can be considered 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 **5–10% probability** ('very unlikely') that infection with salmonid alphavirus 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 (**50–90% probability)** whether infection with salmonid alphavirus 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 (**50–90% probability)** whether infection with salmonid alphavirus 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 was uncertain (**50–90% probability**) whether infection with salmonid alphavirus meets the criteria 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 was uncertain with **50–90% probability** whether Infection with salmonid alphavirus 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 infection with salmonid alphavirus according to Article 8(3) of the AHL are reported in Table 17 in Section 3.4 of the present document.

The AHAW Panel recognises that the outcome of this assessment on SAV is uncertain regarding its eligibility to be listed for Union intervention (ToR 1) and is also uncertain for the categorisation of SAV in certain categories (ToR 2 (a)) due to significant knowledge gaps in certain domains. Further investigations and research may generate information to better understand the epidemiological situation and the impact of the disease in EU, such as:

i) studies to provide information on the geographical distribution of the SAV in different fish species populations,
ii) research to estimate the impact of SAV on animal health, animal welfare and the production in EU,
iii) a better understanding of the implementation and the effectiveness of the mitigating measures and the surveillance activities used by certain MSs to reduce further spread of the virus.

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Abbreviations

AHAW	Animal Health and Welfare
AHL	Animal Health Law
CI	Current Impact
MS	Member State
MSs	Member States
n	Number of Outbreaks
OIE	Office International des Épizooties (World Organisation For Animal Health)
PCR	Polymerase Chain Reaction
PD	Pancreas Disease
PI	Potential Impact
QTL	Quantitative Trait Loci
SAV	Salmonid alphavirus
DSe	Diagnostic Sensitivity
DSp	Diagnostic Specificity
ToR	Term Of Reference
UK	United Kingdom
WG	Working Group
WOAH	World Organisation for Animal Health

Appendix A – Expert's judgement plotted by question

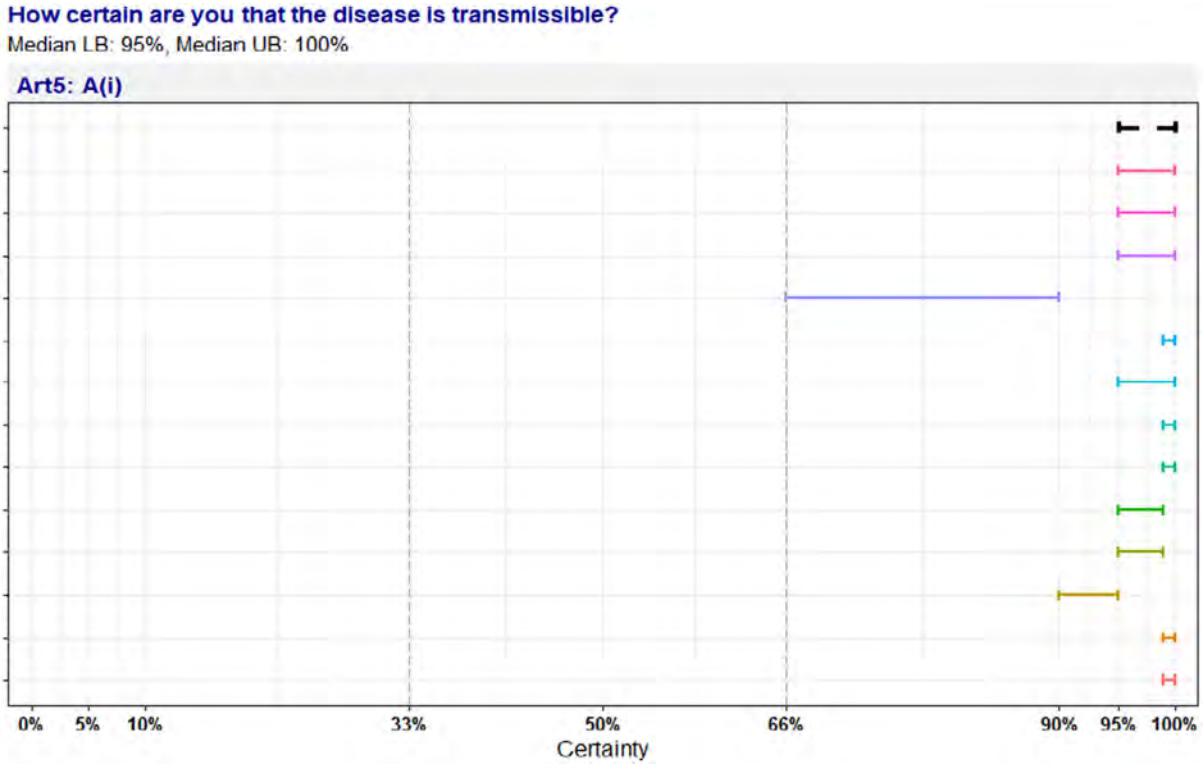

Figure A.1: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion A(i) (the disease is transmissible). The black dotted line on the top indicates the median

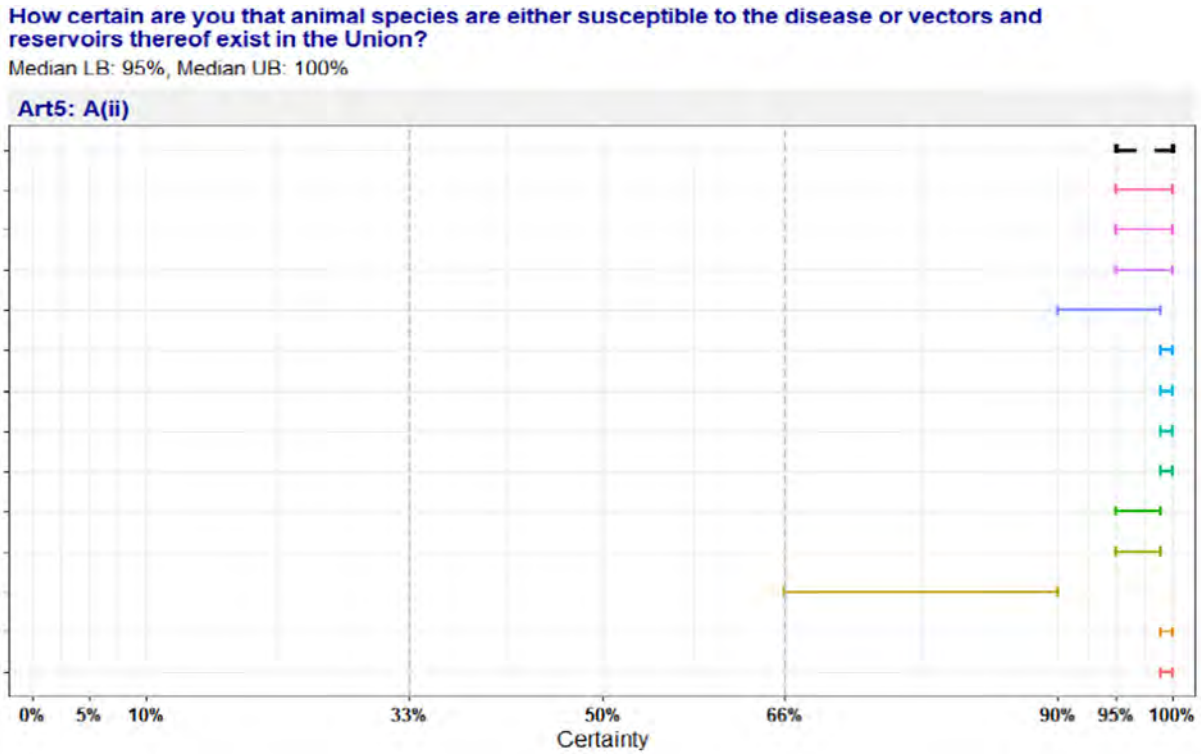

Figure A.2: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion A(ii) (animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union). The black dotted line on the top indicates the median

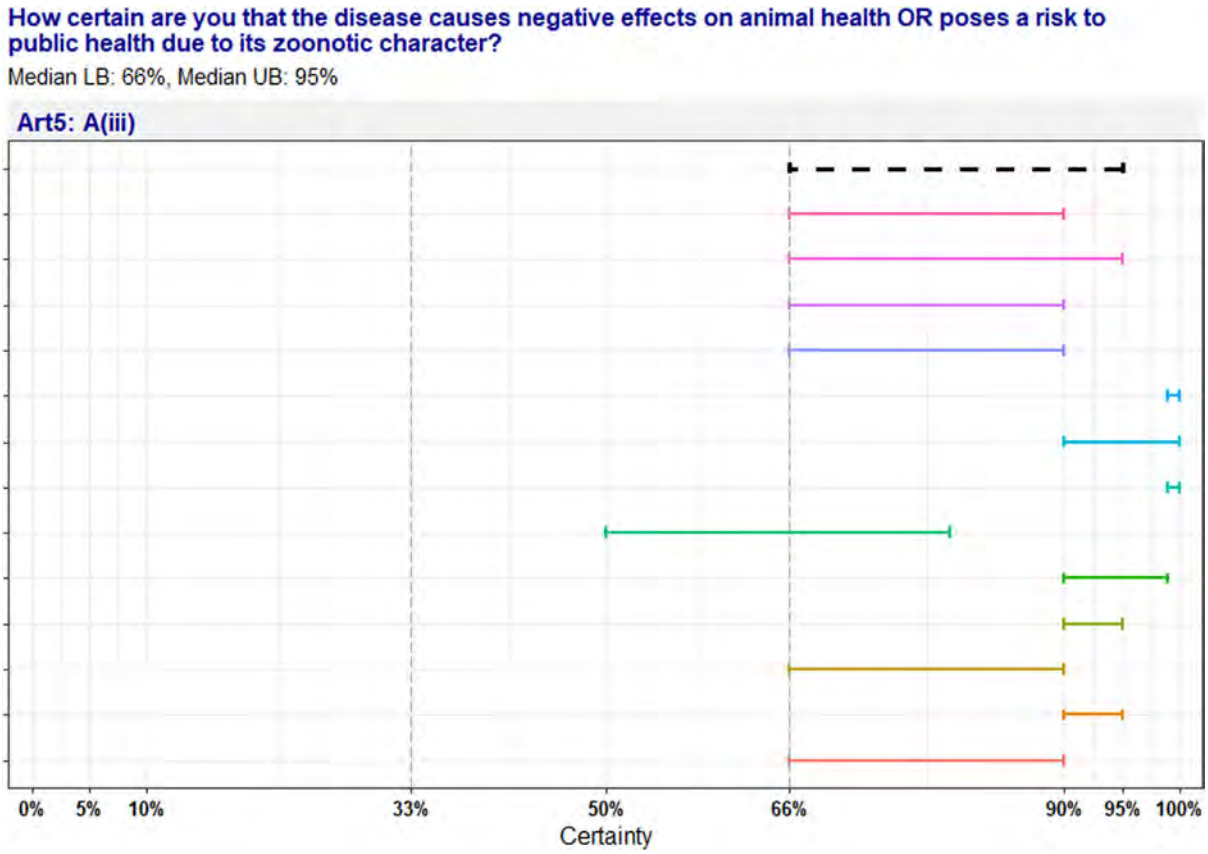

Figure A.3: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion A(iii) (the disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character). The black dotted line on the top indicates the median

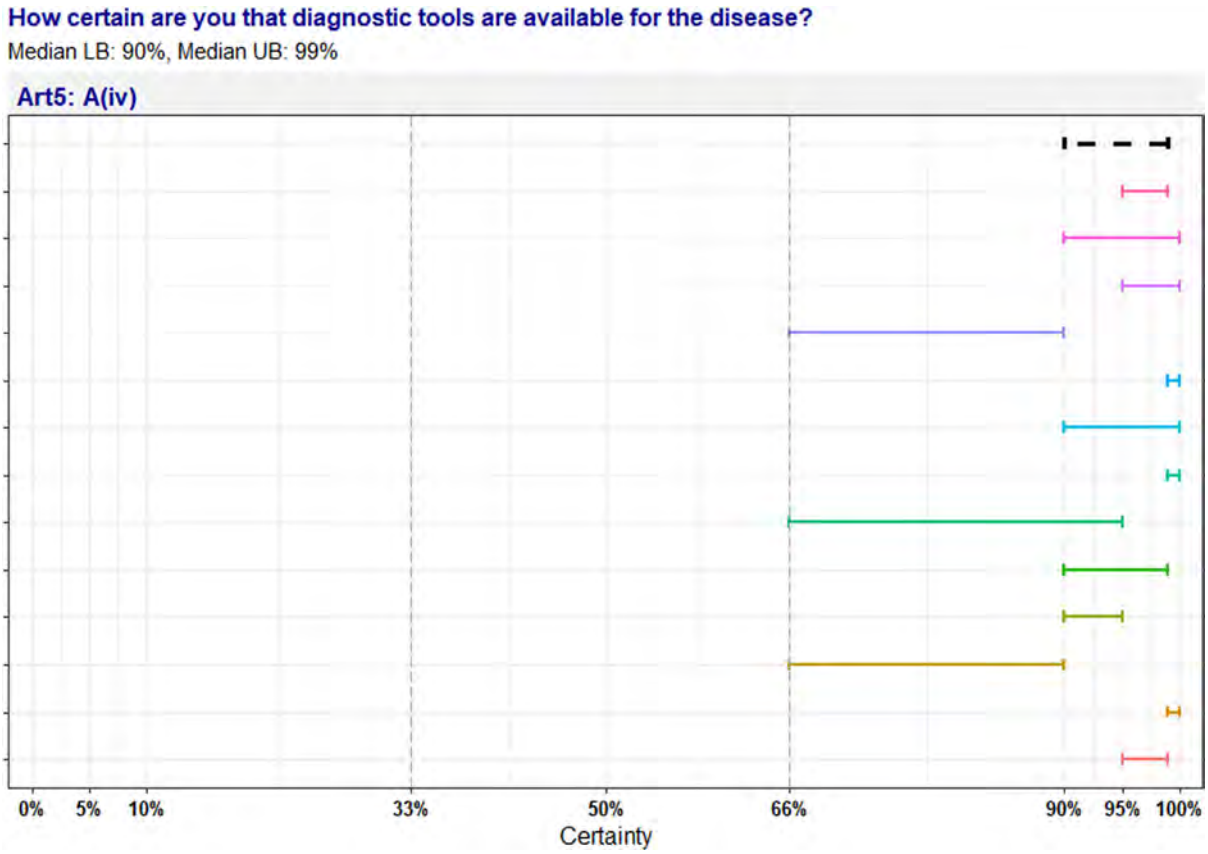

Figure A.4: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion A(iv) (diagnostic tools are available for the disease). The black dotted line on the top indicates the median

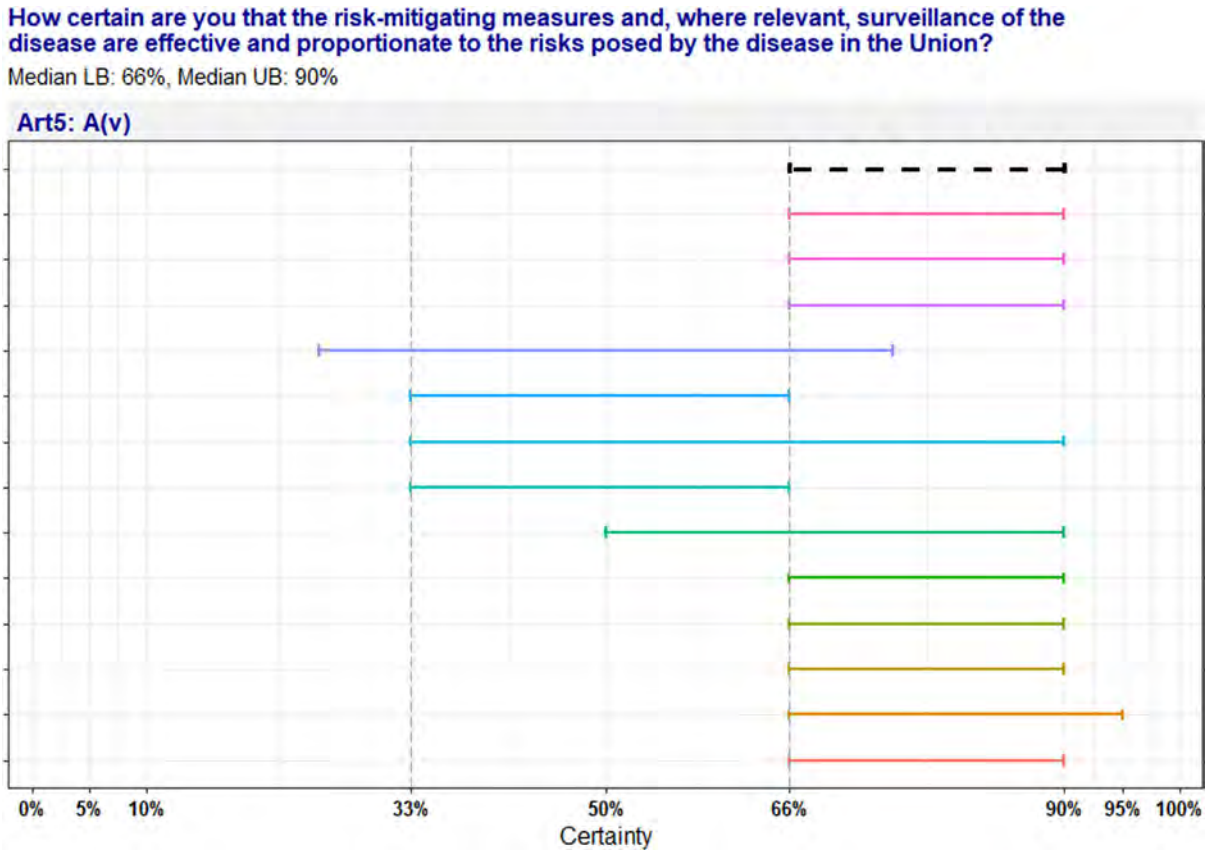

Figure A.5: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion A(v) (risk-mitigating measures and, where relevant, surveillance of the disease are effective and proportionate to the risks posed by the disease in the Union). The black dotted line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

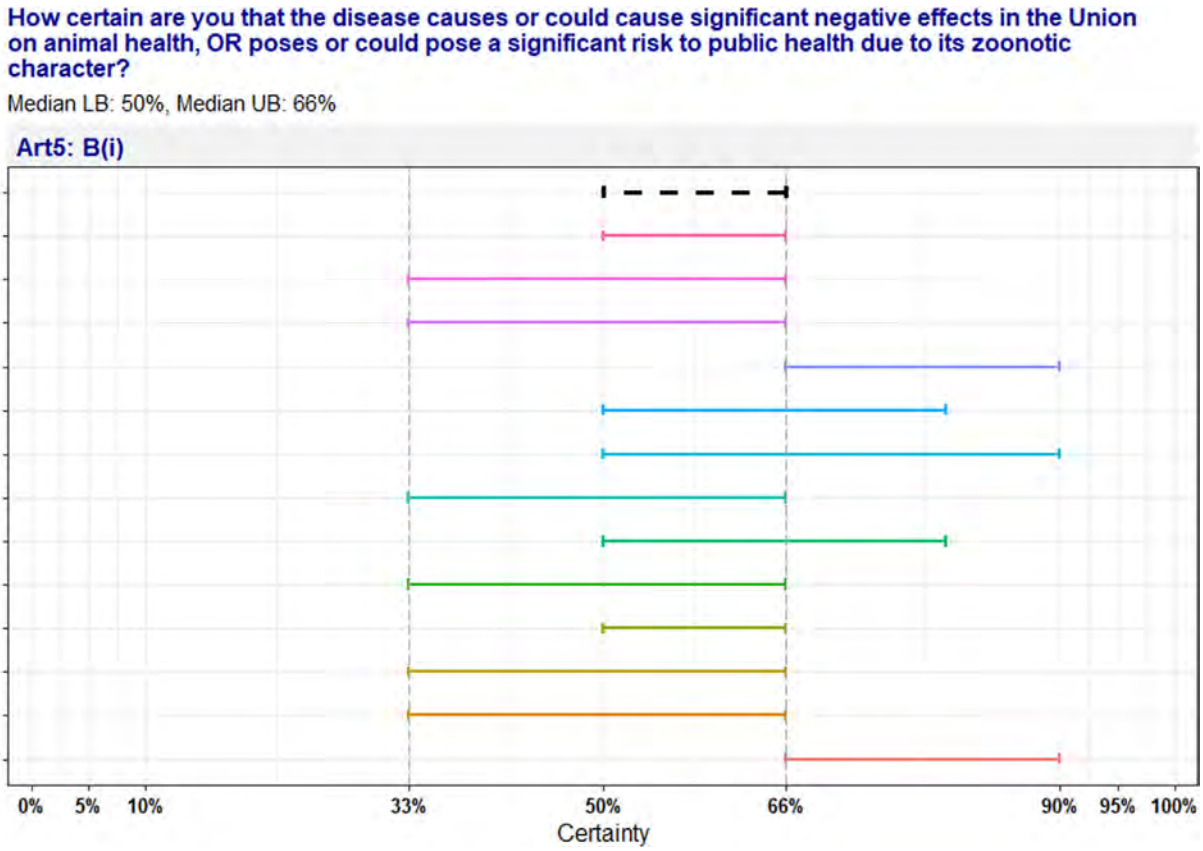

Figure A.6: Individual probability ranges, after the collective judgement, reflecting the uncertain outcome of the criterion B(i) (the disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic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

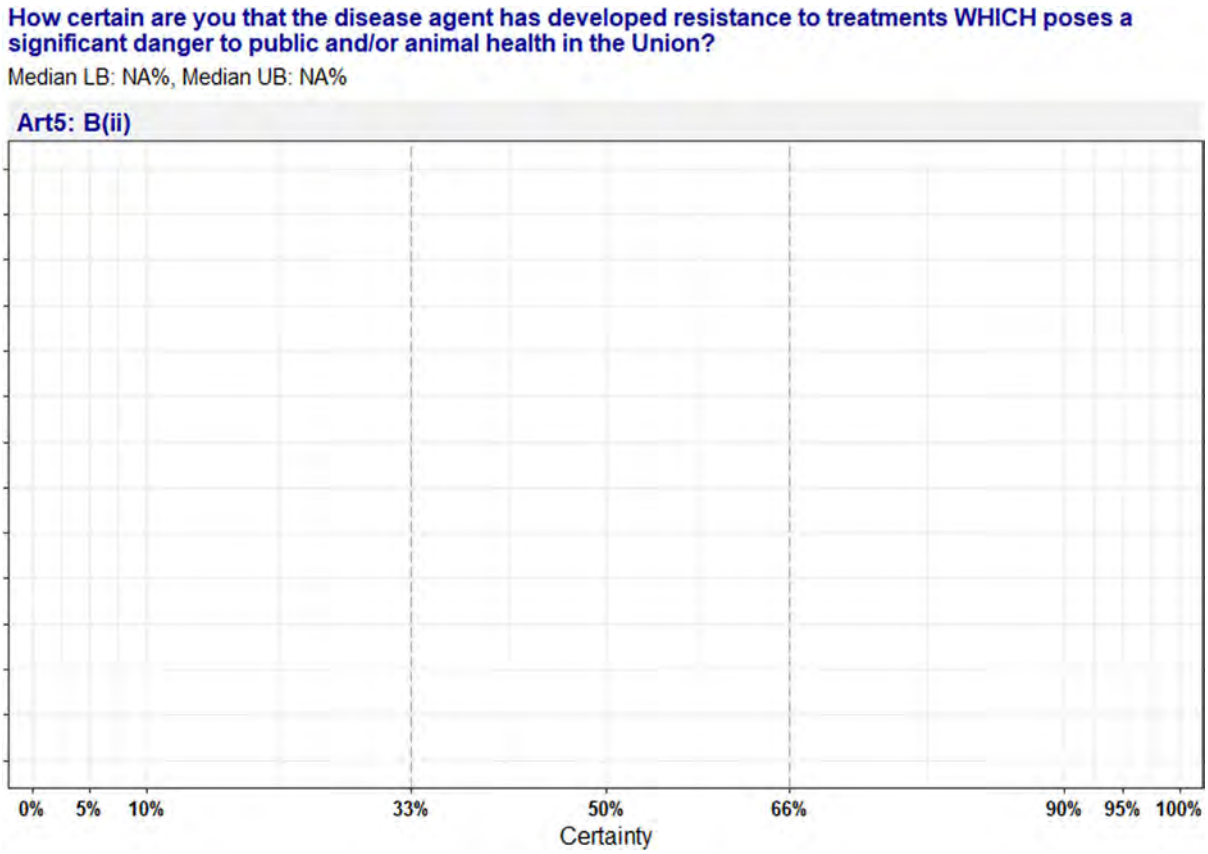

Figure A.7: This question was considered not applicable for the infection of SAV, since there is no available therapy, and no medicines are used for treatment

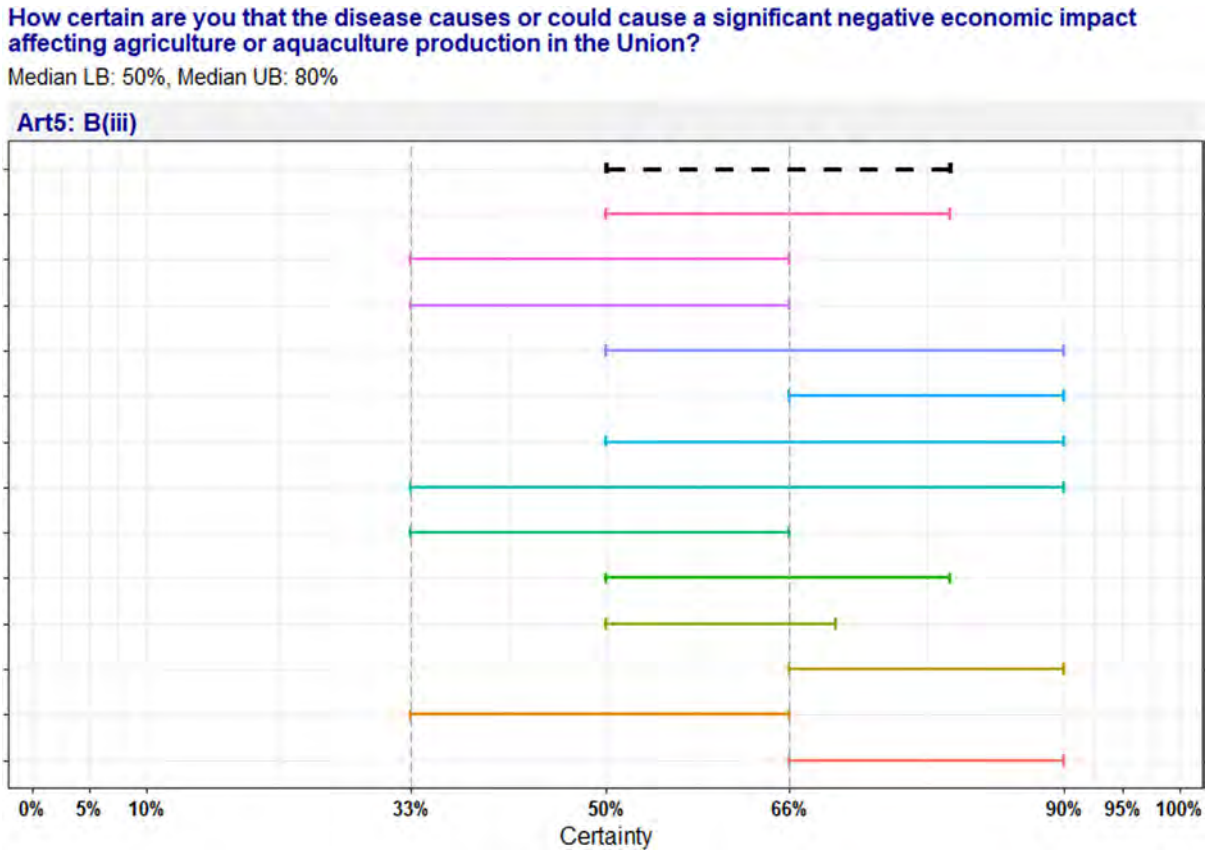

Figure A.8: Individual probability ranges, after the collective judgement, reflecting the uncertain outcome of the criterion B(iii) (the disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union). The black dotted line on the top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

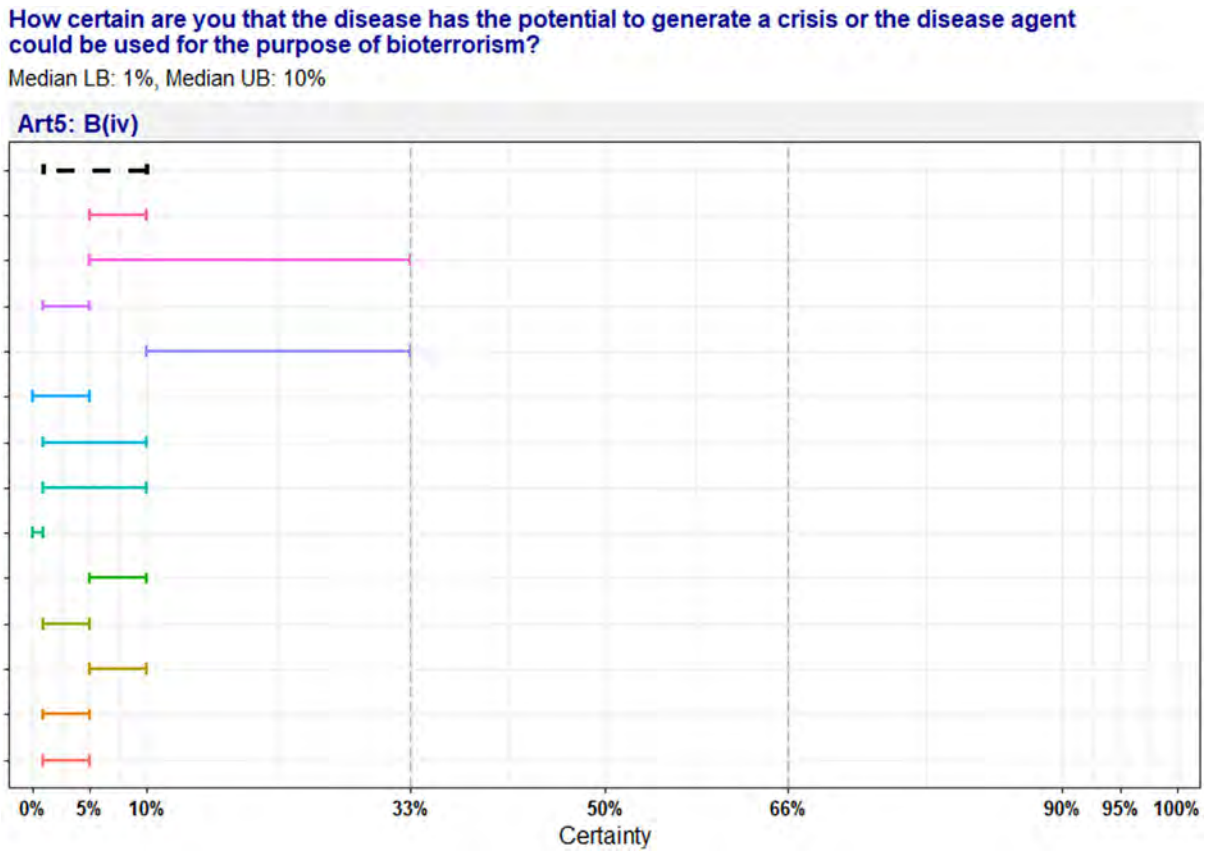

Figure A.9: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion B(iv) (the disease has the potential to generate a crisis, or the disease agent could be used for the purpose of bioterrorism). The black dotted line on the top indicates the median

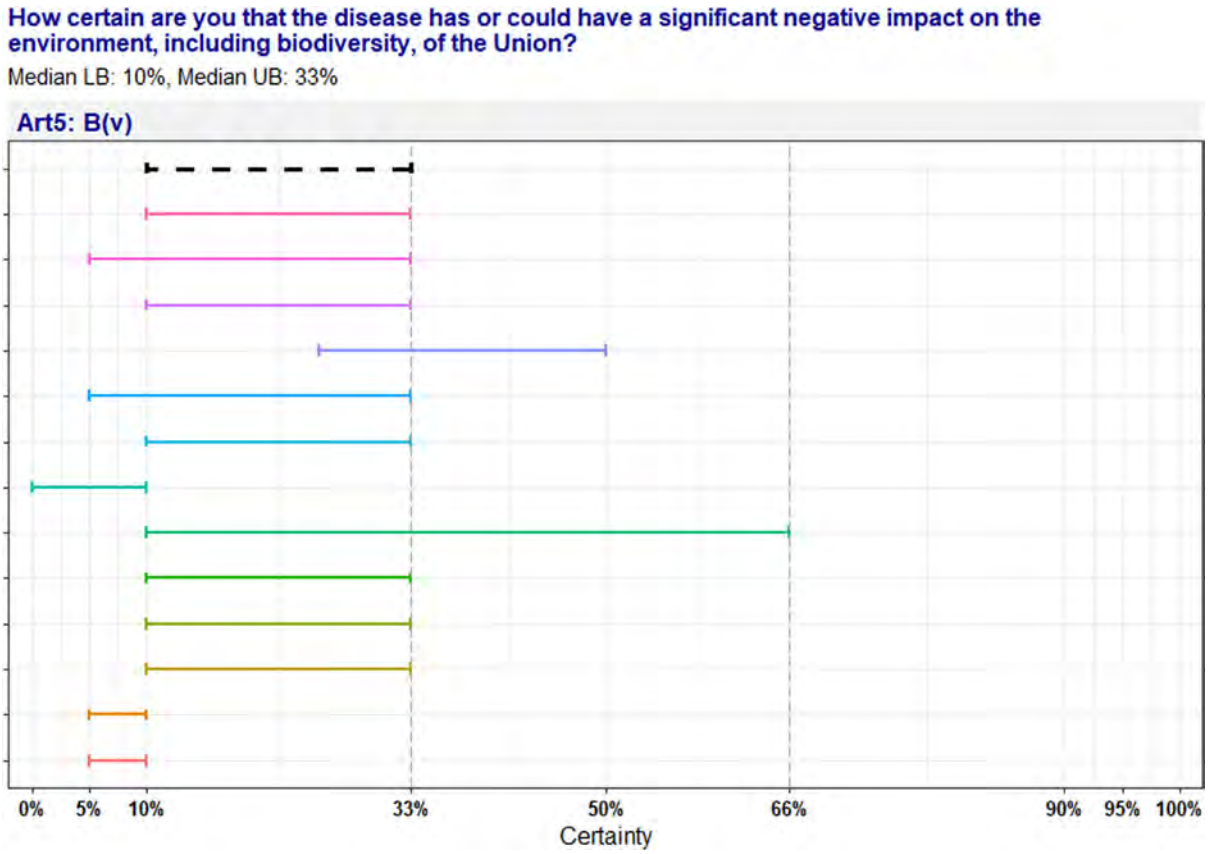

Figure A.10: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion B(v) (the disease has or could have a significant negative impact on the environment, including biodiversity, of the Union). The black dotted line on the top indicates the median

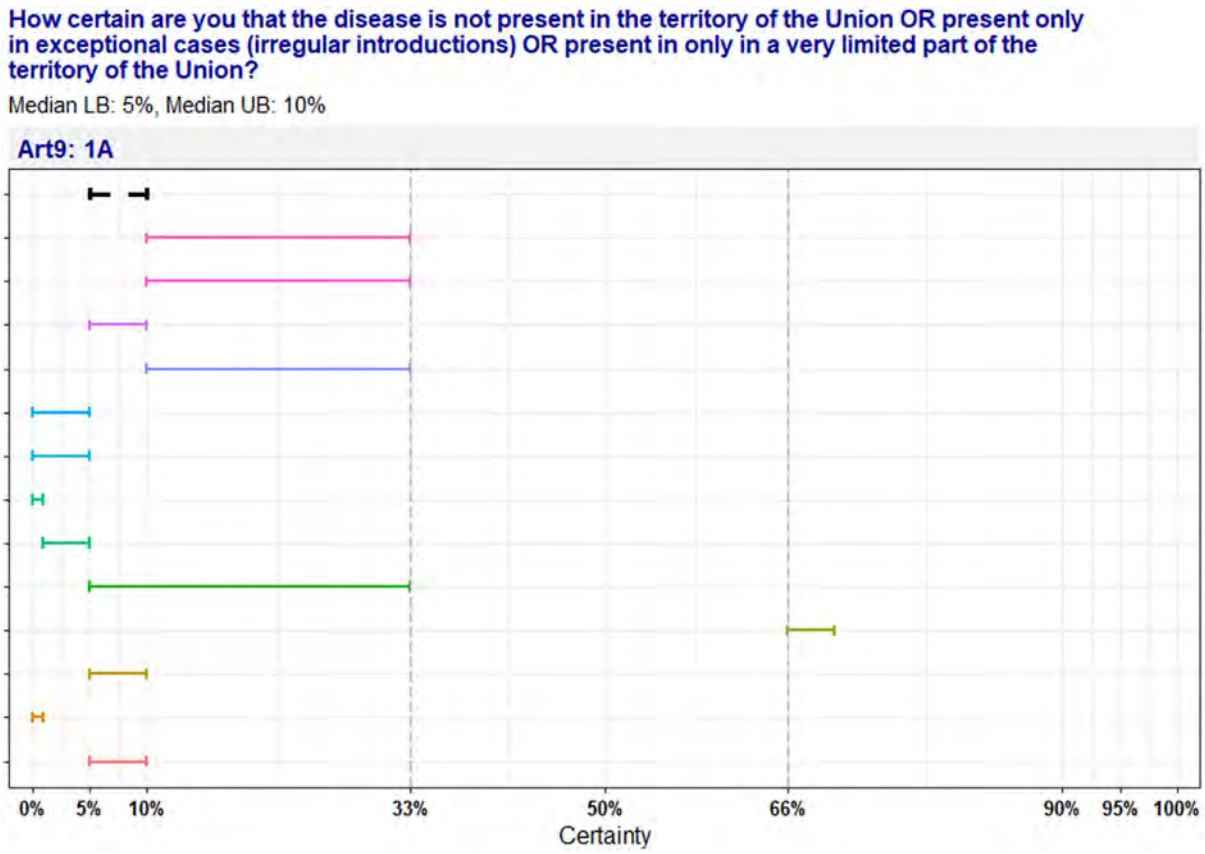

Figure A.11: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 1A (the disease is not present in the territory of the Union or present only in exceptional cases (irregular introductions) or present in only in a very limited part of the territory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

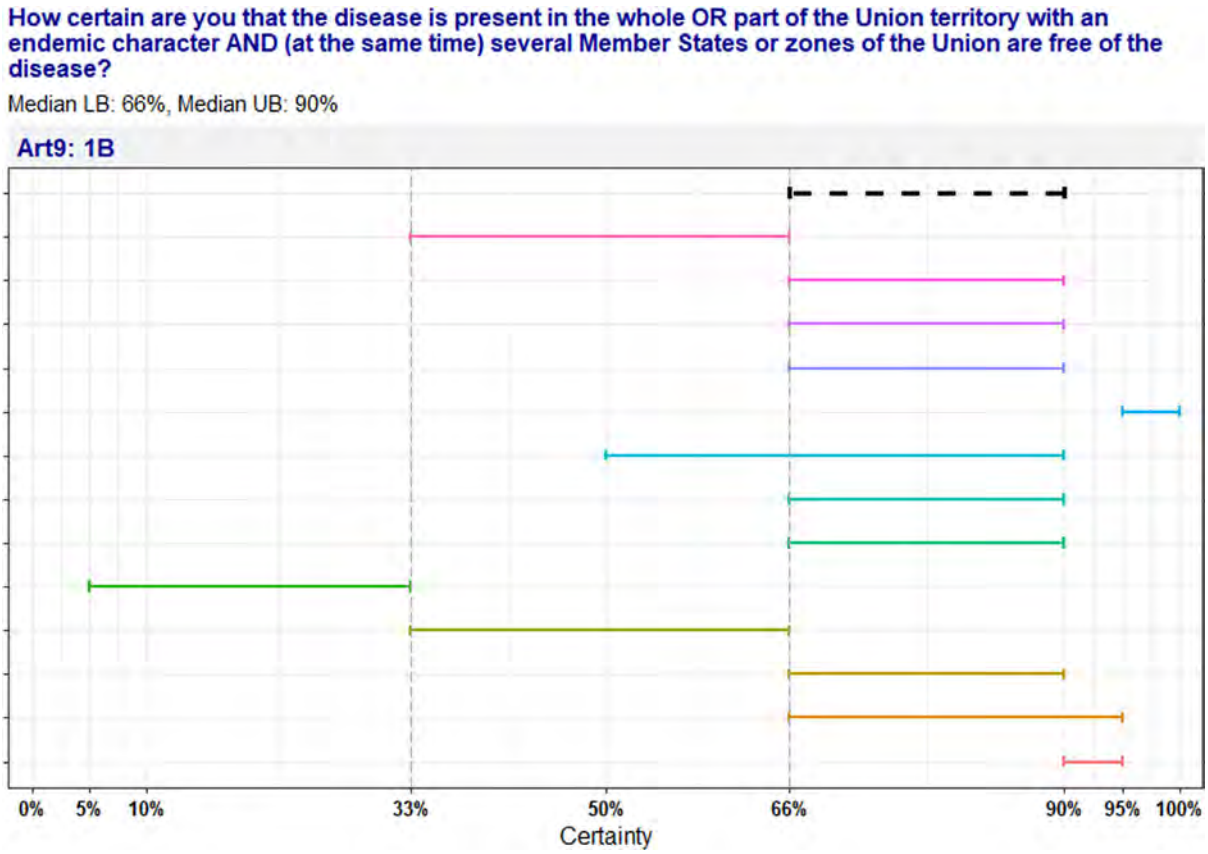

Figure A.12: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion 1B (the disease is present in the whole or part of the Union territory with an endemic character and (at the same time) several Member States or zones of the Union are free of the disease).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

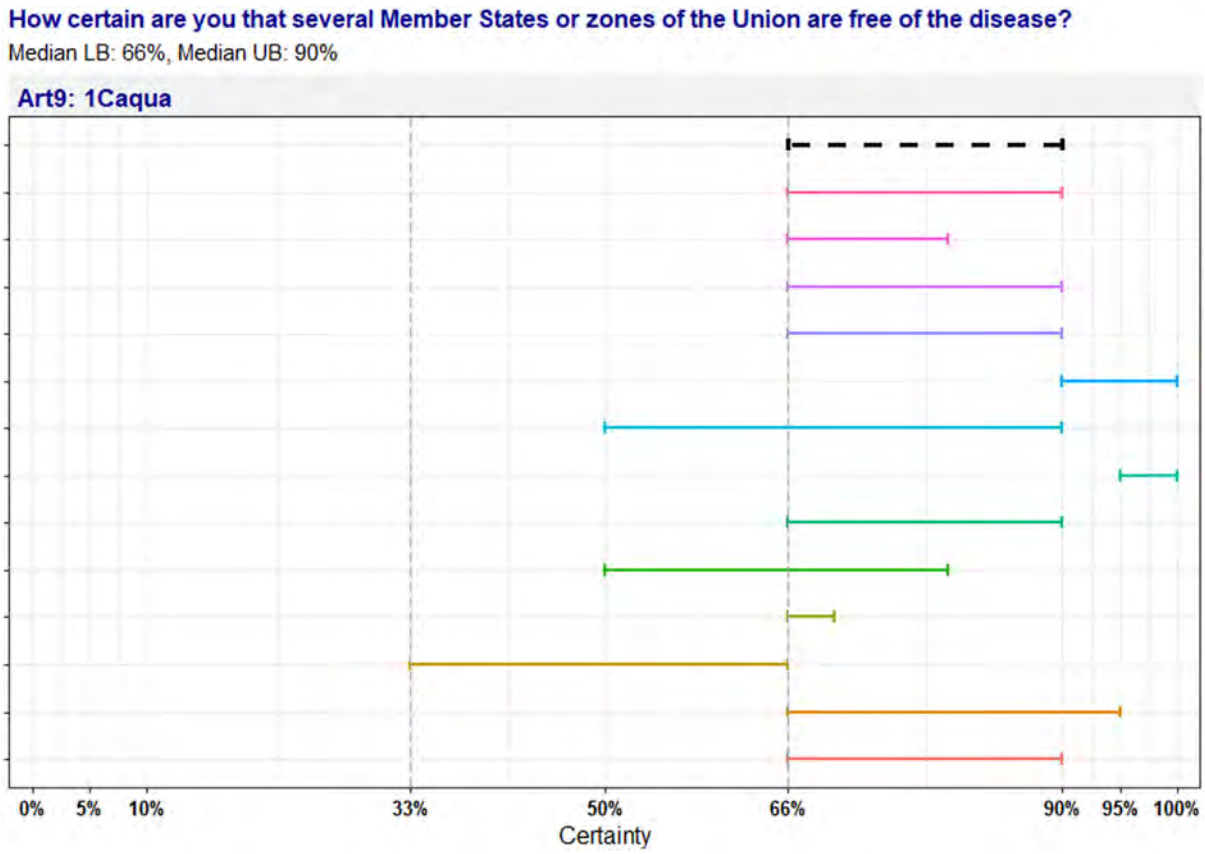

Figure A.13: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion 1Caqua (the disease is present in the whole or part of the Union territory with an endemic character). The black dotted line on the top indicates the median

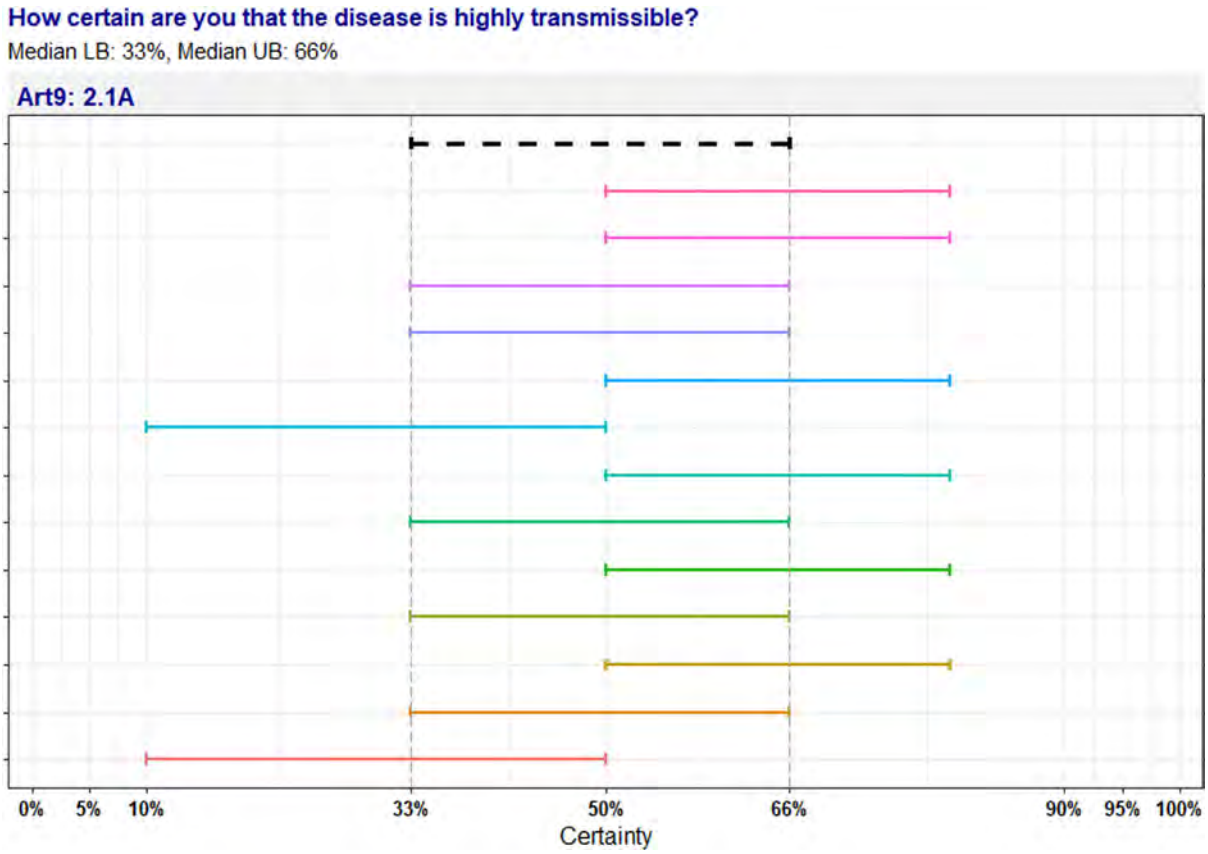

Figure A.14: Individual probability ranges, after the collective judgement, reflecting the uncertain outcome of the criterion 2.1A (the disease is highly transmissible). The black dotted line on the top indicates the median

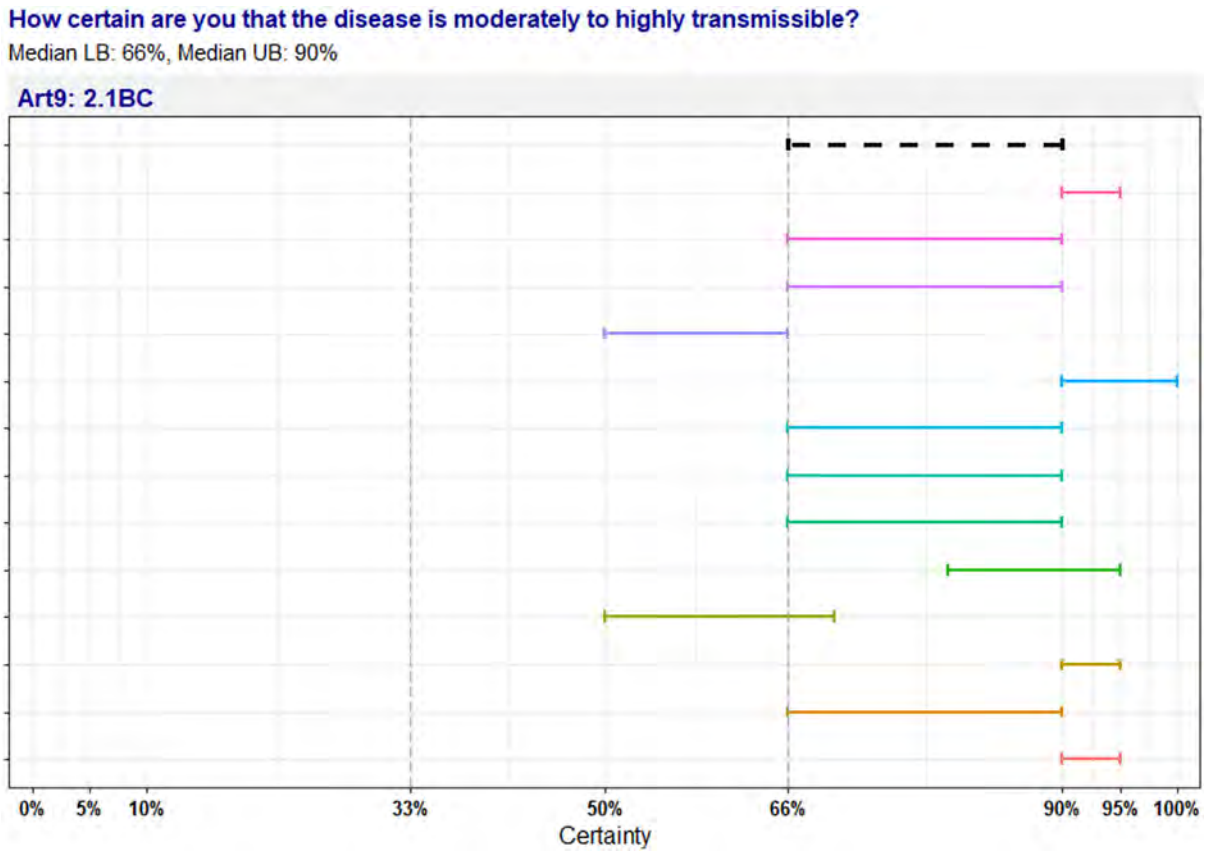

Figure A.15: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion 2.1 BC (the disease is moderately to highly transmissible). The black dotted line on the top indicates the median

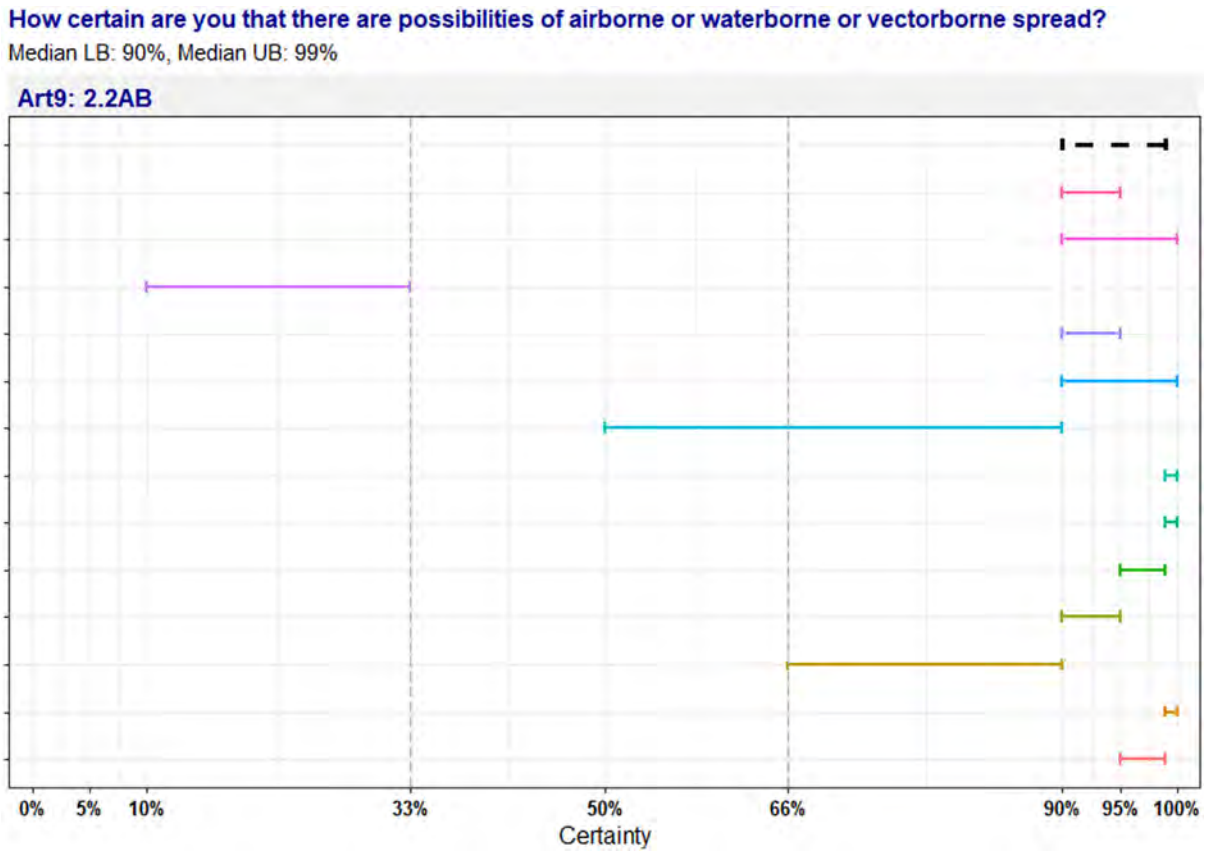

Figure A.16: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion 2.2AB (there are possibilities of airborne or waterborne or vector-borne spread). The black dotted line on the top indicates the median

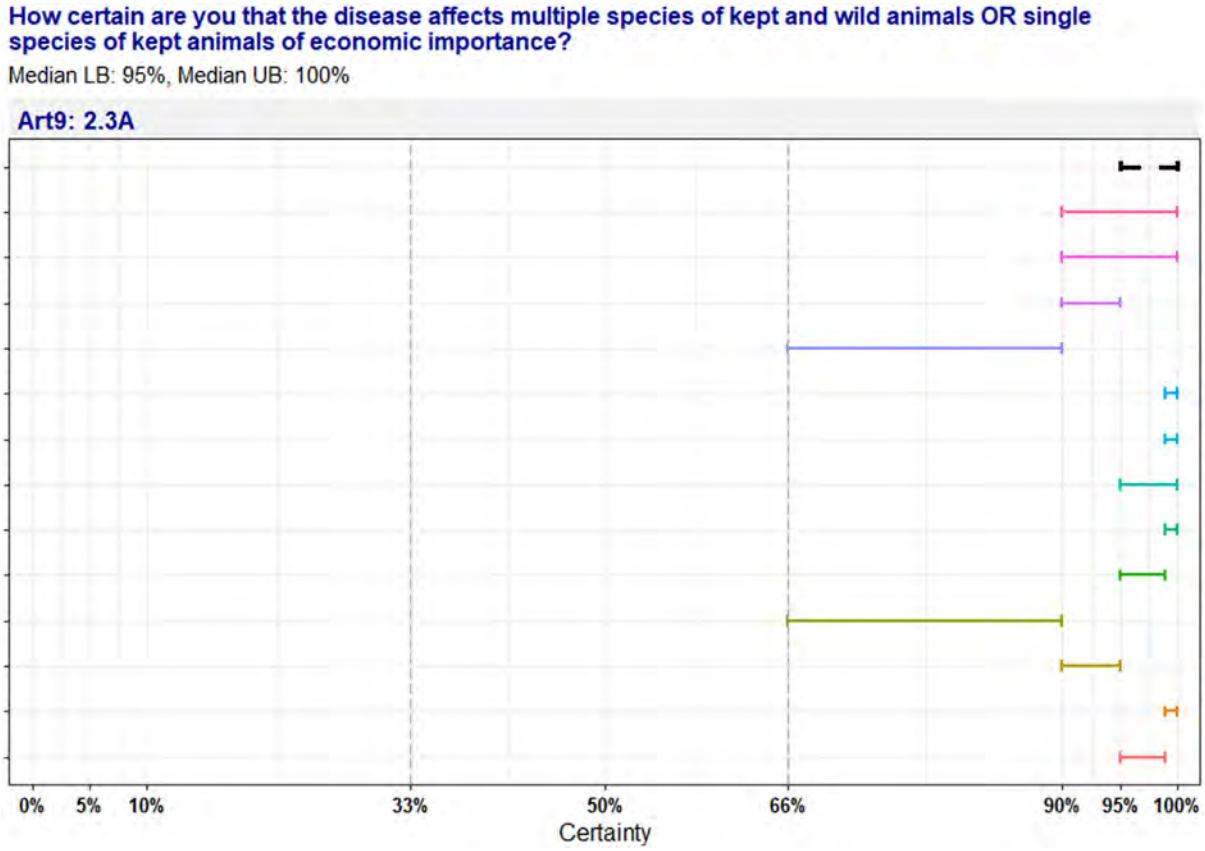

Figure A.17: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion 2.3A (the disease affects multiple species of kept and wild animals or single species of kept animals of economic importance). The black dotted line on the top indicates the median

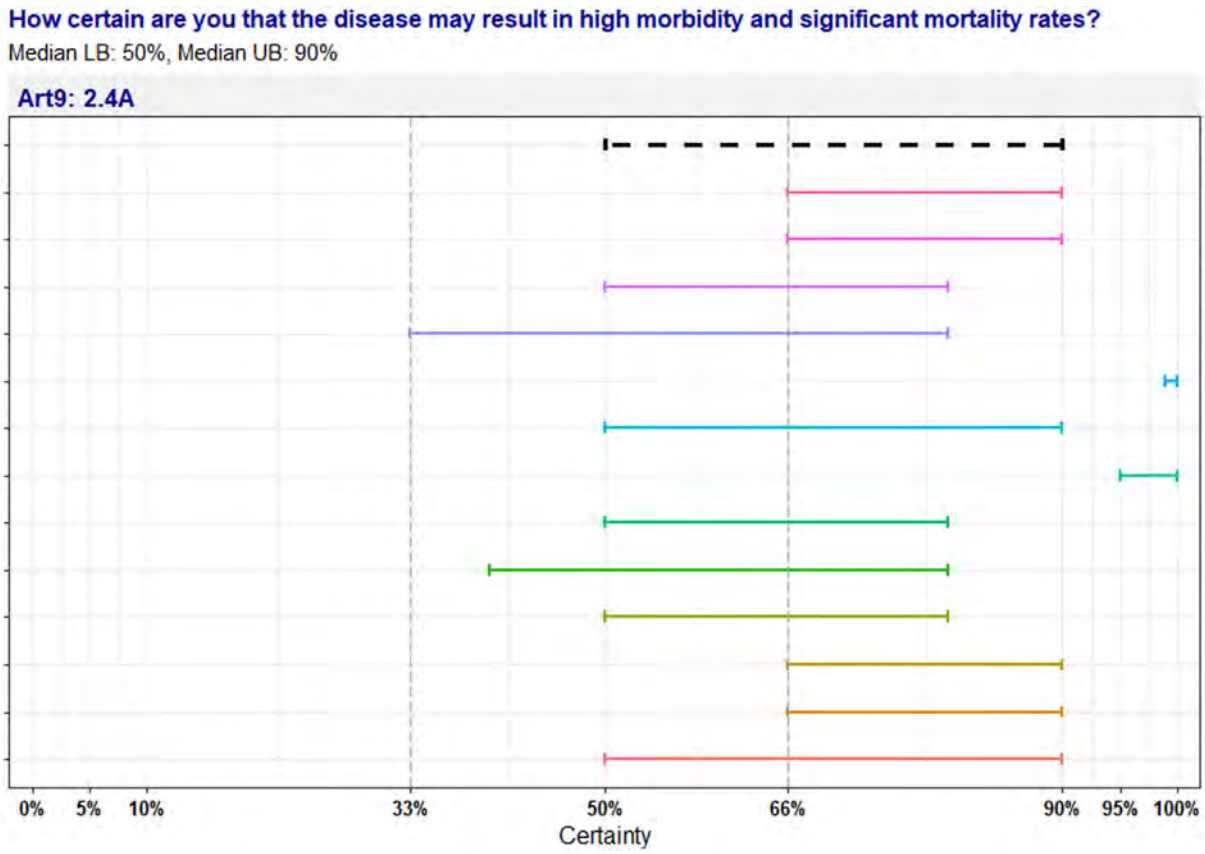

Figure A.18: Individual probability ranges, after the collective judgement, reflecting the uncertain outcome of the criterion 2.4A (the disease may result in high morbidity and significant mortality rates). The black dotted line on the top indicates the median

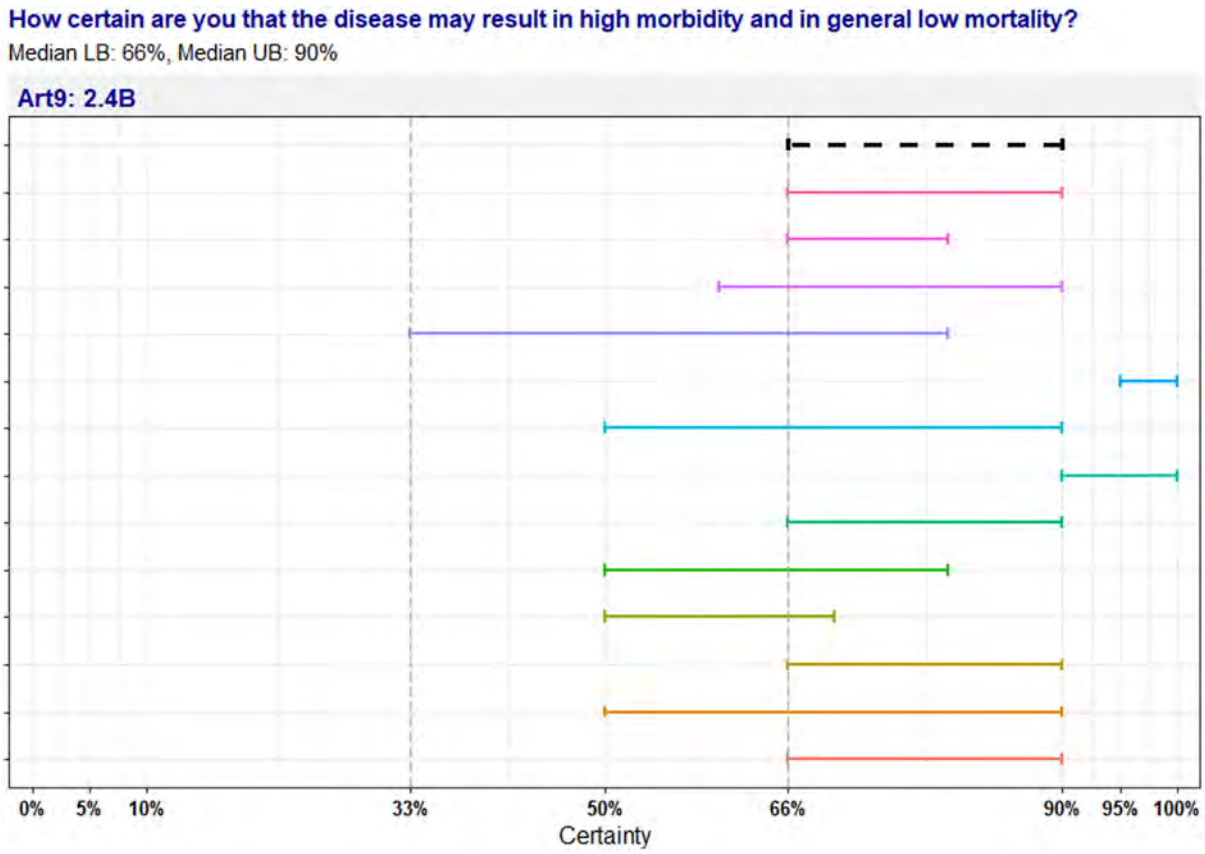

Figure A.19: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion 2.4B (the disease may result in high morbidity with in general low mortality). The black dotted line on the top indicates the median

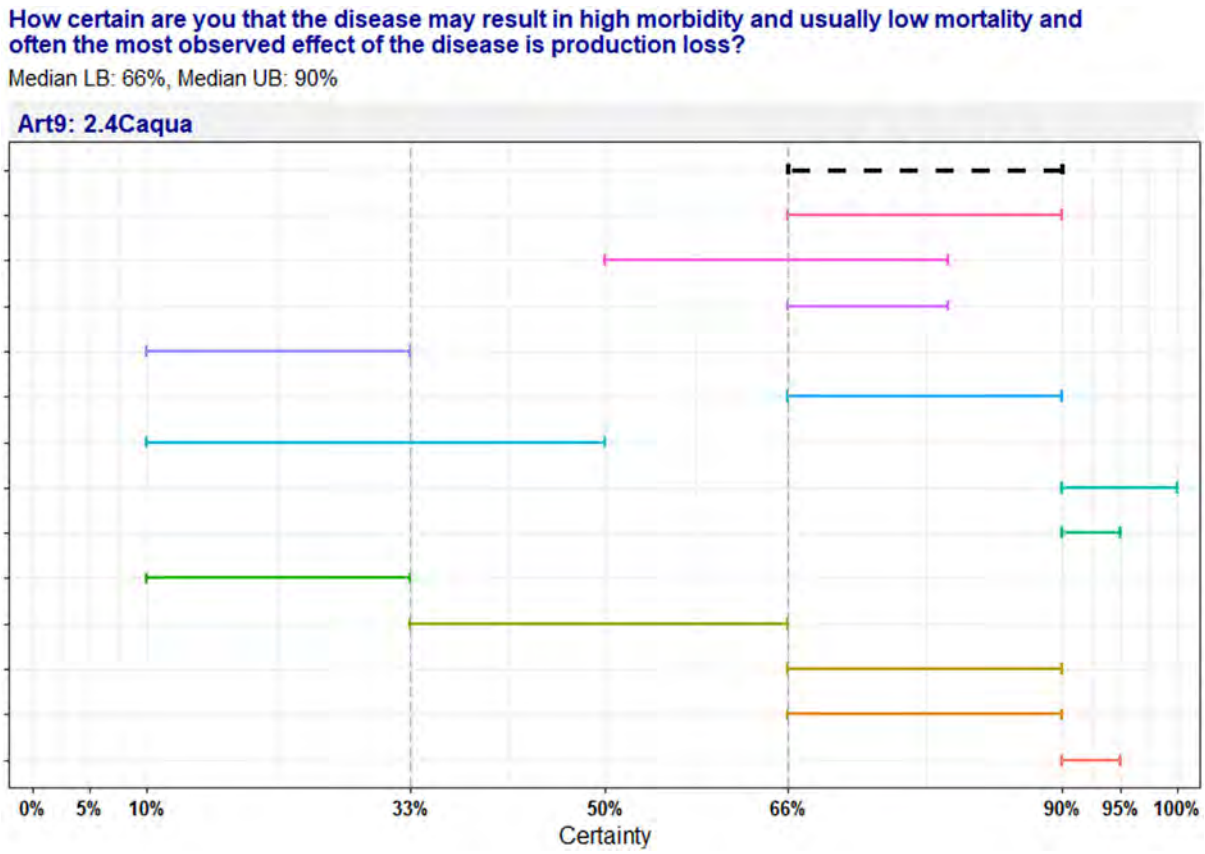

Figure A.20: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion 2.4Caqua (the disease usually does not result in high morbidity and has negligible or no mortality and often the most observed effect of the disease is production loss). The black dotted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

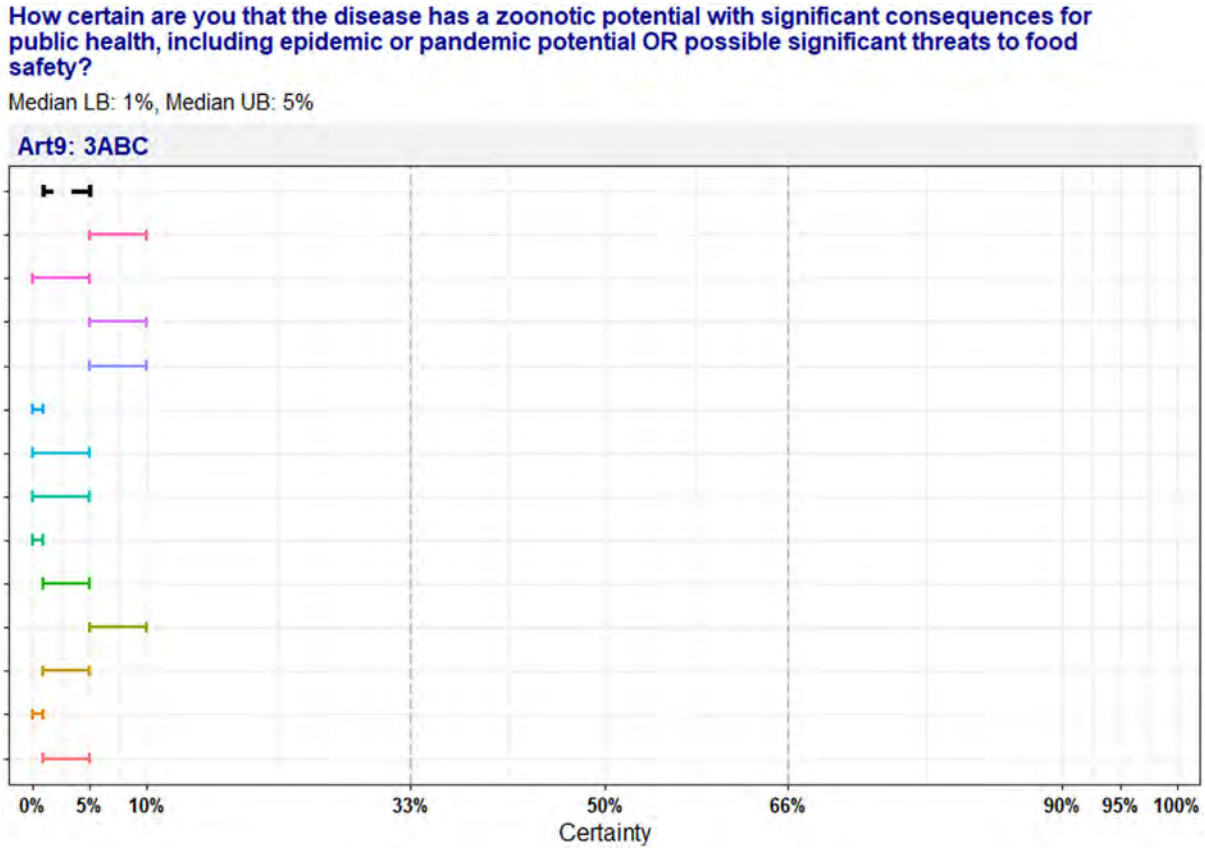

Figure A.21: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 3ABC (the disease has a zoonotic potential with significant consequences for public health or possible significant threats to food safety). The black dotted line on the top indicates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

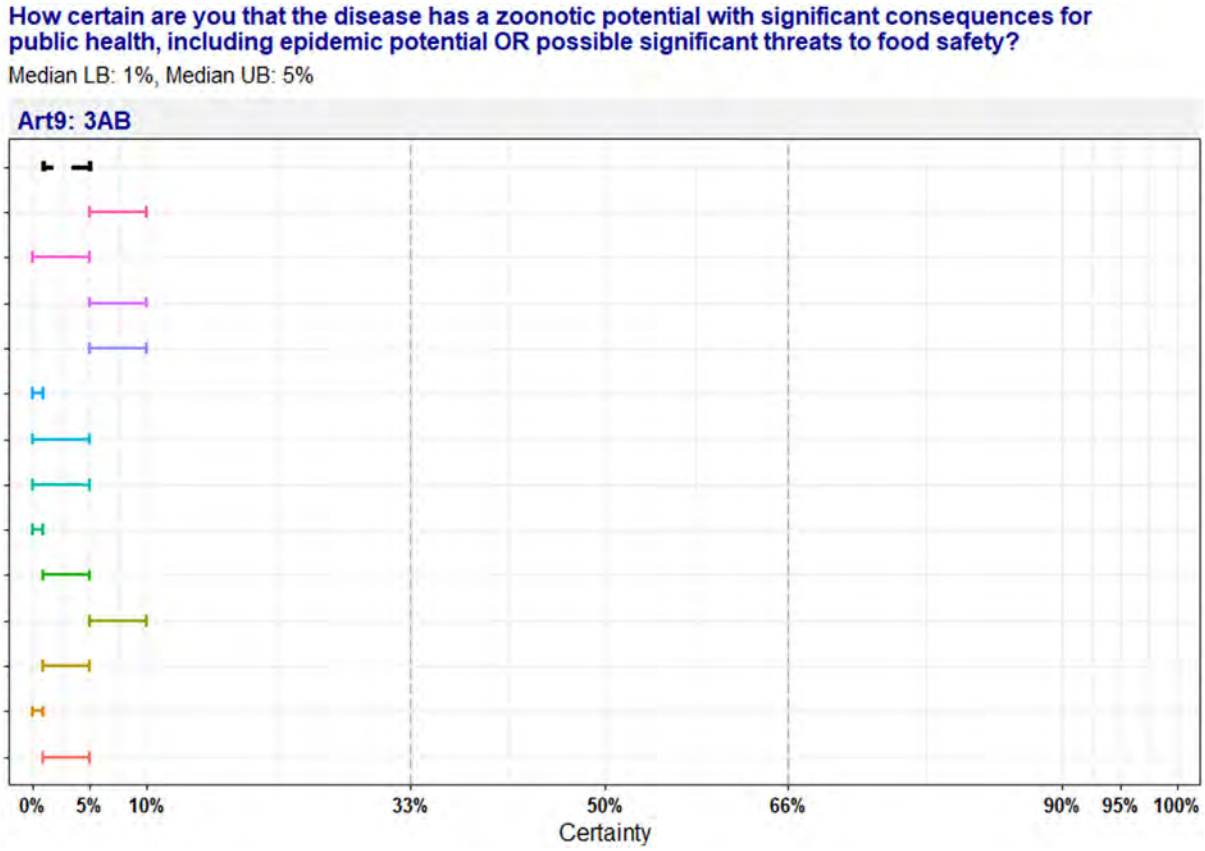

Figure A.22: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 3AB (the disease has a zoonotic potential with significant consequences for public health, including epidemic potential or possible significant threats to food safety). The black dotted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

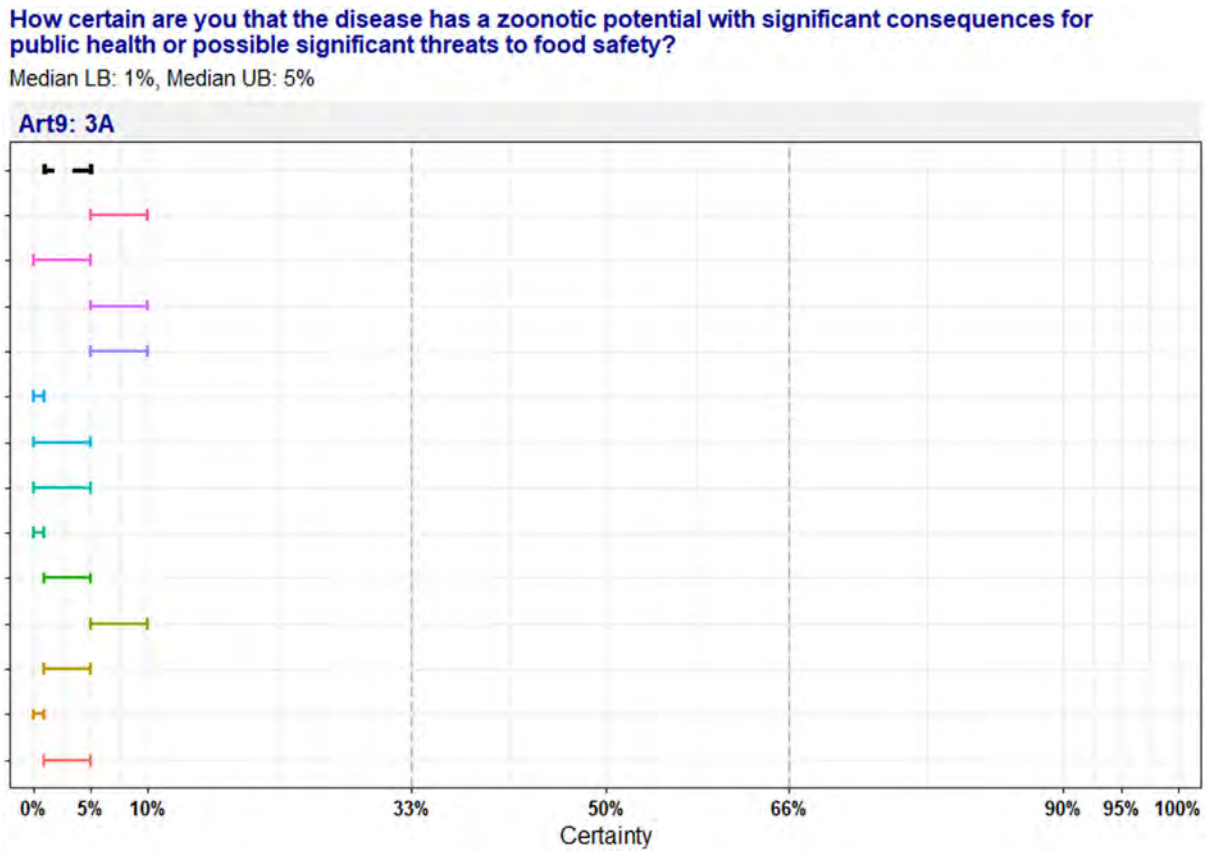

Figure A.23: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 3A (the disease has a zoonotic potential with significant consequences for public health, including epidemic or pandemic potential or possible significant threats to food safety). The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

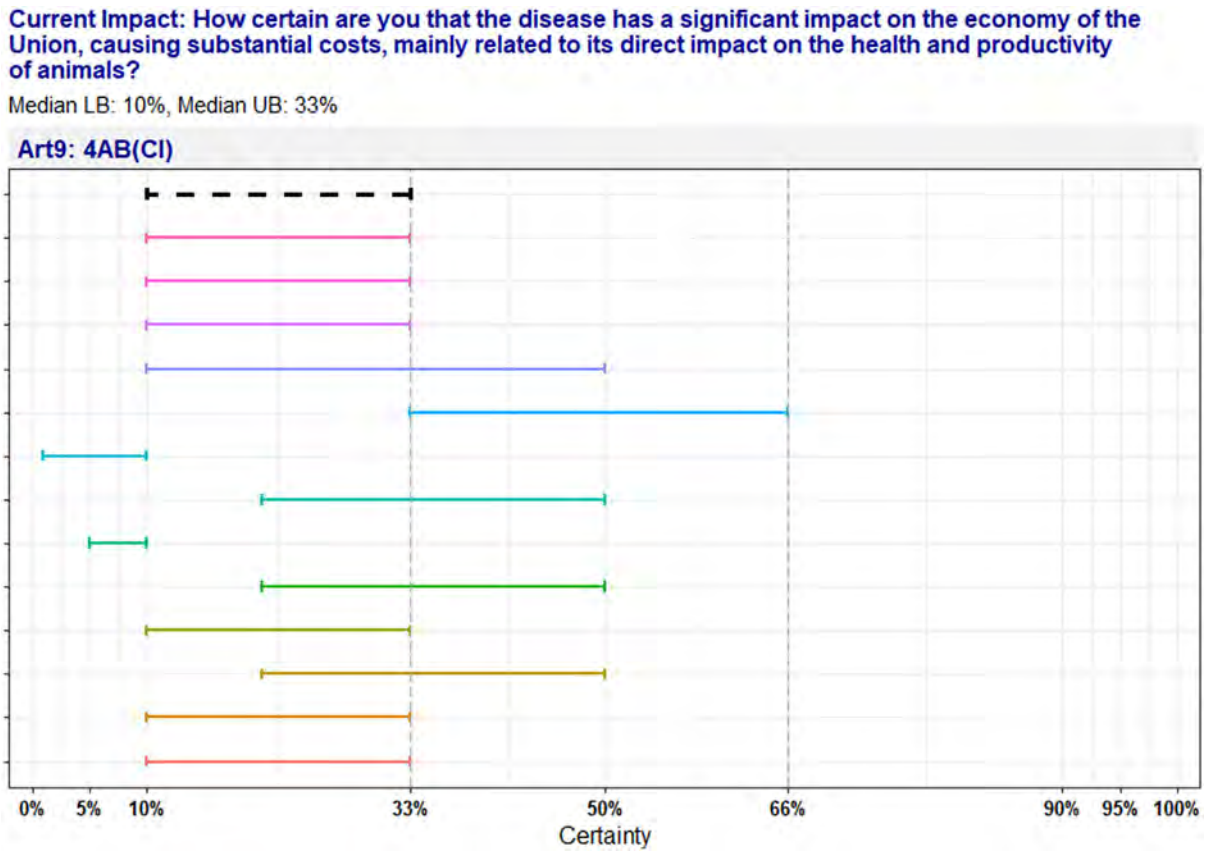

Figure A.24: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 4AB (current impact) (the disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity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

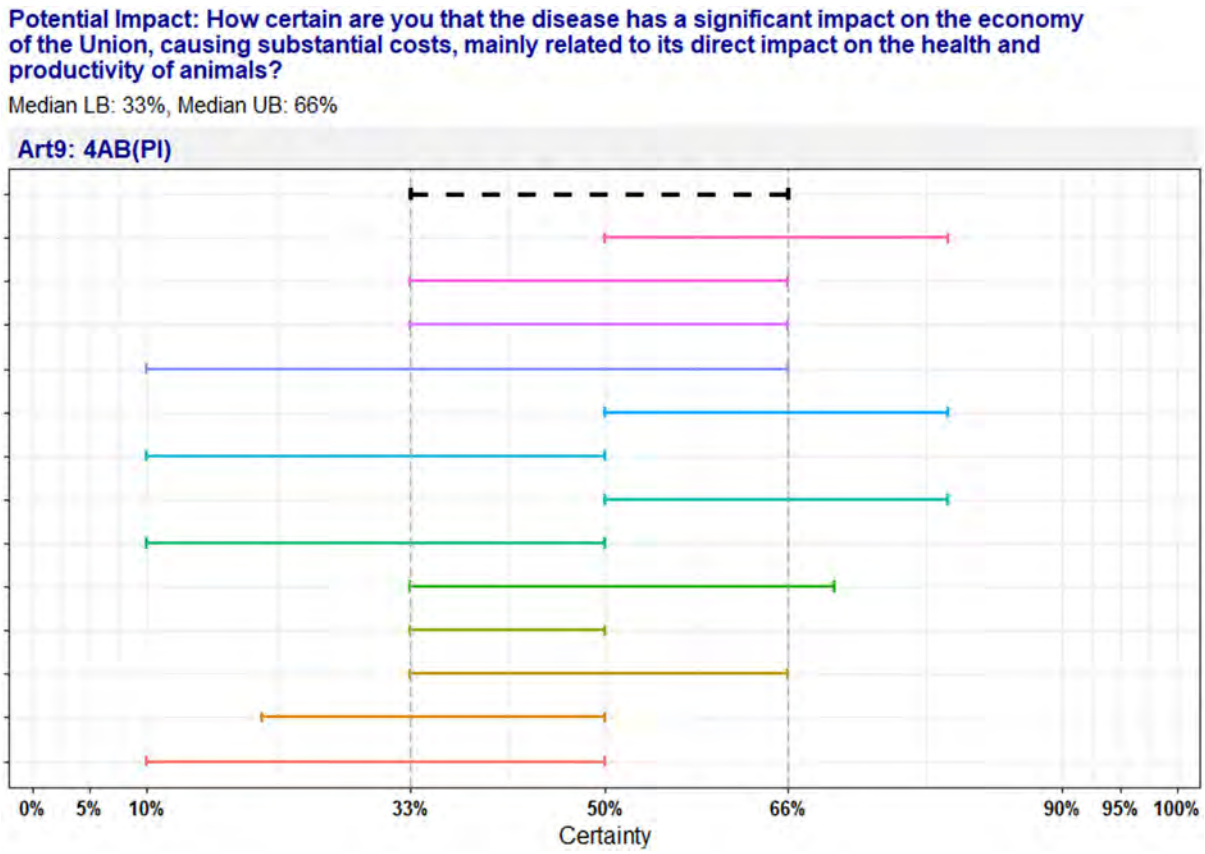

Figure A.25: Individual probability ranges, after the collective judgement, reflecting the uncertain outcome of the criterion 4AB (potential impact) (the disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity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

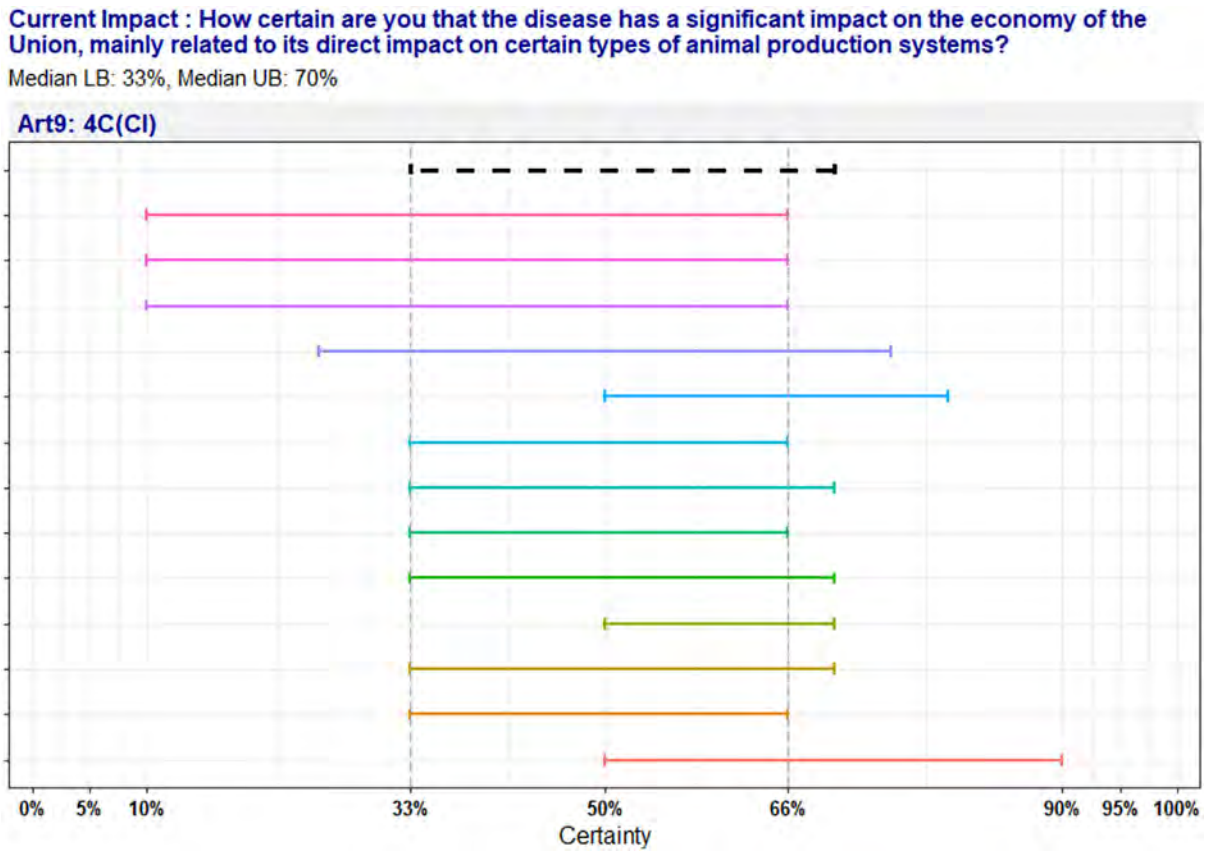

Figure A.26: Individual probability ranges, after the collective judgement, reflecting the uncertain outcome of criterion 4C (current impact) (the disease has a significant impact on the economy of the Union, mainly related to its direct impact on certain types of animal production systems). The black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

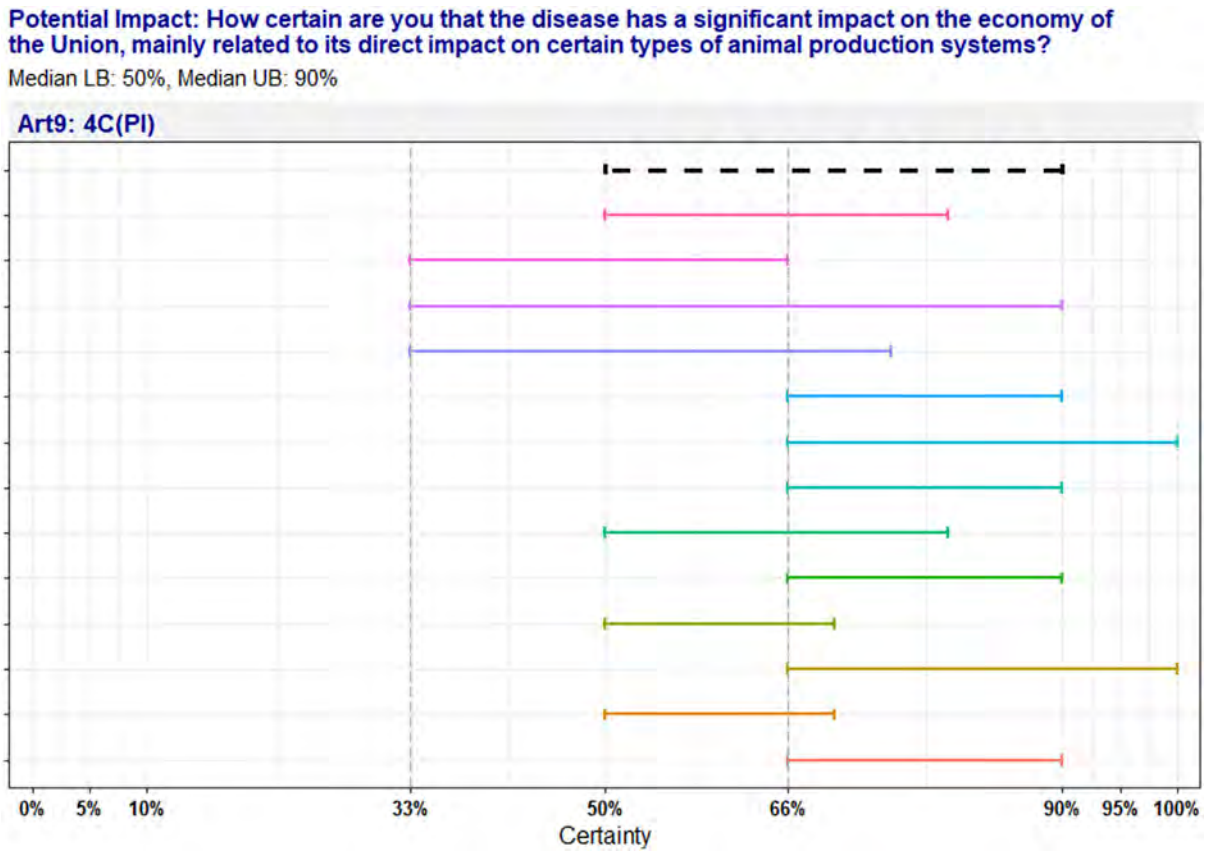

Figure A.27: Individual probability ranges, after the collective judgement, reflecting the uncertain outcome of the criterion 4C (potential impact) (the disease has a significant impact on the economy of the Union, mainly related to its direct impact on certain types of animal production systems). Black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

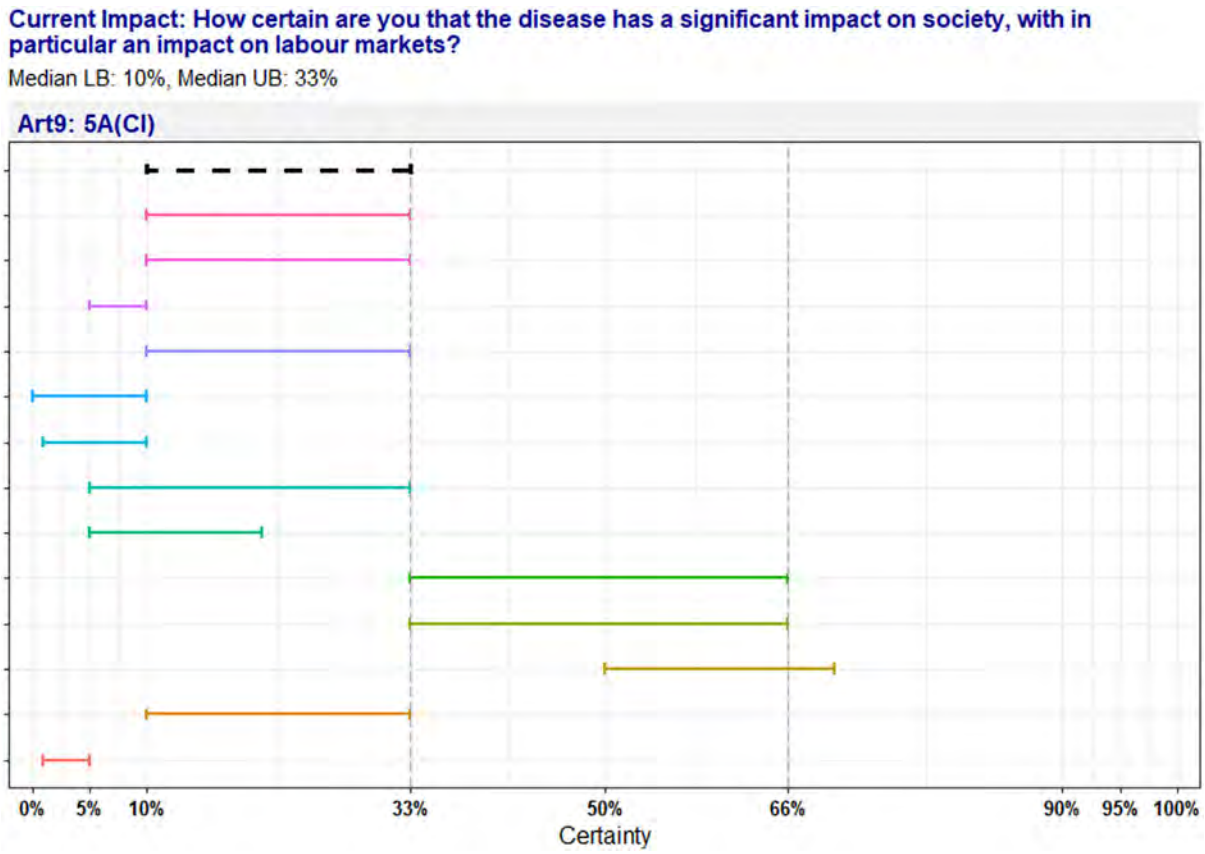

Figure A.28: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 5A (current impact) (the disease has a significant impact on society, with in particular an impact on labour markets). Black dotted line on the top indicates the median

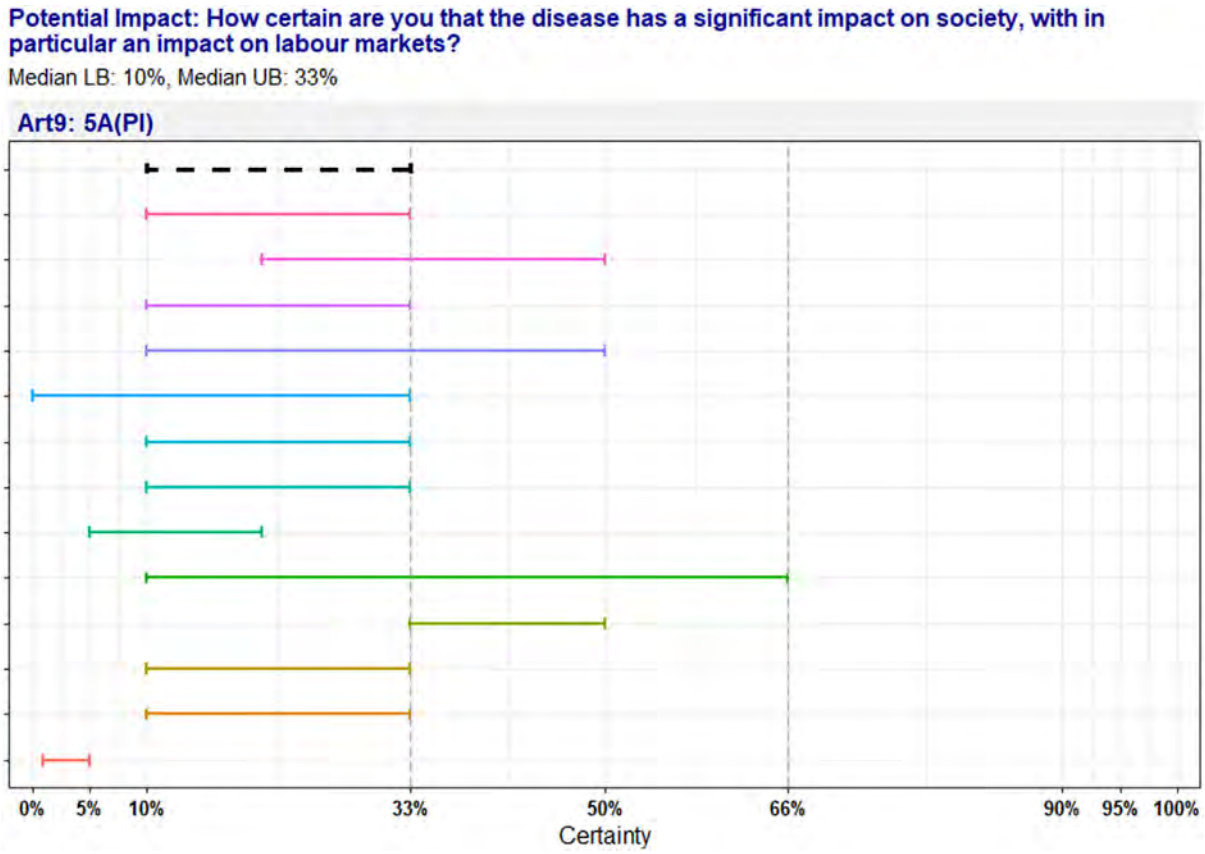

Figure A.29: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 5A (potential impact) (the disease has a significant impact on society, with in particular an impact on labour markets). The black dotted line on the top indicates the median

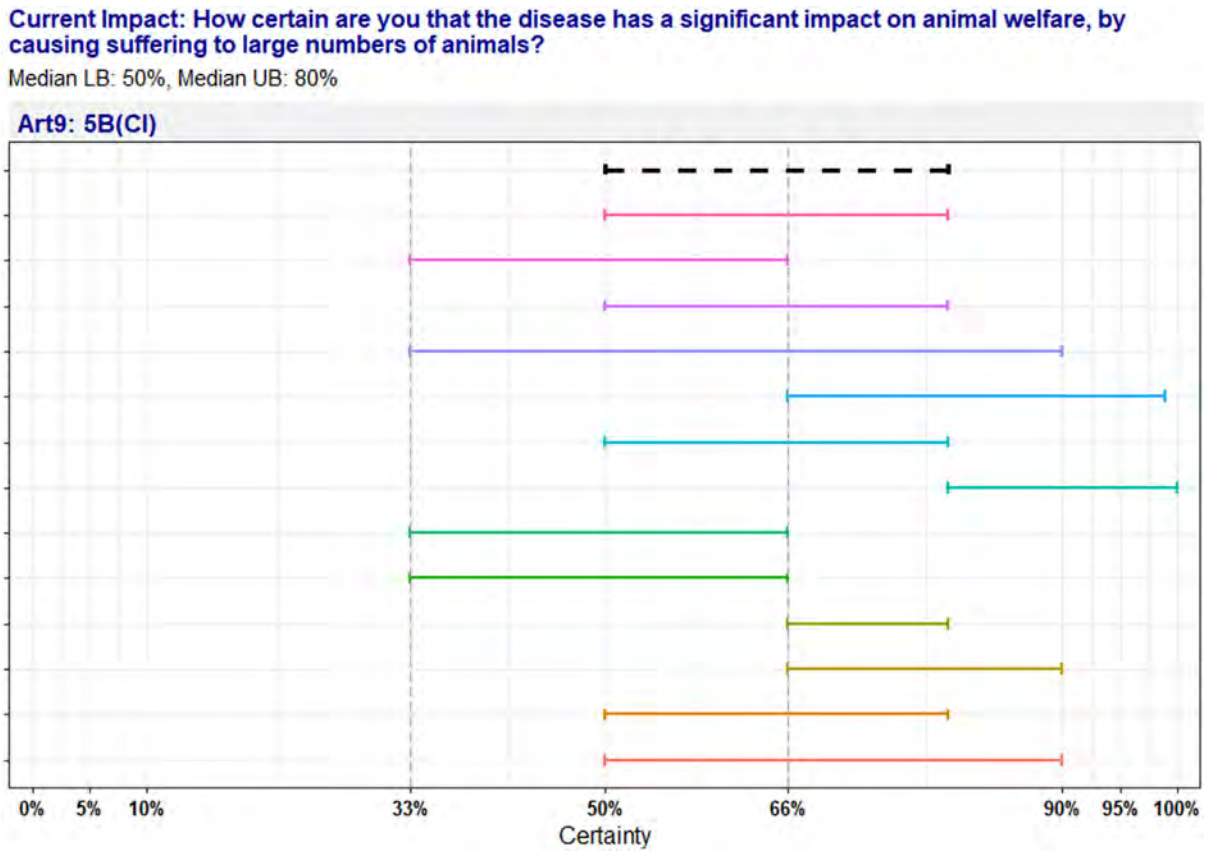

Figure A.30: Individual probability ranges, after the collective judgement, reflecting the uncertain outcome of the criterion 5B (current impact) (the disease has a significant impact on animal welfare, by causing suffering of large numbers of animals). The black dotted line on the top indicates the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

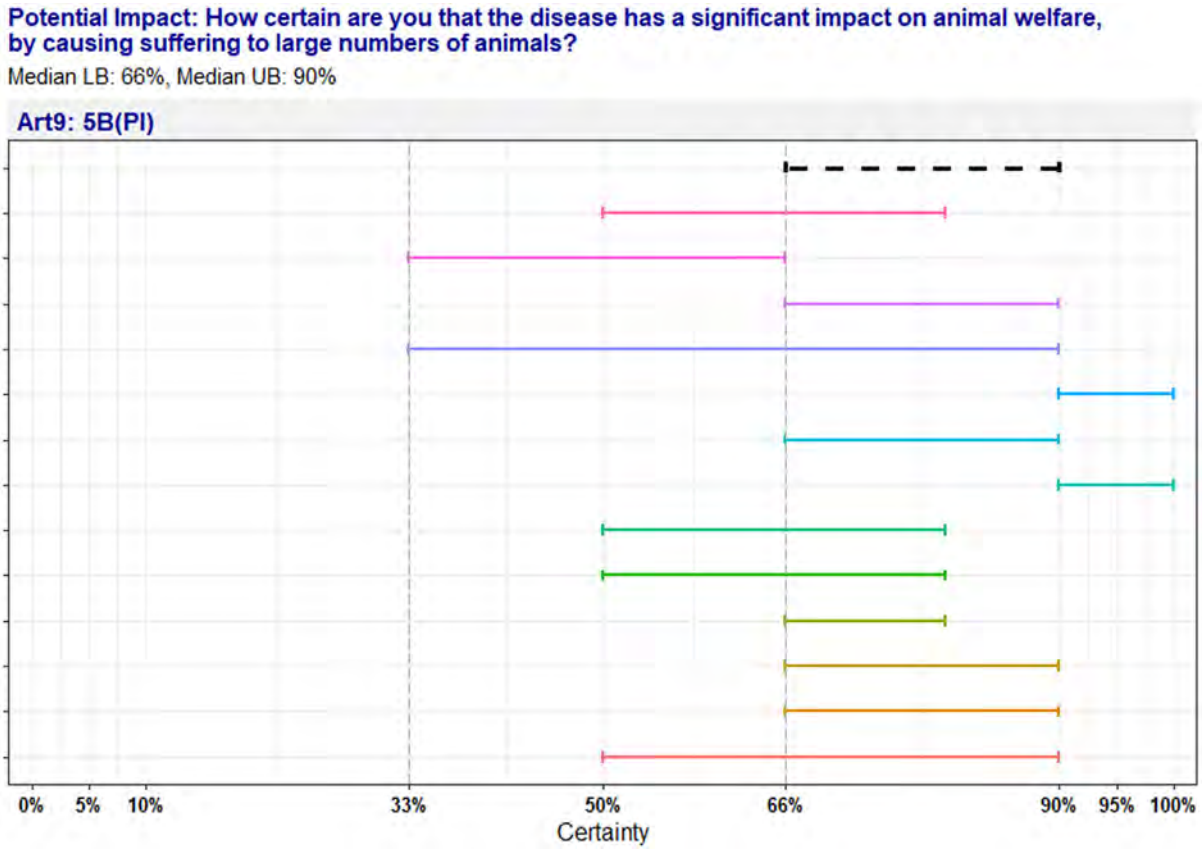

Figure A.31: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion 5B (potential impact) (the disease has a significant impact on animal welfare, by causing suffering of large numbers of animals). The black dotted line on the top indicates the median

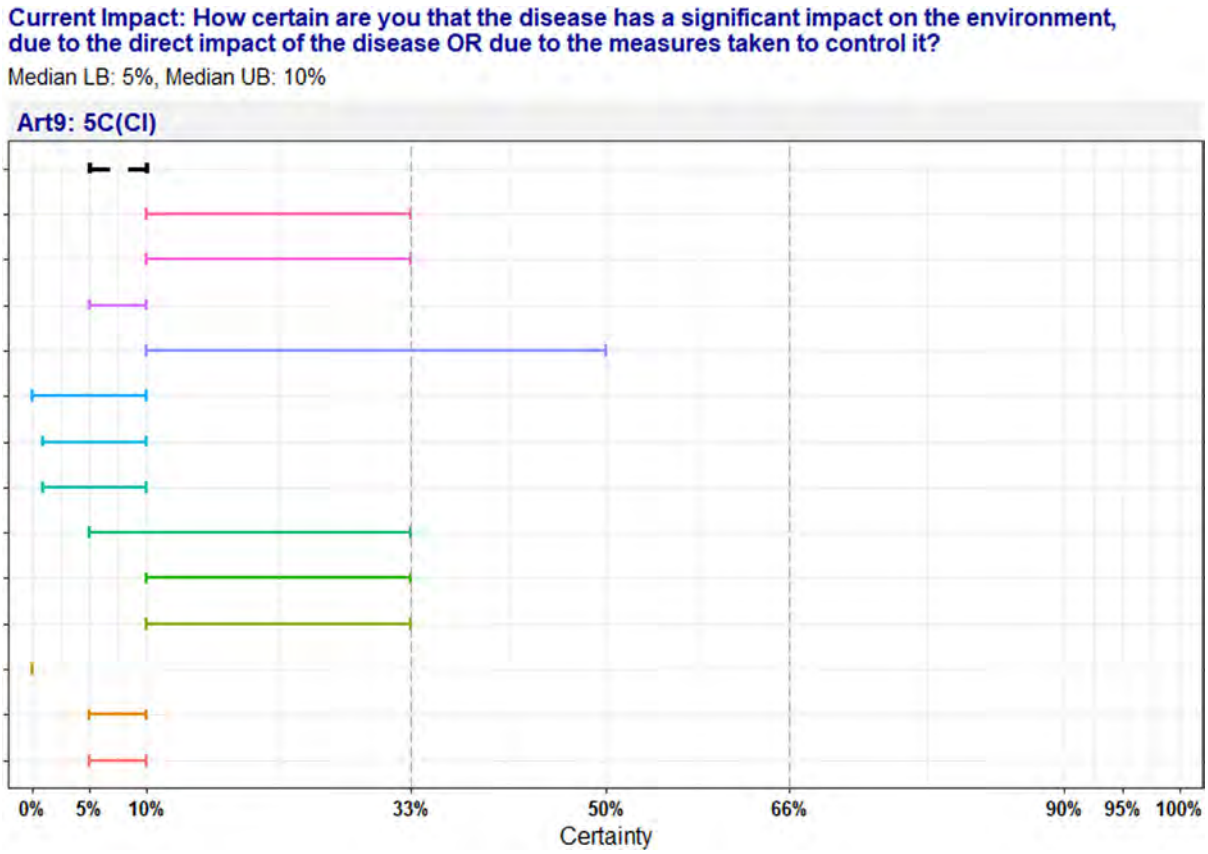

Figure A.32: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 5C (current impact) (the disease has a significant impact on the environment, due to the direct impact of the disease or due to the measures taken to control it). The black dotted line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

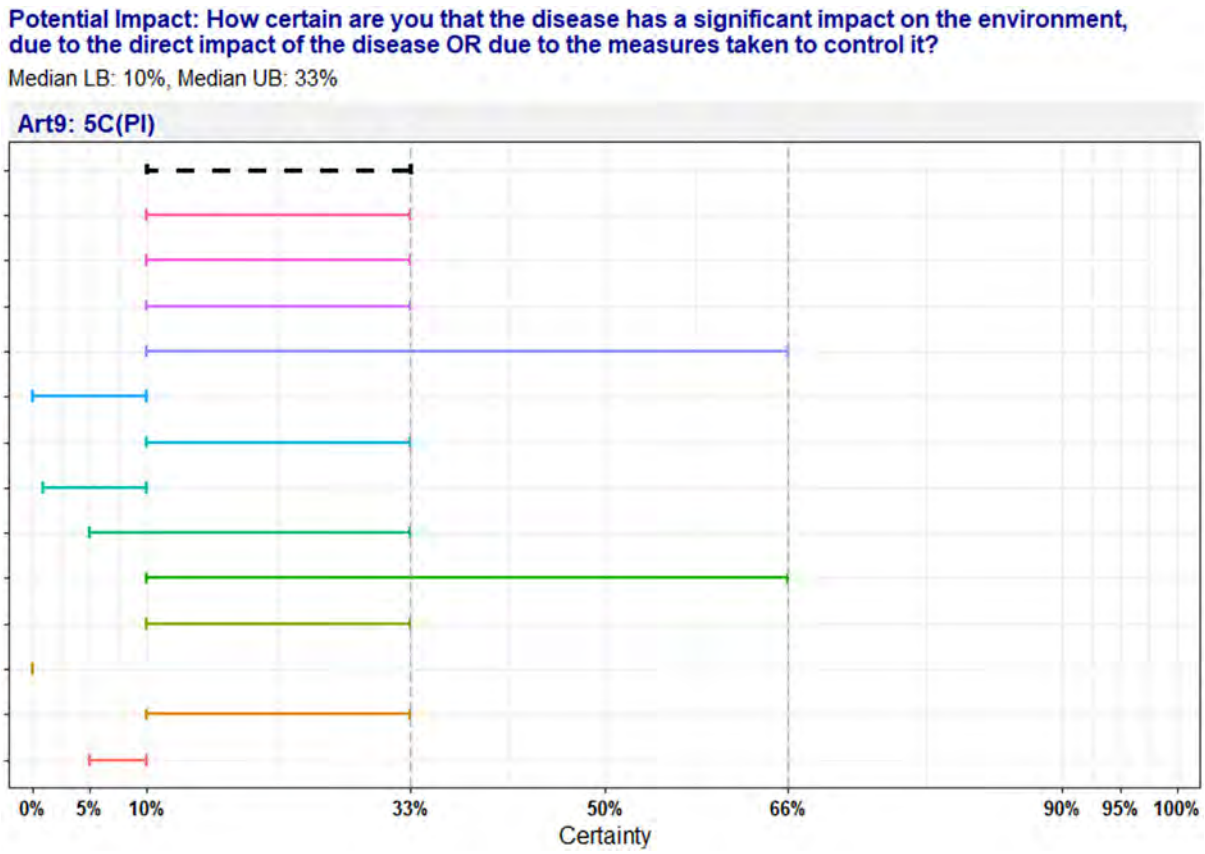

Figure A.33: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 5C (potential impact) (the disease has a significant impact on the environment, due to the direct impact of the disease or due to the measures taken to control it). The black dotted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

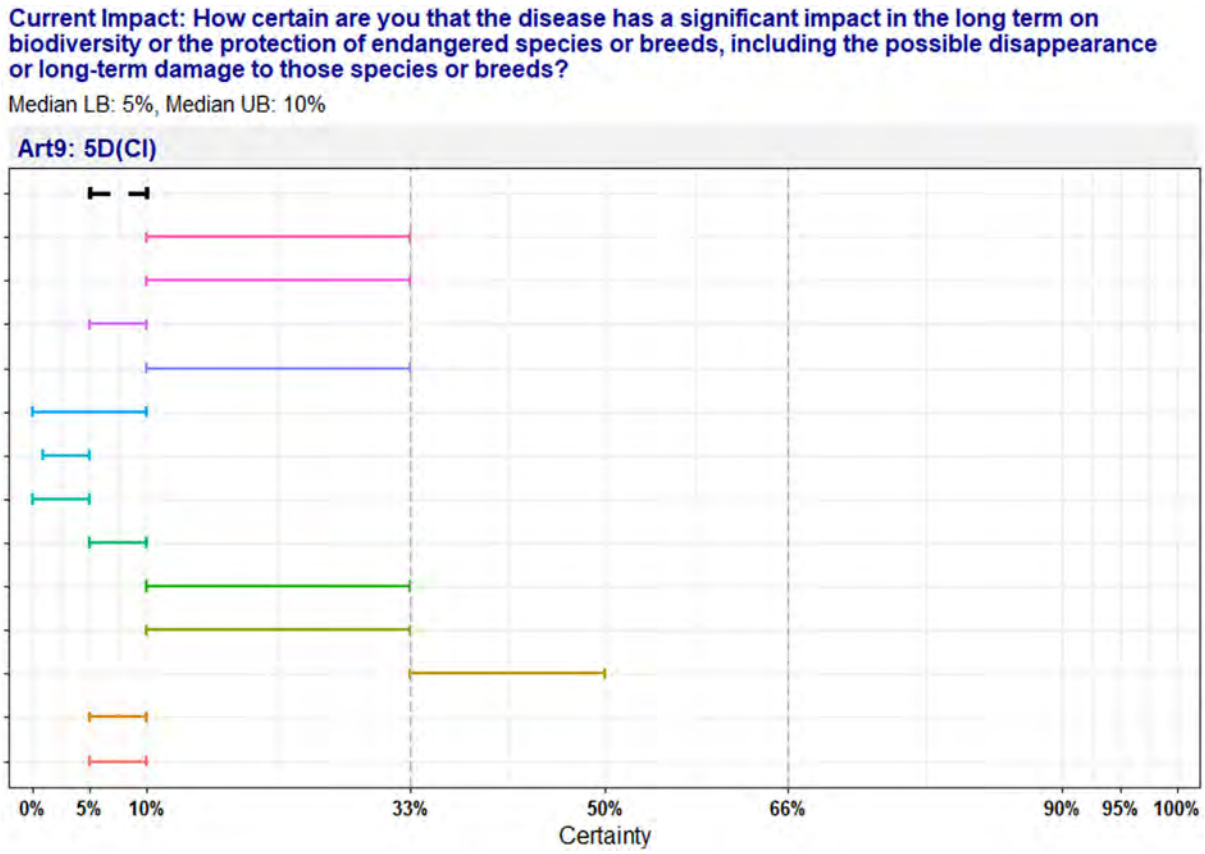

Figure A.34: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 5D (current impact) (the disease has a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance or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

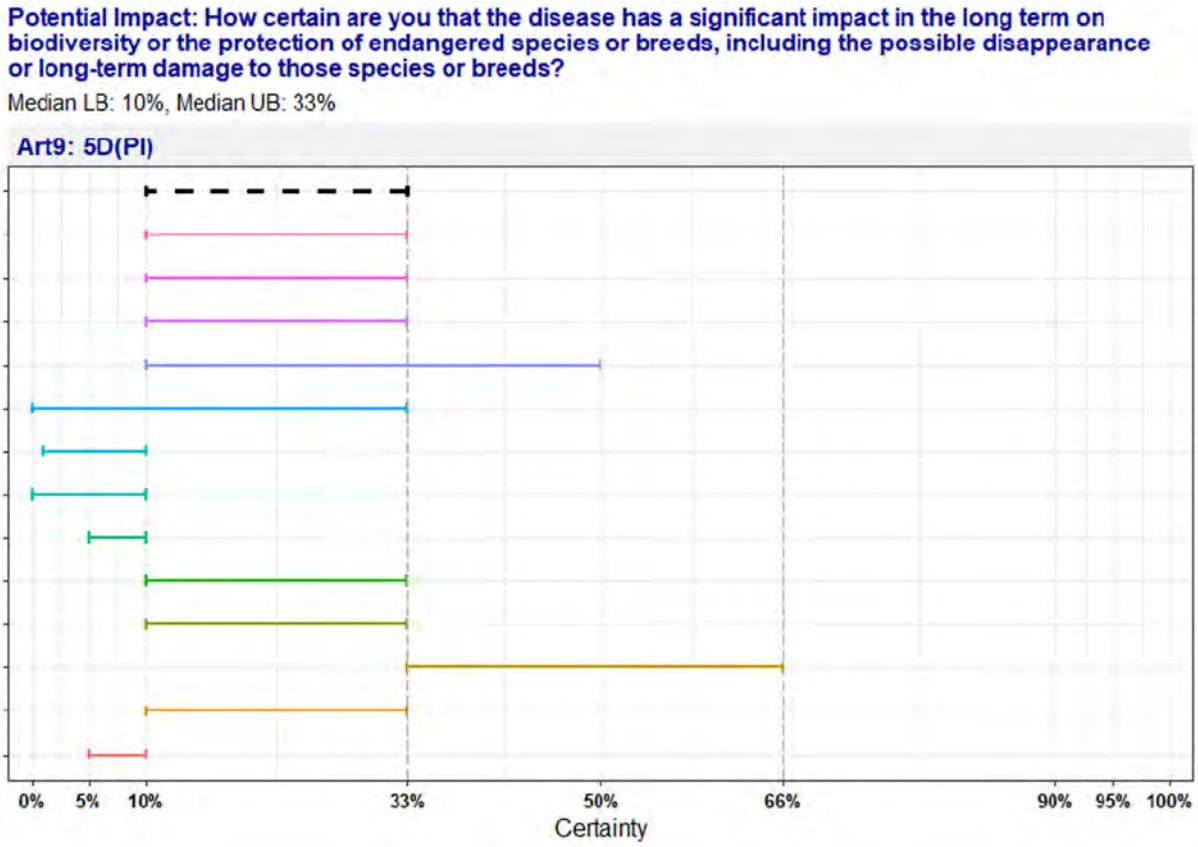

Figure A.35: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 5D (potential impact) (the disease has a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance or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

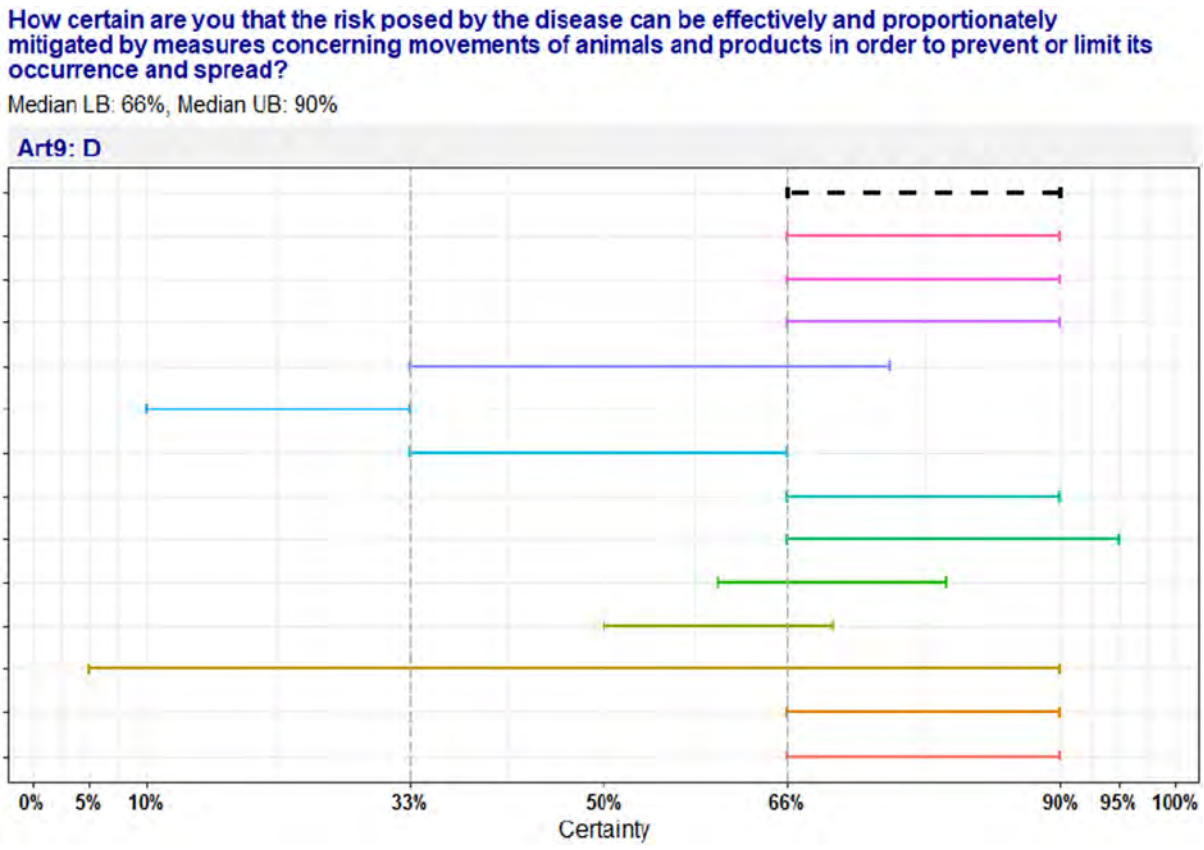

Figure A.36: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion D (the risk posed by the disease can be effectively and proportionately mitigated by measures concerning movements of animals and products in order to prevent or limit its occurrence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

Expert judgement: medians for all questions

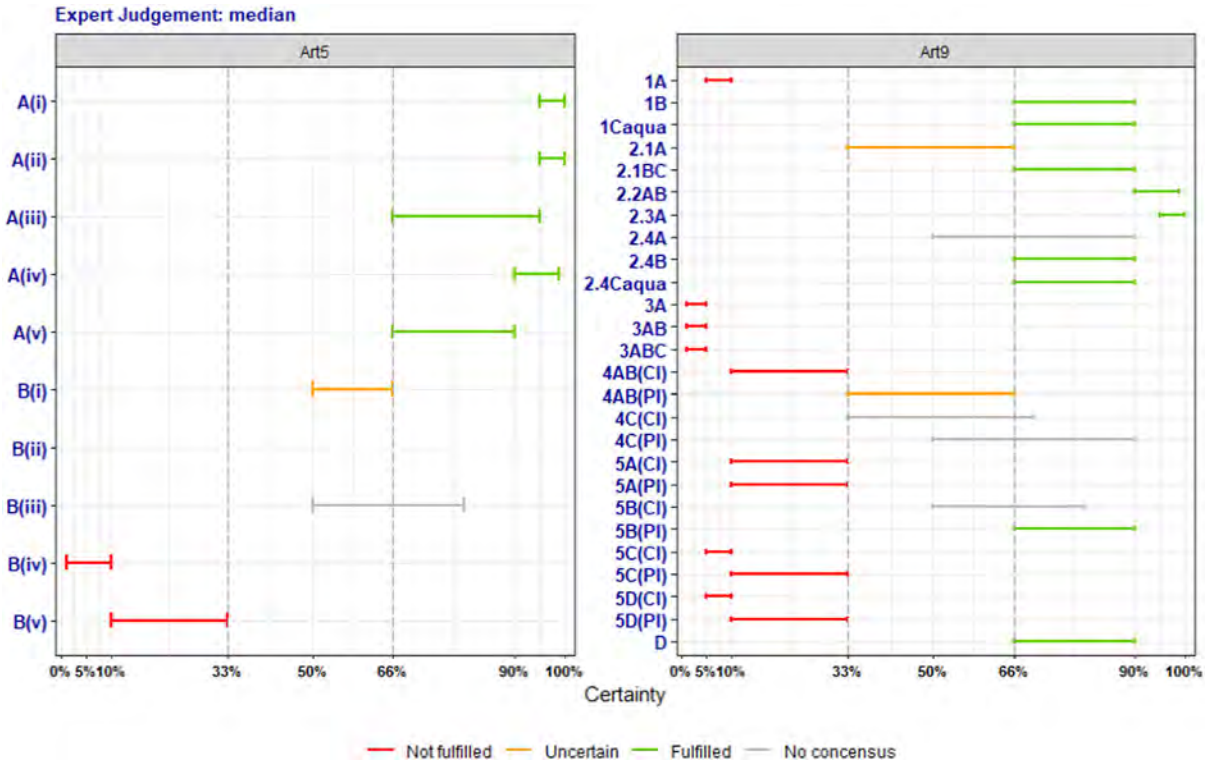

Figure A.37: Medians of the judgement reply in questions related to article 5 (left side) and article 9 (right side)