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# Assessment of listing and categorisation of animal diseases within the framework of the Animal Health Law (Regulation (EU) No 2016/429): infectious pancreatic necrosis (IPN)

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## Abstract

Infectious pancreatic necrosis (IPN) 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 in Article 9, and Article 8 for listing animal species related to IPN. The assessment was performed following a methodology previously 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 here performed, it is uncertain whether IPN can be considered eligible to be listed for Union intervention according to Article 5 of the AHL (50–90% probability). According to the criteria in Annex IV, for the purpose of categorisation related to the level of prevention and control as in Article 9 of the AHL, the AHAW Panel concluded that IPN does not meet the criteria in Section 1 (Category A; 0–1% 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; 33–66%, 33–66%, 50–90% and 50–99% probability of meeting the criteria, respectively). The animal species to be listed for IPN according to Article 8 criteria are provided.



**Keywords:** aquatic animals, Animal Health Law, infectious pancreatic necrosis, listing, categorisation, impact

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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, pp. 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 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 infectious pancreatic necrosis (IPN) according to the criteria of the AHL articles as follows:

- Article 7: IPN profile and impacts;
- Article 5: eligibility of IPN to be listed;
- Article 9: categorisation of IPN 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 IPN.

## 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, 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 diseases in a uniform and consistent way and is the one used also for the current Scientific Opinion and constitutes the Protocol of the Assessment.

For the needs of the listing and categorisation of aquatic animal diseases, the following deviations in Sections 2.1.2 and 2.3.1 of the ad hoc methodology (EFSA AHAW Panel, 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 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 at least 10 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 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% |

# 3. Assessment

## 3.1. Assessment according to article 7 criteria

This section presents the assessment of IPN disease 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 factsheet as drafted by the selected contractor (see Section 2.1 of the Scientific Opinion on the ad hoc methodology) and reviewed by the EFSA working group of experts.

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

IPN is caused by a double-stranded unenveloped RNA virus, the infectious pancreatic necrosis virus (IPNV), which belongs to the genus *Aquabirnavirus* within the family of *Birnaviridae* viruses. It has a worldwide distribution and predominantly infects members of the *Salmonidae* family.

*Aquabirnavirus* strains were first classified based on serological typing into two serogroups (A and B) with nine serotypes within serogroup A and one in serogroup B, using serum neutralisation tests (Hill and Way, 1995). Later on, the isolates were classified into seven genogroups (Blake et al., 2001; Nishizawa et al., 2005). There is a correspondence between the type strain, the serotype and the genotype (Table 2). For instance, the American type strains West Buxton (USA) and Jasper (Canada) correspond to Genotype 1 and Serotypes A1 and A9, respectively (Dopazo, 2020; Tapia et al., 2022).

Although initially isolated from cultured brook trout (*Salvelinus fontinalis*) and considered to induce a disease of great impact in cultured salmonids, IPNV has also been isolated from non-salmonid fish. The International Committee on the Taxonomy of Viruses (ICTV)[3] currently distinguishes three species of a*quabirnaviruses* (Delmas et al., 2019): (i) IPNV which is the type species for *aquabirnaviruses*, (ii) Yellowtail ascites virus (YTAV) which causes diseases in yellowtail fish (*Seriola quinqueradiata*) and (iii) Tellina virus (TV) which infects *Tellinus telius* molluscs. Other closely related viruses, such as the marine birnavirus AY-98, have not yet been approved as a species in the genus *aquabirnavirus* (Munang'andu et al., 2016; Mutoloki et al., 2016; Eriksson-Kallio, 2022). The working definition of IPNV used in this review corresponds to the current broad species ICTV definition and includes all IPNV isolates except for YTAV and TV (Table 2).

IPNV gains entry through the susceptible host's gills, gut and certain areas of the skin. Within a few days, the virus is detected in several tissues; given that it has been detected in circulating leucocytes, it is believed that the presence of the virus in the blood during the viraemia phase is the reason behind the rapid distribution of IPNV through most of the fish tissues. Predilection sites for the primary replication of the virus in internal organs, including the head kidney, where maximum replication is reached, and, during acute infection, also the intestine and pancreas. Pancreatic, pylorus, pyloric caeca and anterior intestine tissues undergo severe necrosis. Degenerative changes also occur in the kidney, liver and spleen. Most fish that survive the disease can become subclinical carriers. These persistently infected fish are a source of horizontal transmission, shedding the virus in their faeces, particularly under stressful conditions like spawning. In persistently infected fish, IPNV is present in macrophages within the haematopoietic tissue of the kidney (Munang'andu et al., 2016; Dhar et al., 2017; Dopazo, 2020). The ability of IPNV to persist in asymptomatic reservoir hosts as a result of an incomplete immunity development, as well as the continuous shedding of the virus from some proportion of infected animals, presents a mechanism for long-term virus maintenance. Moreover, IPNV may survive and be transmitted via a range of vector species (Munro and Midtlyng, 2011).

[3] https://ictv.global/taxonomy.

**Table 2:** Genera of *aquabirnaviruses*: different types of taxonomy and the correspondence between the strain type, the serotype and the genotype

| **Serological typing** | | | **Genotyping isolates** | ***Aquabirnaviruses* species** |
|---|---|---|---|---|
| **(Hill and Way, 1995; Riji John and Richards, 1999; Dixon et al., 2008; Nobiron et al., 2008)** | | | **(Blake et al., 2001; Nishizawa et al., 2005; Dopazo, 2020)** | **Delmas et al. (2019) (ICTV)** |
| **Serogroup** | **Serotypes** | **Strain types** | **Genogroups** | **Species** |
| A | $A_1$ | WB (West Buxton), VR-299 | 1 | Infectious pancreatic necrosis virus (IPNV) |
| | $A_2$ | Sp (Spjarup)[(a)] | 5 | |
| | $A_3$ | Ab (Abild)[(b)] | 2 | |
| | $A_4$ | He (Hecht); 94/01 | 6 | |
| | $A_5$ | Te (TV-2) | 3 | |
| | $A_6$ | Canada 1 | 3 | |
| | $A_7$ | Canada 2 | 4 | |
| | $A_8$ | Canada 3 | 4 | |
| | $A_9$ | Ja (Jasper) | 1 | |
| Not assigned | Not assigned | YTAV | 7 | Yellowtail ascites virus (YTAV) – (marine birnaviruses; MABV) |
| B | B1 | TV-1 | Not assigned | Tellina virus (TV) |
| C | C1 | Blotched snakehead virus (BSNV) | Not assigned | Not assigned |
| D | D1 | Not assigned | Not assigned | Not assigned |
| | D2 | Not assigned | Not assigned | |

The grey shade is for the serotypes and Strain type that belong to Infectious Pancreatic necrosis virus and are those of our concern.
(a): Type strain Sp: from farmed rainbow trout near village Spjarup in Denmark.
(b): Type strain Ab: from farmed rainbow trout near village Abild in Denmark.

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

*Susceptible animal species*

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

The species most susceptible to IPN are salmonids, mainly rainbow trout (*Oncorhynchus mykiss*), brook trout (*Salvelinus fontinalis*), brown trout (*Salmo trutta*), Atlantic salmon (*Salmo salar*) (Smail et al., 2006) and several Pacific salmon species (*Oncorhynchus* spp.), in which the virus produces the most frequent and characteristic clinical signs (Smail and Munro, 2012). Susceptibility is reported to decrease with age in salmonids (Centre for Environment Fisheries and Aquaculture Science, 2021). Fish species naturally susceptible to IPNV are listed in Table 3 (Munang'andu et al., 2016; Fisheries and Ocean Canada, 2017; Rimsta, 2019; Duan et al., 2021; Tapia et al., 2022).

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

The susceptible species (wild and farmed) through natural infection are described in Table 3.

**Table 3:** IPN-susceptible species (wild and farmed) through natural infection

| **Fish species (*Scientific name*)** | **Serotype** | **Genogroup** | **Wild/ farmed** | **Reference** |
|---|---|---|---|---|
| **Amago salmon (*Oncorhynchus rhodurus*)** | $A_1$ | 1 | Farmed | Jung et al. (1999), Zhang and Suzuki (2003) |
| **Arctic charr (*Salvelinus alpinus*)** | $A_8$ | 4 | Farmed | Blake et al. (2001) |
| **Atlantic halibut (*Hippoglossus hippoglossus*)** | $A_2$ | Not available | Farmed | Biering et al. (1994), Rodger and Frerichs (1997) |

| Fish species (*Scientific name*) | Serotype | Genogroup | Wild/ farmed | Reference |
|---|---|---|---|---|
| **Atlantic menhaden** (*Brevoortia tyrannus*) | Serotype 1 | Not available | Wild | Stephens et al. (1980), Nicholson and Caswell (1982), Stephens et al. (1980) |
| **Atlantic salmon** (*Salmo salar*) | $A_6$<br>$A_2$<br>$A_1$ | 3<br>5<br>1<br>6 | Wild and farmed | Blake et al. (2001), Shivappa et al. (2004), Cutrín et al. (2004), Persson et al. (2023) |
| **Brook trout** (*Salvelinus fontinalis*) | $A_1$ | 1, 6 | Farmed | Blake et al. (2001) |
| **Brown/sea trout** (*Salmo trutta*) | $A_2$ | 5, 6 | Farmed | Rexhepi et al. (2011), Ulrich et al. (2018) |
| **Chinook salmon** (*Oncorhynchus tshawytscha*) | $A_2$ | 5 | Wild and farmed | Davies et al. (2010) |
| **Chum salmon** (*Oncorhynchus keta*) | $A_1$<br>$A_3$ | 1<br>2 | Farmed | Jeon et al. (2011) |
| **Coho salmon** (*Oncorhynchus kisutch*) | $A_1$ | 1 | Farmed | Lopez-Lastra et al. (1994), Eissler et al. (2011) |
| **Common dab** (*Limanda limanda*) | $A_5$ | Not available | Farmed | Diamant et al. (1988), Wallace et al. (2008) |
| **Cutthroat trout** (*Oncorhynchus clarkii*) | $A_1$ | 1 | Farmed | Blake et al. (2001) |
| **European eel** (*Anguilla anguilla*) | $A_3$ | Not available | Farmed | Hudson et al. (1981) |
| **Hake** (*Merluccius merluccius*) | Serogroup A | 99.55% degree of nucleotide similarity to the farmed salmon IPNV isolate from the same geographic location (genogroup 5) | Wild | Wallace et al. (2005) |
| **Japanese eel** (*Anguilla japonica*) | $A_3$ | 2 | Farmed | Kim and Oh (2014) |
| **Lake trout** (*Salvelinus namaycush*) | $A_2$ | 5 | Farmed | Maj-Paluch et al. (2020) |
| **Lemon sole** (*Microstomus kitt*) | Serogroup A | Not available | Wild | Wallace et al. (2008) |
| **Pike** (*Esox lucius*) | $A_4$ | 6 | Farmed | Ahne (1978), Hill and Way (1995) |
| **Pink salmon** (*Oncorhynchus gorbuscha*) | Serogroup A | Not available | Wild and farmed | Hill and Way (1995) |
| **Plaice** (*Pleuronectes platessa*) | Serogroup A | Not available | Wild | Wallace et al. (2008) |
| **Rainbow trout** (*Oncorhynchus mykiss*) | $A_1$, $A_3$, $A_4$, $A_7$, $A_9$ | 1,2, 4,5 | Farmed | Bebak and McAllister (2009), Blake et al. (2001) |
| **Snakehead fish** (*Channa striata*) | $A_2$ | Not available | Farmed | Wattanavijarn et al. (1988) |
| **Striped bass** (*Morone saxatilis*) | Closely related antigenically to WB strain | Not available | Farmed | Schutz et al. (1984) |
| **Turbot** (*Scophthalmus maximus*) | $A_3$ | 2 | Farmed | Mortensen et al. (1993), Castric et al. (1987), Duan et al. (2021) |

| Fish species (*Scientific name*) | Serotype | Genogroup | Wild/ farmed | Reference |
|---|---|---|---|---|
| **Whitefish (***Coregonus lavaretus***)** | $A_3$ | 2 | Farmed | Eriksson-Kallio et al. (2016) |
| **Atlantic cod (***Gadus morhua***)** | A2 | 5 | Farmed | Lorenzen et al. (1995) |

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

Fish species that were found to be experimentally susceptible to IPNV, and that are not already mentioned in the list of naturally susceptible fish species in the table above (Table 3) are reported in Table 4.

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

The domestic (farmed) species susceptible to IPNV experimentally are described in Table 4.

**Table 4:** Wild and farmed aquatic animals experimentally susceptible to IPNV

| Aquatic animal species | Wild/ farmed | Experiment setting | Reference |
|---|---|---|---|
| Atlantic cod (*Gadus morhua*) | Not available | Infected by intraperitoneal injection, cohabitation and immersion | Urquhart et al. (2009) |
| Freshwater crayfish (*Astacus astacus*) | Farmed | Injection with Sp* strain | Halder and Ahne (1988) |
| Goldsinny wrasse, (*Ctenolabrus rupestris*) | Farmed | Injection with Sp* strain | Gibson et al. (1998) |
| Spotted wolffish *(Anarhichas minor)* | Wild | Bath-challenge in oxygenated seawater containing isolates H-IPNV/GW98 and S-IPNV/ SH96 | Sommer et al. (2004) |
| Zebrafish (*Danio rerio*) | Not available | Injection with Sp* strain | Rud et al. (2020) |

*: Sp (Spjarup) see also Table 2.

*Reservoir animal species*

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

Both freshwater and marine animals and fish can be carriers of IPNV, particularly around the vicinity of infected farms, where survivors of IPN outbreaks can become lifelong carriers, thus serving as reservoirs of the virus (FHL and VESO, 2003; Ruane et al., 2007). In a survey of 30,000 marine fish on the coast of Scotland, IPNV was isolated according to the method of Munro et al. (2004) and confirmed by enzyme-linked immunosorbent assay (ELISA) in nine species of fish: common dab (*Limanda limanda*), plaice (*Pleuronectes platessa*), lemon sole (*Microstomus kitt*), flounder (*Platichthys flesus*), long rough dab (*Hippoglossoides platessoides*), saithe (*Pollachius virens*), grey gurnard (*Eutrigla gurnardus*), hake (*Merluccius merluccius*) and Whiting (*Merlangius merlangus*). This suggests these species may act as reservoirs of the pathogen (Wallace et al., 2008). However, there is also evidence that IPNV-infected wild salmonid species naturally infected by IPNV do not sustain the infection and are not self-sustaining as a natural infection (i.e. not enzootic) (Munro et al., 1976; FHL and VESO, 2003). IPNV has also been isolated from other asymptomatic species such as grayling (*Thymallus thymallus*) (Ahne, 1980; Dorson, 1982; Hill and Way, 1995), huchen (*Hucho hucho*) (Ahne, 1980; Hill and Way, 1995). In addition, brook trout (*Salvelinus fontinalis*) have been shown to be asymptomatic chronic carriers of IPNV in experimental trials (Bootland et al., 1991).

Birnaviruses have also been isolated from naturally occurring infections in molluscs (limpets, periwinkles, mussels, oysters, scallops, tellina, venerid clams) crustaceans (European crayfish, *Daphnia*, palaemonid shrimps, penaeid prawns, portunid crabs) and rotifers, but it was not clear from the publication whether these comprised IPNV infections (McAllister, 2007). IPNV (WB strain) was shown experimentally to be able to bioaccumulate in blue mussel (*Mytilus edulis*) and be transmitted to naive Atlantic salmon (*Salmo salar*) smolts (Molloy et al., 2013). Another experiment found that swan mussel (*Anodonta cygnea*) was resistant to IPNV, but able to accumulate and maintain substantial levels of

the virus for 35 days (Rud et al., 2020). The following is a list of fish families where aquatic birnaviruses were isolated as a naturally occurring infection (McAllister, 2007), but it was not clarified in the publication if the virus described was IPNV: *Acipenseridae*, *Amiidae*, *Anguillidae*, *Atherinidae*, *Bothidae*, *Carangidae*, *Catostomidae*, *Centrarchidae*, *Cichlidae*, *Channidae*, *Clupeidae*, *Cobitidae*, *Coregonidae*, *Cottidae*, *Cyprinidae*, *Cyprinodontidae*, *Embiotocidae*, *Esocidae*, *Gadidae*, *Gasterosteidae*, *Gobiidae*, *Hiodontidae*, *Ictaluridae*, *Lepisosteidae*, *Moronidae*, *Paralichthyidae*, *Percichthyidae*, *Percidae*, *Petromyzontidae*, *Pleuronectidae*, *Poeciliidae*, *Polyodontidae*, *Salmonidae*, *Sciaenidae*, *Soleidae*, *Thymallidae*, *Triglidae*, *Umbridae*.

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

Farmed fish are an important reservoir of IPNV in aquatic environments, where the virus can be shed from farm waters into surroundings. Similarly, IPNV has also been isolated from other asymptomatic farmed aquatic species such as tilapia (*Tilapia mossambica*) (Mulei et al., 2018), Atlantic cod (*Gadus morhua)* (Duan et al., 2021), common seabream *(Pagrus pagrus*) (Lopez-Jimena et al., 2010). Many farmed fish species are the same as those listed in Parameter 5 since these fishes were found in wildlife and then collected and raised for aquacultural purposes: Barb (*Luciobarbus graellsii*) (Ortega, 1993), goldfish (*Carassius auratus*), discus fish (*Symphysodon*), bream (*Abramis brama*) (Adair and Ferguson, 1981), brook trout (*Salvelinus fontinalis*) (Bootland et al., 1991), Atlantic salmon (*Salmo salar*) (Bowden et al., 2002; FHL and VESO, 2003).

*Vector animal species*

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

There is a range of aquatic and terrestrial species that can transmit IPNV from one water source to another. Shellfish and marine crustaceans such as the noble crayfish (*Astacus astacus*) (Halder and Ahne, 1988), the green shore crab (*Carcinus maenas)*, the planktonic crustacean *Daphnia magna* and the shrimp *Penaeus japonicus* (Mortensen et al., 1993) have been reported to be potential vectors for IPNV. Also, IPNV has been detected in the copepod sea louse (*Lepeophtheirus salmonis*) although there is no evidence that copepods can serve as vectors of any virus in field studies (Johnson et al., 2004) promoted copepod control (Overstreet et al., 2009). In addition, piscivorous bird species, which prey upon IPNV-infected rainbow trout, were shown to excrete the virus (McAllister and Owens, 1992). Under experimental conditions, trout fry were infected through faeces from heron (*Ardea cinerea*) that consumed infected fish (Peters and Neukirch, 1986). IPNV has also been detected in black-headed gulls (*Chroicocephalus ridibundus*) (Eskildsen and Jorgensen, 1973). Indeed, any bird species that frequent fish farms for opportunistic feeding may be a potential route of IPNV transmission (FHL and VESO, 2003). In terms of mammals, mink may be a possible vector (Sonstegard and McDermott, 1972), as IPNV can be recovered from mink faeces 1 week after experimental inoculation of another animal. Shellfish and marine crustaceans such as the noble crayfish (*Astacus astacus*) (Halder and Ahne, 1988), the green shore crab (*Carcinus maenas)*, the planktonic crustacean *Daphnia magna* and the shrimp *Penaeus japonicus* (Mortensen et al., 1993) have been reported to be potential vectors for IPNV. Also, IPNV has been detected in the copepod sea louse (*Lepeophtheirus salmonis*) although there is no evidence that copepods can serve as vectors of any virus in field studies (Johnson et al., 2004) promoted copepod control (Overstreet et al., 2009). In addition, piscivorous bird species, which prey upon IPNV-infected rainbow trout, were shown to excrete the virus (McAllister and Owens, 1992). Under experimental conditions, trout fry were infected through faeces from Heron (*Ardea cinerea) that* consumed infected fish (Peters and Neukirch, 1986). IPNV has also been detected in black-headed gulls (*Chroicocephalus ridibundus*) (Eskildsen and Jorgensen, 1973). Indeed, any bird species that frequent fish farms for opportunistic feeding may be a potential route of IPNV transmission (FHL and VESO, 2003). In terms of mammals, mink may be a possible vector (Sonstegard and McDermott, 1972), as IPNV can be recovered from mink faeces 1 week after experimental inoculation.

Parameter 8 – domestic/farmed vector species (or families/orders)

Many domestic/farmed species are the same as those listed in Parameter 7 since these species were found in the wild and then domesticated. For example, noble crayfish (*Astacus astacus*) (Halder and Ahne, 1988), and other marine crustaceans (Mortensen et al., 1993) have been reported to be potential vectors for IPNV. Also, any bird species that frequent fish farms for feeding may be a potential source of IPNV transmission (FHL and VESO, 2003). In addition, chicken (*Gallus domesticus*)

may also be a possible vector (Sonstegard and McDermott, 1972) as IPNV can be recovered from chicken faeces 1 week after experimental inoculation. Among mammals, cows who were experimentally fed a normal grass silage diet where IPN virus-containing fish silage was added were shown to have the virus detected in their faeces for up to 4 days (Smail et al., 1993b).

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

*Morbidity*

Parameter 1 – Prevalence/incidence

IPNV prevalence among farmed fish ranged from less than 1% to 100%. Farm-level prevalence was found to be between 30% and 70%. Among wild fish, IPNV prevalence ranged between less than 1% and 44% (Table 5).

**Table 5:** IPNV (farm-level) prevalence and incidence in wild and farmed fish

| Country | Time period | Indicator | Study population | Value | Reference |
|---|---|---|---|---|---|
| European countries | | | | | |
| **Ireland** | 2006 | Farm-level IPNV prevalence | Farmed Atlantic salmon: | | Ruane et al. (2007) |
| | | | Marine sites | 60% | |
| | | | Freshwater sites | 30% | |
| **Italy** | Not reported | Farm-level IPNV prevalence | Not reported | 40% | Panzarin et al. (2018) |
| **Norway** | 1991 | Farm-level IPN-mortality incidence rate | Farmed seawater Atlantic salmon (post-smolt) | 39.5% (during the time from sea transfer) | Jarp et al. (1995) |
| **Norway** | 2011–2021 | Farm-level clinical IPN incidence | Farmed salmonids | Range: 19–154 sites/year | Sommerset et al. (2022) |
| **Spain** | 2010–2011 | IPNV prevalence | Wild marine fish: | | Moreno et al. (2014) |
| | | | Oceanographic | 25.7% | |
| | | | River mouth | 44.4% | |
| The United Kingdom at the time of the disease occurrence was an EU MS | | | | | |
| **United Kingdom (Scotland)** | 1990–2002 | Clinical IPN prevalence | Farmed Atlantic salmon (marine sites) | Range: 0.6–12.5% | Bruno (2004) |
| **United Kingdom (Scotland)** | 1990–2002 | IPNV prevalence | Farmed Atlantic salmon (broodstock sites) | Range: 0.69–23.08% | Munro et al. (2010) |
| **United Kingdom (Scotland)** | 1996–2001 | IPNV prevalence | Farmed Atlantic salmon: | | Murray et al. (2003) |
| | | | Saltwater | 49.6% | |
| | | | Freshwater | 10.6% | |
| **United Kingdom (Scotland)** | 2002–2004 | IPNV prevalence | Wild marine fish: | | Wallace et al. (2008) |
| | | | All | 0.2% | |
| | | | Flat fish | 0.3% | |
| | | | Round fish | 0.1% | |
| Non-European countries | | | | | |
| **Chile** | 2010–2013 | Farm-level IPN-mortality prevalence | Farmed Atlantic salmon (marine sites) | Range: 28.8–66.6% | Escobar-Dodero et al. (2019) |
| **Chile** | 2012–2013 | IPNV prevalence | Farmed Atlantic salmon and rainbow trout (freshwater and marine sites) | 100% | Tapia et al. (2015) |

| Country | Time period | Indicator | Study population | Value | Reference |
|---|---|---|---|---|---|
| **Mexico** | 2000–2012 | IPNV prevalence | Farmed trout (freshwater sites) | Range: 3–53% | Ortega et al. (2016) |
| **Turkey** | 2007–2008 | IPNV prevalence | Farmed rainbow trout (marine cage culture) | Range: 0–100% | Ogut and Altuntas (2012) |
| **Turkey** | 2014–2014 | Farm-level IPNV prevalence | Farmed rainbow trout (freshwater sites) | 71% | Büyükekiz et al. (2018) |

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

No information was found in the publications. However, comparing the number of sites where IPNV has been isolated to the number of clinical outbreaks reported in Ireland between 1993 and 2007 (Ruane et al., 2007), we can conclude that an IPNV infection does not automatically lead to a clinical outbreak; for instance, in 2006, IPNV was isolated in 14 Atlantic salmon sites, whereas only six clinical outbreaks were reported that year. Susceptibility generally decreases with age, with high mortality observed in fish fry and fingerlings between 1 and 4 months of age. Atlantic salmon smolts transferred to seawater are also at risk of death, with rates increasing in infected animals 7–12 weeks after their transfer. This is indeed considered a stressful time for fish undergoing physiological adaptation to seawater, which suppresses immunity, thus increasing susceptibility to infection (Urquhart et al., 2008; Canadian Food Inspection Agency, 2020). The implementation of the quantitative trait loci (QTL) breeding in aquacultures reduces the case-morbidity rates since QTL fish are resistant to IPN (FHL and VESO, 2003; Tapia et al., 2022). In addition, underreporting should be considered since IPN is not a notifiable disease.

*Mortality*

Parameter 3 – Case-fatality rate

Mortality rates in the freshwater stage vary considerably from very low to almost 100%, while disease outbreaks in seawater typically result in 10–20% cumulative mortality and can reach 70% in individual sea cages. In the context of experimental studies carried out among salmonids, mortality was found to range from 0% to 100% (Rimsta, 2019). This variation in mortality has been ascribed to factors related to the host species such as age or genetic resistance of fish, environmental stressors and virus characteristics (Frantsi and Savan, 1971; Evensen and Santi, 2008). Crude mortality is often used as a response variable, but no studies have focused on the IPN-specific part of this figure (FHL and VESO, 2003). Examples of mortality rates observed during field outbreaks are described in Table 6.

**Table 6:** Examples of mortality rates observed during field outbreaks

| Country | Time period | Indicator | Study population | Value | Reference |
|---|---|---|---|---|---|
| European countries | | | | | |
| **Finland (inland)** | 2012–2014 | Mortality rate | Farmed rainbow trout and whitefish (freshwater sites) | Range: < 1–40% | Eriksson-Kallio et al. (2016) |
| **Greece** | 2000 | Mortality rate | Rainbow trout (fry and fingerling) | 30–55% | Varvarigos and Way (2002) |
| **Norway** | 1991 | Mortality rate adjusted for significant risk factors | Farmed Atlantic salmon (seawater post-smolt) | 17.8% | Jarp et al. (1995) |
| **Norway** | 2009–2012 | Mortality rate | Farmed Atlantic salmon and rainbow trout (smolt) | Range: 3.9–28.4% (mean: 14%) | Bang Jensen and Kristoffersen (2015) |

| Country | Time period | Indicator | Study population | Value | Reference |
|---|---|---|---|---|---|
| **Norway** | 2019 | Mortality rate | Farmed Atlantic salmon (post-smolt stage; QTL carrying fish) | 10% | Hillestad et al. (2021) |
| UK at the time of the disease occurrence was an EU MS | | | | | |
| **United Kingdom (Scotland)** | 1990–2002 | Mortality rate (daily) | Farmed Atlantic salmon (marine sites) | Range: 0.03–0.5%/day | Bruno (2004) |
| **United Kingdom (Scotland)** | 1999 | Mortality rate | Farmed Atlantic salmon (post-smolt) | 11% | Smail et al. (2006) |
| **United Kingdom (Scotland)** | 2002 | Mortality rate | Farmed Atlantic salmon (freshwater fry) | Range: 0–60% | McLoughlin and Weigall (2002) |
| Non-European countries | | | | | |
| **Chile** | 2010–2013 | Mortality rate | Farmed Atlantic salmon (marine sites) | Range: 0.01–13% | Escobar-Dodero et al. (2019) |
| **China** | 2016 | Mortality rate | Farmed rainbow trout | ~ 100% | Zhu et al. (2017) |
| **Iran** | 2009 | Mortality rate | Farmed rainbow trout (fry) | 90% | Ghasemi et al. (2011) |
| **Iran** | 2015–2017 | Mortality rate | Farmed rainbow trout | Range: 30–60% | Ahmadivand et al. (2020) |
| **Turkey** | 2002 | Mortality rate | Rainbow trout (fry) | 50% | Candan (2002) |

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

Parameter 1 – Report of zoonotic human cases (anywhere)

IPN is not a zoonotic disease. There is no evidence in the literature that IPNV infects humans.

#### 3.1.1.4. Article 7(a)(iv) The resistance to treatments, including antimicrobial resistance

Parameter 1 – Resistant strain to any treatment; even at laboratory level

Not applicable. No effective treatment for IPN 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 the infectious period in animals

Fish become infectious and begin shedding IPNV after about 2 days of latency and continue shedding the virus for about the next 10 days (McAllister, 2007). Urquhart et al. (2008) observed that viral shedding from acutely infected fish occurs over a period of 12 days and that peak viral shedding occurs just prior to, or at the time of, death following challenge by intraperitoneal infection. It is important to take into account the fact that fish surviving IPNV infection can become asymptomatic carriers of the virus for long periods of time, possibly for life (Hill, 1982).

Parameter 2 – Presence and duration of the latent infection period

Fish become infectious and begin shedding the virus after about 2 days of latency (McAllister, 2007). Experimental infection trials using fingerling trout indicate that there is a latent period of about 2 days after infection before infected fish begin to shed detectable quantities of IPNV into the water (Smith et al., 2000).

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

Survivors of an IPN epidemic can become persistent carriers and intermittently shed the virus in excretory and reproductive products, typically during periods of stress (Wolf and Quimby, 1969;

Dorson, 1982; Hill, 1982; Melby et al., 1991). This results in the shedding of more viruses, which increases the risk of infecting virus-free fish stocks and of the recurrence of IPN in the carrier population (FHL and VESO, 2003). In Atlantic salmon, the carrier state is very frequent in fish that survive an IPN outbreak, and they are anticipated to become lifelong carriers (Melby et al., 1991). Rainbow trout adults, whether experimentally (Ahne and Thomsen, 1986) or naturally infected (Yamamoto, 1974), have an unpredictable persistence of the IPNV carrier state, ranging from 10 months to over 2 years (Bootland et al., 1991). The natural carrier state occurs more frequently and persists for a longer time in brook trout than in rainbow trout (Yamamoto, 1974; Sadasiv, 1995; Rodriguez Saint-Jean et al., 2003). Furthermore, persistent IPNV strains can also be recovered from QTL-resistant fish (Benkaroun et al., 2021).

*Environment*

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

Due to the demonstrated stability of *aquabirnaviruses* in a wide range of temperatures, pH and salinity, IPNV can survive for long periods of time in a variety of environmental scenarios and different types of reservoirs (Dopazo, 2020; Woo et al., 2020).

Previous studies have shown that IPNV is stable in seawater for at least 11 days, but gradually loses infectivity in media of lower salinity (Moewus-Kobb, 1965). Tu et al. (1975) demonstrated that IPNV suspended in a fresh stream or well water, retained almost all its infectivity for about 10 days at 4°C and 5 days at 15°C. Barja et al. (1983) reported that IPNV remained infective for up to 15–20 days in freshwater. Toranzo and Hetrick (1982) showed inactivation of the virus after 17 days at 15°C and 9 days at 20°C. IPNV appears to be more stable in seawater with reported survival of 20 days and 14–17 days, as reported by Barja et al. (1983), Toranzo and Hetrick (1982) and Ruane et al. (2007). It would be expected that survival of the virus at 4°C in seawater would also follow a similar pattern to survival in fresh water (Oidtmann et al., 2018).

In addition, IPNV has been isolated from sediments during routine surveys around fish farms in Spain, although it was not confirmed whether the isolates were of farmed origin (Rivas et al., 1993). IPNV was also detected in faeces up to 72 h after feeding a contaminated fish silage mixture (with normal grass silage) to cows (Smail et al., 1993b).

#### 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)

Once IPNV has been introduced into a population, horizontal transmission occurs as the virus is disseminated in the surrounding freshwater or seawater via the faeces and urine of infected fish and as fish pass contaminated water through their buccal cavity and over their gills (Mangunwiryo and Agius, 1988; Smith et al., 2000). Moreover, the survivors of an infection usually become carriers of the virus (see Section 3.1.1.4), acting as reservoirs of the virus and spreading it during stress episodes via faeces (Munro and Midtlyng, 2011; Dopazo, 2020). It appears that carrier fish represent the most significant source of horizontal transmission (FHL and VESO, 2003). In addition, a range of vectors and reservoirs may serve as passive mechanical vectors for horizontal transmission of IPNV to fish. For instance, piscivorous birds predating on rainbow trout fry infected with IPNV were shown to excrete the virus in their faeces (McAllister and Owens, 1992; McAllister, 2007).

Vertical transmission of IPNV to progeny has been shown to occur via eggs in brook trout (Bootland et al., 1991) and rainbow trout (Wolf et al., 1963; Ahne, 1983). Dorson and Torchy (1985) used artificially infected rainbow trout sperm to fertilise virus-free eggs and this resulted in clinical disease in the progeny fry. Although the study by Bootland et al. (1991) demonstrated vertical transmission in brook trout, it was noted that transmission is very unpredictable and there is therefore little probability of observing this outside laboratory conditions (Laidler, 2002).

It has never been shown with certainty that vertical transmission can occur for Atlantic salmon (Ahne, 1985; Dorson and Torchy, 1985; Laidler, 2002; FHL and VESO, 2003). However, previous research indicated the presence of IPNV in gonads and gonadal fluids of maturing broodstock, and showed experimentally that a virus could enter the ovum adsorbed to spermatozoa and can survive with the ovum (McLoughlin and Weigall, 2002). Moreover, Scotland's control programmes in freshwater

salmon farms found that the systematic removal of IPNV-positive genital products leads to a decline in the incidence of IPN outbreaks (FHL and VESO, 2003). IPNV has also been detected in eyed eggs and in yolk sac fry (Ahne, 1985). It has never been shown with certainty that vertical transmission can occur for Atlantic salmon (Ahne, 1985; Dorson and Torchy, 1985; Laidler, 2002; FHL and VESO, 2003). However, previous research indicated the presence of IPNV in gonads and gonadal fluids of maturing broodstock, and showed experimentally that virus can enter the ovum adsorbed to spermatozoa and can survive with the ovum (McLoughlin and Weigall, 2002). Moreover, Scotland's control programmes in freshwater salmon farms found that the systematic removal of IPNV-positive genital products leads to a decline in the incidence of IPN outbreaks (FHL and VESO, 2003). IPNV has also been detected in eyed eggs and in yolk sac fry (Ahne, 1985), thereby indicating that eggshells could be involved in the transmission of viruses from one generation to the next and that eggshells may be important in horizontal dispersal in fry that have begun to take in nutrients.

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

Not applicable. IPN is not zoonotic.

*Speed of transmission*

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

Data on the incidence of IPN have been described previously (see Section Morbidity, Parameter 1).

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

Table 7 below presents the transmission rate found in the publications.

**Table 7:** Transmission rate (beta) and (from R0 and infectious period) between animals

| Country | Time period | Indicator | Study population | Transmission rate (beta) | Reference |
|---|---|---|---|---|---|
| **United Kingdom (Scotland)** | 1996–2003 | Basic reproduction ratio | Farmed salmon: | | Murray (2006) |
| | | | Freshwater | 1.41 | |
| | | | Seawater | 1.45 | |
| **Ireland** | 1994–2005 | Basic reproduction ratio | Farmed salmon: | | Ruane et al. (2007) |
| | | | Freshwater | 2.39 | |
| | | | Seawater | 1.66 | |
| **Mexico** | 2000–2012 | Transmission rate | Rainbow trout | 1.28 | Ortega et al. (2016) |
| **NA (experimental)** | NA | Transmission rate | Rainbow trout (fry) | 0.013 | Smith et al. (2000) |

NA: not available.

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

*Presence and distribution*

Parameter 1 – Map where the disease is present in the EU

A map was not available from WAHIS. A map presenting the geographical distribution at the country level of IPN outbreaks occurrence in Europe per year is available from the Universidade de Santiago de Compostela.[4] The map in Figure 1 presents the EU countries in Europe where IPN occurred from 2014 to 2021 according to the annual reports of the European Reference Laboratory for Fish and Crustaceans.[5]

[4] https://www.usc.gal/gl/institutos/acuicultura/difusion/aportacions-cientificas.html.
[5] https://www.eurl-fish-crustacean.eu/fish/survey-and-diagnosis.

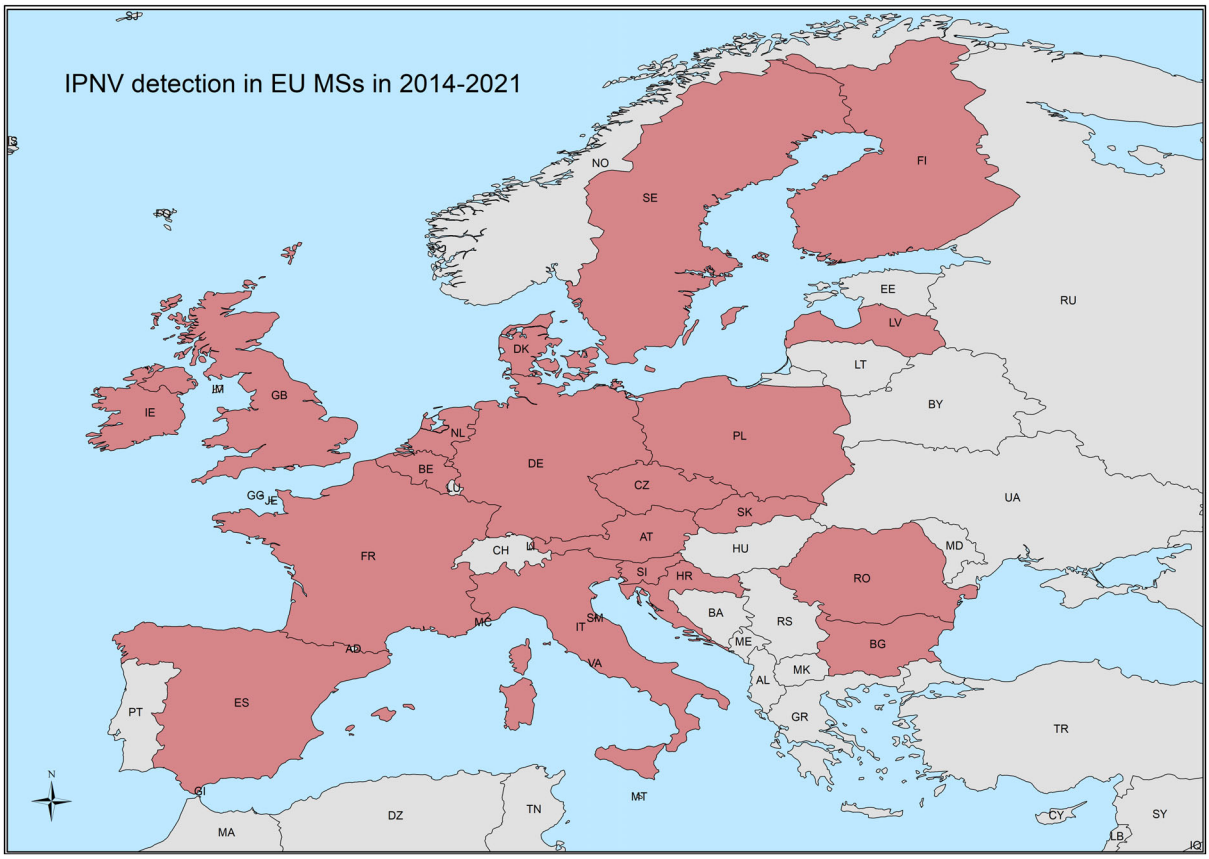



**Figure 1:** EU MSs where IPNV was detected based on the annual reports of the European Reference Laboratory for Fish and Crustaceans. This map has been developed through ArcGIS.

**Disclaimer:** The designations employed and the presentation of material on this map do not imply the expression of any opinion whatsoever on the part of the European Food Safety Authority concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.

An additional map presenting the geographical distribution at country level of IPN outbreaks occurrence in Europe per year is available by the Universidade de Santiago de Compostela.[4]

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

IPN is known to be endemic to salmonid farming in many areas around the world (Murray, 2006; McAllister, 2007; Ruane et al., 2007; Ogut et al., 2013; Panzarin et al., 2018; Escobar-Dodero et al., 2019). For instance, in 2006 in Ireland, IPNV prevalence exceeded 56% of marine sites and 29% of freshwater sites; therefore, the disease was considered endemic (Ruane et al., 2007). Intermittent shedding by carriers is thought to be a principal mechanism by which the virus ensures endemic persistence (Smith et al., 2000). Conversely, IPNV can be identified sporadically, as found for instance in Swedish east coast farms (SVA National Veterinary Institute, 2020).

*Risk of introduction*

This criterion is not relevant for IPN as IPNV has already been introduced in EU countries and is endemic in several EU countries.

Parameter 3 – Routes of possible introduction

IPNV has already been introduced in EU countries. In general, the virus could be introduced into a new area via infected live/dead animal/egg, contaminated water or other contaminated material. Jarp et al. (1995) carried out an epidemiological study of Norwegian sea sites holding and showed that the risk of clinical IPN was significantly associated with the number of hatcheries delivering smolt to the site. IPNV may be introduced to a hatchery via eggs, fry, anthropogenic fomites, different animals and

water (Rimsta, 2019). The water supply for a hatchery can harbour fish and invertebrates that are carriers of the IPNV. The introduction of free virus via the water supply is thought to occur, although no one has yet isolated IPNV from open or closed water supplies (Maheshkumar et al., 1991; Bebak et al., 1998). Predatory birds can transfer infected fish between raceways and from water supplies outside of a hatchery and IPNV has also been imported on bird faeces (McAllister and Owens, 1992) and bird bills, beaks, feathers and legs (Peters and Neukirch, 1986; Smith et al., 2000).

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

This parameter is not relevant for the assessment since IPNV has already been introduced in EU and the disease is endemic.

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

Not applicable because the risk of introduction to the EU is not relevant as the disease is endemic. Information on the infectious period at the individual level is provided in Section 3.1.5.

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

This parameter is not relevant for the assessment since IPNV has already been introduced in EU and the disease is endemic.

IPN is not a listed disease as defined in Regulation (EU) 2016/429. However, Denmark, Finland, Slovenia and Sweden apply specific national control measures designed to limit the impact of the disease since compartments and zones in these areas are regarded as being free of the disease (Commission Implementing Decision (EU) 2022/1188). In this context, in Sweden, there is active surveillance in place for IPNV in imported quarantined eels; 120 glass eels are sampled at arrival, and after 2 months 120 cohabitated rainbow trout are sampled for detection of the virus (SVA National Veterinary Institute, 2020).

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

Not applicable because the risk of introduction to the EU is not relevant as the disease is endemic. Information on the latent period at the individual level is provided in Section 3.1.5.

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

This parameter is not relevant for the assessment as IPNV has already been introduced in the EU and the disease is endemic.

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

*Diagnostic tools*

Parameter 1 – Existence of diagnostic tools

IPN diagnosis is based on prior disease history of the farm and fish population, clinical signs and a histopathological examination verifying the presence of characteristic lesions. However, clinical signs and pathology cannot be used to distinguish IPN from other viral diseases and the absence of clinical signs does not ensure that fish are free of IPNV. Confirmatory diagnosis involves isolation of the virus in cell culture followed by immunological or molecular confirmation (FHL and VESO, 2003; Dhar et al., 2017).

Virus isolation by cell culture propagation remains the reference standard for diagnosing IPNV infection in salmonid fish. A former WOAH manual (no longer available) recommended teleost cell lines include BF-2, CHSE-214 or RTG-2. Tissues used in the inoculation of cells include the kidney, spleen and heart, brain or liver. Ovarian fluids from brood fish at the spawning time may also be used (Eriksson-Kallio, 2022).

The antibody-binding methods used for IPNV diagnosis include neutralisation assays, ELISA, immunofluorescence assays (FAT/IFAT), immunohistochemistry (IHC), co-agglutination tests, immunoblots and flow cytometry. Rodriguez Saint-Jean et al. (2001) demonstrated that flow cytometry might be considered the most reliable antibody-binding method to diagnose IPNV, followed by IFAT (Eriksson-Kallio, 2022).

Reverse transcriptase polymerase chain reaction (RT-PCR) for detecting IPNV nucleic acids has been in use since the mid-1990s. RT-PCR is considered an accurate, rapid and sensitive method used for routine diagnostic confirmation of IPNV (Rodriguez Saint-Jean et al., 2001; Chong, 2022).

Sanger sequencing, considered the reference standard of sequencing technology, is a method to determine nucleotide sequences in DNA based on gel electrophoresis (Sanger et al., 1977). Partial sequence data from the VP2 gene sequence are commonly used for the determination of the IPNV genogroup. The obtained sequences can also be used for phylogenetic analysis (Eriksson-Kallio, 2022).

*Control tools*

Parameter 2 – Existence of control tools

Although in most EU countries there are no official control measures against IPN in place, the disease can be prevented through a combination of intensive monitoring, biosecurity, targeted vaccines and resistant broodstock (Dhar et al., 2017). Some EU countries apply specific national measures to limit the impact of the disease since these areas are regarded as being partly free of the disease (Commission Implementing Decision (EU) 2022/1188). For example, in Sweden, in order to maintain their free status, both passive and active surveillance activities are in place based on the risk of IPNV introduction in the farms. In addition, active surveillance is implemented in imported quarantined fish (eels) and whenever potential invasive alien species (like the marble crayfish) are discovered (SVA National Veterinary Institute, 2020). Denmark has since 1971 had a national surveillance programme for IPNV in place. In 2019, 26 freshwater fish farms were registered as being IPN-free. Most of these farms are situated along small rivers, where the water source is mainly well water or borehole water. The majority of these IPN-free farms have broodstock and dispatch eggs, fry and fingerlings to Danish trout farms or export them (Danish Veterinary and Food Administration, 2022).

### 3.1.2. Article 7(b) The impact of the 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

IPNV and/or aquatic birnaviruses have been reported in 19 European Union Ms: Austria, Croatia, Czechia, Denmark, Finland (Eriksson-Kallio, 2022), France (Castric et al., 1987), Germany, Greece, Ireland (Ruane et al., 2007), Italy, the Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden (SVA National Veterinary Institute, 2020) and the UK[6] (Bucke et al., 1979; Ulrich et al., 2018). IPN has been also reported in Norway[7] (Sommerset et al., 2022) and Switzerland[4] (Bucke et al., 1979).

IPNV has not been notifiable to WOAH since 2005; thus, reporting is down to the individual MS and is reliant on the effectiveness of surveillance in each country, so knowledge gaps may exist. The Universidade de Santiago de Compostela[8] has mapped IPNV across Europe, which was also used to supplement the above list. More information can be found here: https://www.usc.gal/es/institutos/acuicultura/difusion/aportacions-cientificas.html.

*The loss of production due to the disease*

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

IPN is economically important due to its lethality for salmonid fry in freshwater production and in post-smolts after transfer to seawater (Dhar et al., 2017).

In Norway, during the period 1994–2000, 40–70% of all seawater sites experienced IPN outbreaks with the average mortality ranging between 10% and 20% (FHL and VESO, 2003). From 1991 to 2002, IPN had an impact on salmon post-smolt survival in Norwegian studies of 6.4–12.0% (Munro and Midtlyng, 2011). A study from Norway on cumulative mortality in the first 6 months after sea transfer showed that mortality in salmonid cohorts with IPN increased to approximately 7.2% as compared with a 'baseline' cohort with a mortality of 3.4% (Bang Jensen and Kristoffersen, 2015; Dhar et al., 2017).

[6] Not EU MS since 31 January 2020, but there is important considerations in the region for IPN.
[7] Not EU MS but there is important considerations in the region for IPN.
[8] https://www.usc.gal/es/institutos/acuicultura/difusion/aportacions-cientificas.html.

A survey conducted in 2001 in Scotland showed an average loss due to IPN of 20–30% in salmon post-smolts (Ruane et al., 2007).

In Ireland, in total 910,000 fish died because of IPNV and a further 750,000 were culled during the 2006 IPN outbreak in salmon rearing units (Ruane et al., 2007).

The effect of IPN on salmon production is particularly serious as it can also cause the death of smolts, shortly after they are put to sea. As these smolts are 0.5–2 years old when they are put to sea, they represent a considerable investment, and their loss is economically serious. IPN may also cause losses to salmon production by suppressing of appetite and associated reduced growth rates (Damsgård et al., 1998; Murray et al., 2004).

Moreover, Roberts and Pearson (2005) reported that IPN-recovered freshwater Atlantic salmon frequently developed a greatly distended intestine associated with the accumulation of undigested food. In seawater, after the initial, often significant (50% or more) losses, there were many fish that failed to grow and became chronically emaciated and prone to sea louse infection.

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

IPN is not a zoonotic disease. There is no evidence in the literature that IPNV 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 the case level and related level and duration of impairment

IPNV infection varies from inapparent or subclinical, in which losses are limited, to acute outbreaks, in which mortality affects nearly the entire population in the affected fish farm. The severity and cumulative mortalities of IPN infection in salmonids depend on the combination of several factors related to the host, the virus and the environment (Dorson and Touchy, 1981; Rodriguez Saint-Jean et al., 2003). Clinical signs of IPN are unspecific but can include hyperpigmentation, unilateral exophthalmia, coelomic distention, the presence of a mucoid pseudo-cast extruding from the vent and haemorrhages at the base of and in the fins as well as on the body surface. In addition, behavioural changes include anorexia and an agonal corkscrew swimming motion interspersed with ataxia (Wolf, 1988). Marked pathological changes can accompany IPNV infection, such as severe necrosis of pancreatic tissue characterised by condensation of chromatin (pyknosis). Mortality due to IPN is higher in young fish at ages of less than 6 months and rare in older fish. Under experimental conditions, fish die between 3 and 20 days after infection. As mentioned above, survivors of exposure to IPNV may become virus carriers for an extended period (McAllister, 1983; Wolf, 1988; Rodriguez Saint-Jean et al., 2003; McAllister, 2007). However, Damsgård et al. (1998) reported that an IPNV carrier condition in Atlantic salmon did not affect appetite and weight gain when compared with the non-carriers.

#### 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

None of the naturally IPN-susceptible wildlife species is included in CITES or IUCN lists of endangered species. However, the European eel (*Anguilla anguilla*), one of the experimentally susceptible wildlife species (see the Section on Susceptible animal species) is currently present in the two lists.

Parameter 2 – Mortality in wild species

Despite the widespread occurrence of IPNV in salmonid farms from Scotland and Norway, no significant effect on wild fish has been observed in those countries. No histopathological signs of IPN were found in wild fish sampled from Irish rivers where hatchery outbreaks had been reported. These findings seem to indicate that IPN is not self-sustaining as a natural infection in wild fish (FHL and VESO, 2003; Ruane et al., 2007). A survey conducted on wild fish in the Scottish Loch Awe has shown a low prevalence of IPNV infection, restricted around a rainbow trout farm where infected stocks had been found previously. No signs of clinical disease were observed in infected wild fish (Munro et al., 1976). However, it is noteworthy that mortality in the youngest fish (fry/parr[9]) may be difficult to observe due to rapid decomposition of corpses; therefore, wild losses are probably underestimated as not directly observed.

[9] When the fry grows to 2 in. long, it is called a parr or fingerling.

*Environment*

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

As discussed previously (see the Section on 'Persistence of the disease in an animal population or the environment') fish surviving IPNV infection often remain carriers for long periods and the virus may also survive in the environment such as in the water.

### 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

IPN is not listed in CFSPH[10] and is not a WOAH-listed disease.[11]

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

IPN is not listed in the Encyclopaedia of Bioterrorism Defence of Australia Group.[12]

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

IPN 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

As IPN is not listed by WOAH, the manual on diagnostic tools is no longer available. IPN is no longer included in the WOAH manual. Due to its widespread, often endemic occurrence in the salmonid culturing regions of the world, WOAH has delisted the disease and it is no longer a listed and notifiable disease.

*Effectiveness*

Parameter 2 – Se and Sp of diagnostic test

In Canada, the performance of RT-qPCR and the virus isolation test has been validated to assess their fitness as diagnostic tools for the detection of IPNV (Fisheries and Ocean Canada, 2017). The authors report high accuracy estimates of 97% for diagnostic sensitivity (Se) and 98% for diagnostic specificity (Sp) obtained for both tests when samples were from naïve and diseased populations. The estimates generated for the RT-qPCR test using samples from apparently healthy populations remained high at 83–91% for Se and 86–92% for Sp. Poor accuracy was observed for the virus isolation test with samples from the same population (i.e. 22–27% for Se and 87–90% for Sp). The results indicated that the cell culture test is not a suitable tool for the detection of IPNV in apparently healthy populations given the high probability of false-negative results.

Rodriguez Saint-Jean et al. (2001) comparatively evaluated six diagnostic methods for IPNV detection using the seroneutralisation as the reference assay: indirect immunofluorescence, flow cytometry, immunoperoxidase, immunodot blot, immune *Staphylococcus* protein A and RT-PCR. Positive reactions were obtained in 100% of the samples tested by RT-PCR, 90.4% by the flow cytometry, 80.7% by the indirect immunofluorescence assay, 67.5% by the immunoperoxidase, 62.6% by the immunodot blot and only 27.7% by immuno-Staphylococcus protein A test. Therefore, RT-PCR and flow cytometry were the most sensitive methods for the routine detection of IPNV in fish.

There is no one RT-qPCR that can detect all the genotypes of IPNV, and therefore, a combination of methods is used.

[10] http://www.cfsph.iastate.edu/DiseaseInfo/.
[11] http://www.oie.int/animal-health-in-the-world/oie-listed-diseases-2016/.
[12] http://www.australiagroup.net/en/human_animal_pathogens.html.

*Feasibility*

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

For virus isolation, moribund fish are the best for sampling and must be alive when collected (Rodriguez Saint-Jean et al., 2003). Tissues used in the inoculation of cells include head kidney, spleen and heart, encephalon, or liver. Ovarian fluids from brood fish at spawning time may also be used. For surveillance, organ samples from a maximum of 10 fish may be pooled. In the case of small fish, several pools of 5–10 typical diseased fish should be examined. For larger fish, visceral pools could also be a good choice sampling for delivery to the laboratory, and at least 10–15 selected moribund individuals must be tested in pools of 3–5 fish each (Rodriguez Saint-Jean et al., 2003; Eriksson-Kallio, 2022).

Most immunodiagnostic assays apart from the serum neutralisation test will not detect the carrier status if used directly on fish blood/tissue samples, unless they are inoculated onto cell lines initially (Chong, 2022).

In the context of the active IPN surveillance implemented in Sweden and Denmark, cell culture is performed in pooled samples from different organs (spleen, kidney, heart/brain) in order to detect or rull out the presence of IPNV. A pool consists of organs from up to ten fish (SVA National Veterinary Institute, 2020).

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

*Availability*

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

A licensed (authorised) inactivated whole-virus vaccine (IWV) (Gomez-Casado et al., 2011; Munang'andu and Evensen, 2015; Chong, 2022) is currently in use in Canada, Chile, Ireland, Norway and the United Kingdom. Successful recombinant VP2 (and VP3) capsid proteins subunit vaccines are used in Canada, Chile, Norway and the USA (for more details, see the table 8 below Chong, 2022). There are currently no licensed (authorised) live IPNV vaccines in use, and DNA vaccines have not shown superior protection over IWV vaccines (Mikalsen et al., 2004; Munang'andu et al., 2012; Dhar et al., 2017; Ma et al., 2019a; Eriksson-Kallio, 2022).

**Table 8:** List of IPNV vaccines extracted from the publication of Chong (2022)

| IPN vaccines | | |
|---|---|---|
| **Vaccine type** | **Efficacy** | **Status** |
| Inactivated with formalin or β-propriolactone(1) | Protection by injection, not by oral or immersion | Experimental. Not practical for use in young fry |
| Live attenuated(1) | Production by passage through cells using serotype not protective, but avirulent IPNV strain from *Perca fluvialis* was protective when used as immersion hyperosmotic vaccination | Experimental |
| Subunit recombinant DNA(1) | Based on Sp serotype using the VP2 virus protein synthesised in *Escherichia coli*. No protection against IPNV Sp and IPNV Buhl. rVP2 vaccine in a multivalent product (furunculosis, cold water vibriosis) protected against IPNV in Atlantic salmon smolts. | Experimental<br>Commercial use in Norway |
| Inactivated whole virus antigen in multivalent vaccine by Pharmaq AS, Aqua health/Novartis(2) | Vaccination of smolts before going to sea. Generally, reduces mortality but can have variable results in field. | Commercial use in Norway |
| Recombinant VP2 protein IPN antigen vaccine Intervet Norbio(2) | Protective | Commercial use in Norway |

| IPN vaccines | | |
|---|---|---|
| **Vaccine type** | **Efficacy** | **Status** |
| ALPHA-JECT by Pharmaq (IPN and furunculosis)(2) | General belief that it is protective, more research needed | Commercial use in Ireland |
| Oral IPN vaccine by Schering Plough-AquaVac(2) | General belief that it is protective, more research needed | Commercial use in Chile |
| Subunit vaccine AquaVac IPN oral by Merck Animal health(3) | VP2 and VP3 capsid proteins | Commercial use in Canada |
| Norvax Minova-6 by Intervet international(3) | VP2 capsid protein | Commercial |
| Birnagen Forte, Aqua health Ltd. Novartis(3) | Inactivated IPNV | Commercial use in Canada |
| Centrovet, Chile(3) | Inactivated IPNV | Commercial use in Chile |
| Microteck international, British Columbia(3) | VP2 protein (Trivalent SRS/IPNV/*Vibrio*) | Commercial use in Chile and Canada |

(1): Rodriguez Saint-Jean et al. (2003).
(2): Ruane et al. (2007).
(3): Dhar et al. (2014).

Parameter 2 – Availability/production capacity (per year)

Information on the availability and the production capacity of the vaccines was not found in the literature.

*Effectiveness*

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

There are a limited number of publications demonstrating the efficacy of the IPNV vaccines (Rimstad, 2014). The majority of commercial IPNV vaccines aim to protect salmonid fish in the post-smolt stage in seawater. However, even if the vaccines were efficient, this would still leave the fish vulnerable to IPNV at a young age prior to vaccination. In Norway, outbreak data indicate that current vaccines against IPNV have limited efficacy under field conditions (i.e. commercial farming of Atlantic salmon) (Rimstad, 2014). Although 85% of all smolts at the national level were vaccinated in 2002, the effect of this high coverage on the IPN situation was not revealed (FHL and VESO, 2003). Vaccination against IPNV has not totally resulted in preventing the impact of IPNV because it is most severe in fry, which are not fully immunocompetent, but applying vaccination to broodstock may reduce the risks of vertical transmission (Chong, 2022).

In a well-controlled field study reported by Erdal et al. (2003), two IPN-vaccinated groups of Atlantic salmon showed 50.6 and 53.2% relative protection during a natural outbreak of IPN 6 weeks after sea transfer. Evaluation of protection from vaccination against IPN in a GCP field trial in Norway (Erdal et al., 2003).

Munang'andu et al. (2012) estimated the hazard risk (HR) ratios for the different IPNV vaccines based on post-challenge mortality data in Atlantic salmon and showed that IWV vaccine was more protective than the other vaccine delivery systems ($HR_{inactivated}$ = 0.108 vs. $HR_{other\ vaccines}$ = 1.368–2.211). Inactivated whole-virus vaccines induce strong responses because they retain surface-exposed antigens and the inactivated genomic component.

Parameter 4 – Duration of protection

No information was found in the publications.

*Feasibility*

Parameter 5 – Way of administration

Three major routes of vaccine delivery are used for IPN aquatic vaccination: injection (intraperitoneal and intramuscular), immersion and oral administration. Although different oral and bathing vaccination procedures have been described, IPNV vaccines are usually administered by intraperitoneal injection and aim to protect salmonid fish in the seawater stage (Rimstad, 2014).

However, oral vaccination is the preferred method from a fish farmer's perspective as it is stress-free and can be delivered to juvenile fish just developing immunity, prior to release in seawater (Chen, 2017). Ongoing research includes the improvement of the oral delivery of IPN antigens. The expense and inconvenience of injectable vaccines limit their usefulness in large-scale aquaculture beyond one vaccination cycle, so the use of oral vaccines to boost immune activation is attractive (Dhar et al., 2017).

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

No effective treatment for IPN is currently available.

*Availability*

Parameter 1 – Types of drugs available on the market

As currently there is no treatment available for IPN, Parameter 1 is not applicable for the assessment.

Parameter 2 – Availability/production capacity (per year)

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

Parameter 3 – Therapeutic effect in the field (effectiveness)

As currently there is no treatment available for IPN, Parameter 3 is not applicable for the assessment.

*Feasibility*

Parameter 4 – Way of administration

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

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

*Availability*

Parameter 1 – Available biosecurity measures

As mentioned previously, IPNV may be transmitted via eggs, fry, anthropogenic fomites, different animals and water. In order to reduce significantly the prevalence of the virus, control measures should consist of a combination of strict biosecurity measures in freshwater and importation of IPNV-free ova/smolts (Ruane et al., 2007). It is essential to obtain stock from IPNV-free sources and to use protected water supplies whenever new fish are introduced. IPNV is very difficult to be inactivated; however, Ruane et al. (2007) and WOAH (2003) cited in Dhar et al. (2017) described that disinfectants with the following properties have been shown to be useful to inactivate IPNV: chlorine (30 ppm for 5 min) and iodophor-based disinfectants, alkaline solutions > pH 12, temperatures > 60°C, formalin based (3% for 5 min). Water may be treated for virus inactivation with UV (> 1200 J $m^{-2}$) or ozone (0.1–0.2 mg $L^{-1}$) (Graham, 2006). In IPNV-free areas, testing of fish eggs and exclusion of IPNV-infected eggs are required, as iodophor treatment is not effective as a means of control (McAllister, 1983).

Previously, WOAH recommended to establish a programme of individual parent testing, which promoted the immediate disposal of ova from IPN-positive parents as soon as laboratory results were made available. Salmon brood stock testing data from 2004 to 2006 in Ireland, where the detection of the IPNV was based on the testing of sample pools (ovarian fluid, milt or kidney/brain/heart) between 1–10 fish using cell culture followed by a confirmatory ELISA test, showed that the highest number of positive isolations were observed in the organ samples submitted for testing (Ruane et al., 2007).

*Effectiveness*

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

A site-specific biosecurity and water quality improvement plan introduced into the Marine Harvest Norway, Bessaker site in 2000–2001 resulted in the successful eradication of the virus (G. Ritchie, Marine Harvest, pers. comm. cited in Ruane et al., 2007).

Rexhepi et al. (2014) demonstrated that the application of good sanitary practices helps to reduce IPN outbreaks in rainbow trout farms. This was shown by comparing results from a study conducted before and after preventive measures such as egg disinfection, sanitation before introducing a new fish stock and use of pathogen-free water (IPNV-positive fish farms rates of 53.8% and 22.2%, respectively).

*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, feed the fish and maintain the environmental quality of the water they are held in (EFSA AHAW Panel, 2017b).

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

*Availability*

Parameter 1 – Available movement restriction measures

Due to its widespread, often endemic occurrence in salmonid populations, WOAH has delisted the disease, which eliminated official movement restrictions and compulsory culling policies. However, as stipulated in Commission Implementing Decision (EU) 2022/1188, areas regarded as being partly free of the disease (areas in Denmark, Finland, Slovenia and Sweden) are allowed to apply restrictions on the import of fish from countries with a lesser health status with respect to IPNV. To date, only parts of EU countries have been recognised as IPN-free. Since farmed fish are likely to be the most important reservoir of IPNV, and carriers are capable of shedding sufficient virus to establish an infection in exposed populations, transfers of farmed fish between farms are therefore one of the highest risks in the introduction of IPNV and one of the most effective ways of introducing the virus into a farm. It is therefore recommended to conduct a risk assessment before any movement of live fish takes place onto a farm (Scottish Government, 2019; Sommerset et al., 2022).

*Effectiveness*

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

Ruane et al. (2007) indicated in 2007 that all clinical outbreaks of IPN in Ireland had been associated with imports and that if the imports from infected sites were stopped, the disease could potentially be eradicated. A practical solution to the problem would be the screening of broodstock/ova for IPNV and fish movements.

*Feasibility*

Parameter 3 – Feasibility of restriction of animal movement

No information was found in the publications.

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

*Availability*

Parameter 1 – Available methods for killing animals

As described in the aquatic code of the World Organisation for Animal Health (Chapters 7.3 and 7.4) (WOAH, 2022), 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 (EFSA AHAW Panel, 2009) reported the following methods used for emergency slaughter: pharmacological, electrical and maceration. The brood stock 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/stopping spread of the disease

Killing and removal of fish from an infected farm effectively eliminates further contamination of the environment and thus is effective in reducing the spread of the disease via water or fomite

transmission. However, as described in previous sections, the environment will remain contaminated if no further biosecurity measures are taken (EFSA AHAW Panel, 2017b). Eriksson-Kallio et al. (2016) reported an example of a rainbow trout farm in Finland that, despite applying eradication measures consisting of the destruction of fish, thorough mechanical cleaning and disinfection of tanks and equipment followed by fallowing for 1 month, the farm was still infected with IPNV the following year.

*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 is not widely used. Studies on fish welfare before slaughter have concluded that many of the traditional systems used to stun fish including $CO_2$ narcosis are not acceptable in terms of welfare, as they cause stress before death than could be avoided. 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 culling by different methods (EFSA AHAW Panel, 2017b).

#### 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 moribund and dead fish shed more IPNV than carrier fish, prompt removal and safe disposal of mortalities 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 mortalities from fish farm tanks and cages and their safe disposal (e.g. by composting or ensiling) (FHL and VESO, 2003).

An alkaline hydrolysis method in which macerated fish mortalities are exposed to high pH ($>$ 13) for 7 days inactivates high titres of IPNV and is recommended as a biosecurity treatment method for fish by-products that contain fish pathogens (Dixon et al., 2012b). However, ensiling (a method of carcass disposal that involves lowering the pH to $<$ 4) was determined to not be a biosecurity method for disposal of fish mortalities (Smail et al., 1993a; Dixon et al., 2012a; Canadian Food Inspection Agency, 2020).

*Effectiveness*

Parameter 2 – Effectiveness of disposal option

No information was found in the publications.

*Feasibility*

Parameter 3 – Feasibility of disposal option

No information was found in the publications.

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

*Availability*

Parameter 1 – Available breeds resistant to the pathogen

As past research has demonstrated that there is genetic variation in resistance to IPNV in both Atlantic salmon and rainbow trout populations (Storset et al., 2007; Guy et al., 2009), breeding companies have gone into selectively breeding fish resistant to IPNV since the beginning of the 2000s. This large-scale production of IPN-resistant salmon for the aquaculture industry has been made possible by genetic mapping of the (QTL) affecting disease resistance against IPNV that explains 80–100% of genetic variation in fish susceptibility to IPNV at the first feeding fry (freshwater) and post-smolt (seawater) stages, in two separate populations, Scotland and Norway (Houston et al., 2008; Moen et al., 2009; Flores-Mara et al., 2017; Tapia et al., 2022). First, mutations in the epithelial

cadherin gene (*cdh1*) were identified as the likely causative genetic variation for IPNV resistance in Atlantic salmon (Houston et al., 2008, 2010; Moen et al., 2009, 2015; Rodríguez et al., 2019; Hillestad et al., 2021). Subsequent work however implicates the Nedd-8 activating enzyme gene as the underlying candidate gene (Pavelin et al., 2021).

*Effectiveness*

Parameter 2 – Effectiveness of having resistant breeds

Selective breeding for resistance to clinical disease in IPNV has proven to be a highly effective strategy for the salmon aquaculture industry, with a single QTL conferring high resistance to disease. An important element of selective breeding in this instance is that resistance is conferred on all stages of Atlantic salmon that are susceptible to the disease (i.e. first feeding fry and post-smolts) (FHL and VESO, 2003). In Norway, IPN has been managed well for many years by using QTL selection combined with the systematic extinction of house strains. Following the inclusion of this QTL into the breeding programmes, the salmon industry witnessed a sharp decline in the number of IPN outbreaks throughout Norway, dropping from 223 to only 19 reported cases from 2009 to 2019 (~ 90% decrease) (Munang'andu et al., 2016; Sommerset et al., 2020). An independent economic analysis (Economic impact report from AbacusBio Ltd cited in Research Excellence Framework, 2021) showed that between August 2013 and July 2020, marker-assisted selection for resistance to IPN had nearly eradicated this disease from farmed salmon stocks, averting the death of 8,000,000–18,000,000 salmon across Chile, Norway and Scotland, thus increasing salmon production by between 36,800 and 79,600 tonnes across the three countries. The total value of this increased production, after accounting for feeding costs, has been between £108,000,000 and £234,000,000 to the global salmon farming industry.

However, in 2019, a new variant of IPNV was identified from a field outbreak in western Norway that had caused significant mortality, even in genetically resistant salmon. Although the overall the number of IPN detections has not increased since then, the reports indicate that efforts must be made to map mechanisms for IPN QTL salmon for protection against the new IPNV variant (Hillestad et al., 2021; Sommerset et al., 2022).

*Feasibility*

Parameter 3 – Feasibility of having these resistant breeds

A selective breeding study was initiated in 1996 to assess the feasibility of selecting salmon resistant to IPNV and included a series of field and experimental trials challenging known full-sib Atlantic salmon families with IPNV. A total of 376,541 seawater and 28,182 freshwater fish subjected to IPNV challenge covering a 14-year period in 17 separate locations across seven sites. The results of the study indicated that selecting salmon for resistance to both seawater and freshwater IPNV challenge was clearly feasible, and that adverse effects of selection for other important production traits were not expected (Guy, 2011). Experimental challenge of salmon fry (freshwater) has indicated that those having both sire and dam carrying the resistance QTL haplotype showed 0% mortality, while those with a single resistant parent showed 1–2% mortality. In contrast, fully susceptible fish showed a mortality of 69% (Houston et al., 2010). The feasibility of selective breeding has now been clearly demonstrated by the decline in the number of IPN outbreaks experienced by countries that have been applying the technology in salmon aquaculture such as Norway (Hillestad et al., 2021; Research Excellence Framework, 2021).

Next to what has been done in Atlantic salmon, Rodríguez et al. (2019) have shown that given the heritability for resistance values calculated using genomic information in rainbow trout (time to death: 0.53 and binary survival: 0.82), the selection to improve resistance to IPN in that species would also be feasible.

### 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)

Important principles of disease control, like the elimination of vertical transmission and spread of IPNV through infected broodstock and persistently infected fingerlings or smolt, are considered of

major importance for the spread of the virus. In Norway, no one has analysed the total implementation of these principles. Reasons for this are mainly economic and practical: Costs connected to extensive test programmes are enormous and the benefit uncertain (FHL and VESO, 2003).

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)

When IPNV was detected in Finland inland farms in 2012–2013, the estimated eradication costs outweighed the expected benefits, and eradication of IPNV from continental Finland was not considered feasible. Finnish authorities decided to limit the national control programme to IPNV strains belonging to Genogroup 5, which are known to be highly pathogenic, causing mortality and clinical disease (Eriksson-Kallio et al., 2016).

Parameter 3 – Cost of surveillance and monitoring

No information was found in the publications.

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

No information was found in the publications.

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

IPN was considered a serious viral disease in salmon production. It is economically important due to its lethality for salmonid fry in freshwater production, and in post-smolts after transfer to seawater (Ariel and Olesen, 2001; Dhar et al., 2017). In 1998, In Norway, before the wide use of selective breeding in the salmon industry, the economic losses related to IPN were estimated to exceed €12 million (Munro and Midtlyng, 2011). A survey conducted in 2001 in Scotland showed an average loss due to IPN equated to an immediate cash value of £2 million, and this was considered as an underestimation (Ruane et al., 2007). The potential value of the fish lost due to IPN outbreak in salmon rearing units in Ireland in 2006 was estimated at €26–31 million (Ruane et al., 2007). The effect of IPN on salmon production is particularly serious as it can also cause the death of smolts shortly after they are put to sea. Since these smolts are half to 2 years old when they are put to sea, they represent a considerable investment, so their loss is economically serious (Murray et al., 2004).

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

Contrary to chemotherapeutics that may cause 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 IPN (Ma et al., 2019b). Conversely, 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 (Norwegian Biotechnology Advisory Board, 2020). In a survey conducted in Norway by VESO in 2003, only a minority among fish health personnel and fish farmers agreed that the IPN problem would have been more prominent without the current management. The most common remark, when asked to propose suggestions for a future strategy, was that broodstock control should have been stricter (FHL and VESO, 2003).

#### 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 important side effects on fish welfare such as pain, appetite loss, tissue adhesions around the injection site, pigmentation and intra peritoneum granuloma (Maria Poli, 2009). Therefore, as stated previously, oral vaccination is the preferred method from a fish farmer's perspective as it is stress-free.

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

EFSA (EFSA AHAW Panel, 2009) assessed the welfare aspects of killing farmed Atlantic salmon and reported that pre-slaughter crowding and pumping would subject the fish to metabolic and handling stress. There is also always a certain risk of poor welfare involved when live fish are transported. When fish are transported under good conditions (open transport), then the fish may recover from crowding and handling during the transport. As the fish are supplied to the stunning or killing unit operation, there is a high risk that salmon is 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. Using mills for maceration, fish should be previously stunned, and fish should then be instantaneously killed.

Parameter 2 – Wildlife depopulation as a control measure

Not applicable.

#### 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 slaughter such as anaesthetics might affect the environment if discharged into the 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).

Parameter 2 – Mortality in wild species

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

## 3.2. Assessment of infectious pancreatic necrosis according to Article 5 criteria of AHL on its eligibility to be listed

### 3.2.1. Detailed outcome on Article 5 criteria

In Table 9 and Figure 2, the results of the expert judgement on the Article 5 criteria of the AHL for infectious pancreatic necrosis are presented.

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

**Table 9:** Outcome of the expert judgement on Article 5 criteria

| **Criteria to be met by the disease:** According to the AHL, a disease shall be included in the list referred to in point (b) of paragraph 1 of Article 5 if it has been assessed in accordance with Article 7 and meets all of the following criteria | | **Outcome** | | | |
|---|---|---|---|---|---|
| | | **Median range (%)** | **Criterion fulfilment** | **Number of NA** | **Number of experts** |
| A(i) | The disease is transmissible | 99–100 | Fulfilled | 0 | 15 |
| A(ii) | Animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union | 99–100 | Fulfilled | 0 | 15 |
| A(iii) | The disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character | 90–100 | Fulfilled | 0 | 15 |
| A(iv) | Diagnostic tools are available for the disease | 95–100 | Fulfilled | 0 | 15 |
| 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 | 50–90 | Uncertain | 1 | 15 |
| **At least one criterion to be met by the disease**: In addition to the criteria set out above at point A(i)–A(v), the disease needs to fulfil at least one of the following criteria | | | | | |
| B(i) | The disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic character | 66–90 | Fulfilled | 0 | 15 |
| 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 | 15 | 15 |
| B(iii) | The disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union | 66–95 | Fulfilled | 0 | 15 |
| B(iv) | The disease has the potential to generate a crisis, or the disease agent could be used for the purpose of bioterrorism | 1–5 | Not fulfilled | 0 | 15 |
| 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 | 15 |

NA: not applicable. Green is used for fulfilled, red for not fulfilled and orange for uncertain.

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

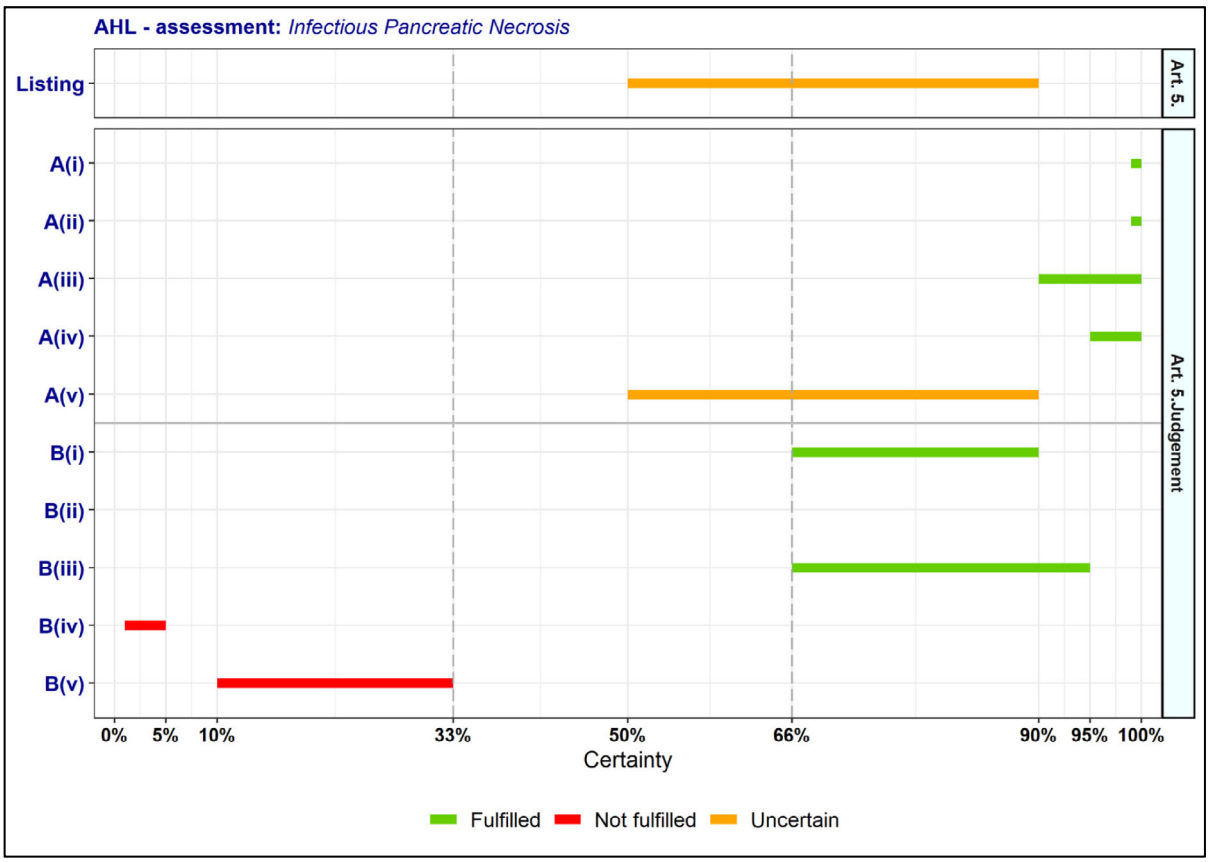



**Figure 2:** Outcome of the expert judgement on Article 5 criteria and overall probability of infectious pancreatic necrosis on eligibility to be listed

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

***Criterion A(v)*** *(risk-mitigating measures and, where relevant, surveillance of the disease are effective and proportionate to the risks posed by the disease in the Union):*

- The experience in risk mitigating measures and surveillance activities to control IPN is coming from some regions in Scandinavian Countries (e.g. Norway) and it is uncertain if they can be effective in other EU countries.
- The IPNV is widespread in the EU, and therefore, it is uncertain how effective the surveillance activities and mitigation measures may be to control the disease. As a result, there is also uncertainty around the cost–benefit of their implementation. On the other hand, surveillance activities and mitigation measures are necessary to follow up and eliminate the spread in case of IPNV occurrence in aquaculture.
- The effectiveness of the control measures is variable among different animal species. For example, for salmon, vaccines are available and breeds resistant to IPNV exist, so there is higher certainty for the effectiveness of the mitigation measures and surveillance activities while for rainbow trout, the uncertainty is higher since these options are not available.
- When IPN is introduced for the first time in a country or zone it becomes endemic, and usually it cannot be eradicated. Mitigation measure in that case is to establish IPN-free compartments based on certified IPN-free broodstocks.
- Genetic selection has proven an efficient practice for disease control in Norway.

### 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 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 9, infectious pancreatic necrosis complies with four criteria of the first set (A(i)–A(iv)), but there is uncertainty (50–90% probability) on the assessment on compliance with criterion A(v). Therefore, it is uncertain whether infectious pancreatic necrosis 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 infectious pancreatic necrosis being eligible to be listed is 50–90% (see Figure 2).

## 3.3. Assessment of infectious pancreatic necrosis according to criteria in Annex IV for the purpose of categorisation as in Article 9 of the AHL

In Tables 10–14 and related graphs (Figures 3–5), the results of the expert judgement on infectious pancreatic necrosis according to the criteria in Annex IV of the AHL, for the purpose of categorisation as in Article 9, are presented.

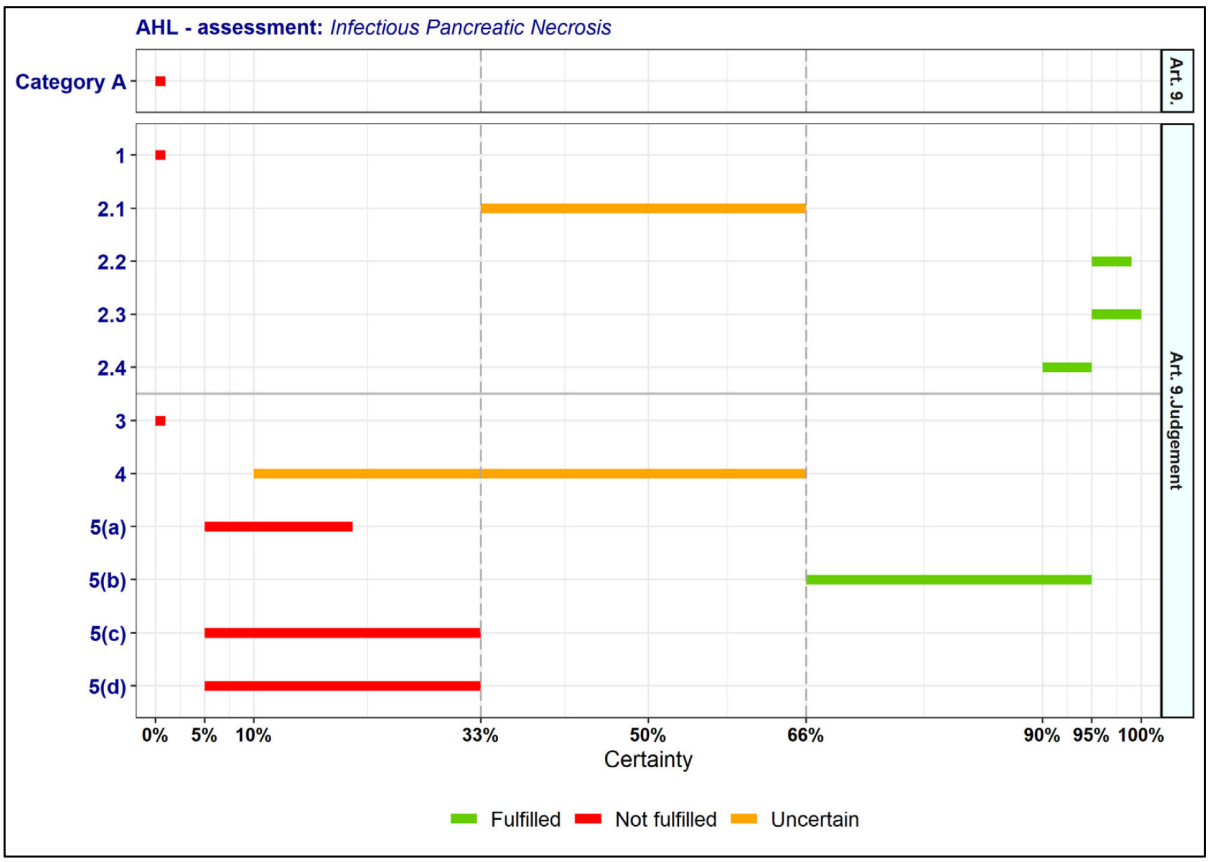
The distribution of the individual answers (probability ranges) provided by each expert for each criterion are reported in Appendix A.

### 3.3.1. Detailed outcome on Category A criteria

**Table 10:** Outcome of the expert judgement related to the criteria of Section 1 of Annex IV (Category A of Article 9)

| **Criteria to be met by the disease:** The disease needs to fulfil all of the following criteria | | **Outcome** | | | |
|---|---|---|---|---|---|
| | | **Median range (%)** | **Criterion fulfilment** | **Number of NA** | **Number of experts** |
| 1 | The disease is not present in the territory of the Union or present only in exceptional cases (irregular introductions) or present in only in a very limited part of the territory of the Union | 0–1 | Not fulfilled | 0 | 15 |
| 2.1 | The disease is highly transmissible | 33–66 | Uncertain | 1 | 15 |
| 2.2 | There are possibilities of airborne or waterborne or vector-borne spread | 95–99 | Fulfilled | 0 | 15 |
| 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 | 15 |
| 2.4 | The disease may result in high morbidity and significant mortality rates | 90–95 | Fulfilled | 0 | 15 |
| **At least one criterion to be met by the disease**: In addition to the criteria set out above at point 1–2.4, the disease needs to fulfil at least one of the following criteria | | | | | |
| 3 | The disease has a zoonotic potential with significant consequences for public health, including epidemic or pandemic potential or possible significant threats to food safety | 0–1 | Not fulfilled | 1 | 15 |
| 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 | 15 |
| 5(a) | The disease has a significant impact on society, with in particular an impact on labour markets | 5–20 | Not fulfilled | 0 | 15 |
| 5(b) | The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals | 66–95 | Fulfilled | 0 | 15 |
| 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 | 15 |
| 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 | 15 |

NA: not applicable. Green is used for fulfilled, red for not fulfilled and orange for uncertain.




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 criteria of Section 1 of Annex IV and overall probability of the infectious pancreatic necrosis to be fitting in Category A of Article 9

#### 3.3.1.1. Reasoning for the uncertain outcome on Category A criteria

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

- The difference between high and moderate–high transmissibility in the question is not clearly defined. R0 is more than 1, but less than 2.5, and these values do not suggest high transmissibility, although this may vary among virus genotypes and animal species.
- Reproduction of the disease under experimental conditions with non-invasive challenge methods is not efficient. Nevertheless, under field conditions, if infected fish are introduced in a farm, then the IPNV will be transmitted, and the farm will remain infected.
- Prevalence among farmed animals appears to be high, while it is low in wild animals. Morbidity varies considerably. Prevalence ranged from 1% to 100%.

**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):

- There is no evidence in the literature about the IPN impact on the economy of the Union overall to quantify the costs on animal health and production. In addition, there is gap of knowledge on the impact of IPN on the aquaculture sector in the Union.
- For the countries where IPN occur, and aquaculture is a significant economic sector, the financial impact can be considered significant. Nevertheless, this impact may vary based on the aquatic animal species, the implementation of vaccination and the use of resistant to IPN breeds (IPN-QTL).
- It may be possible to control IPN, but this has not been achieved in most countries; consequently, the economic significance is not deemed that important.

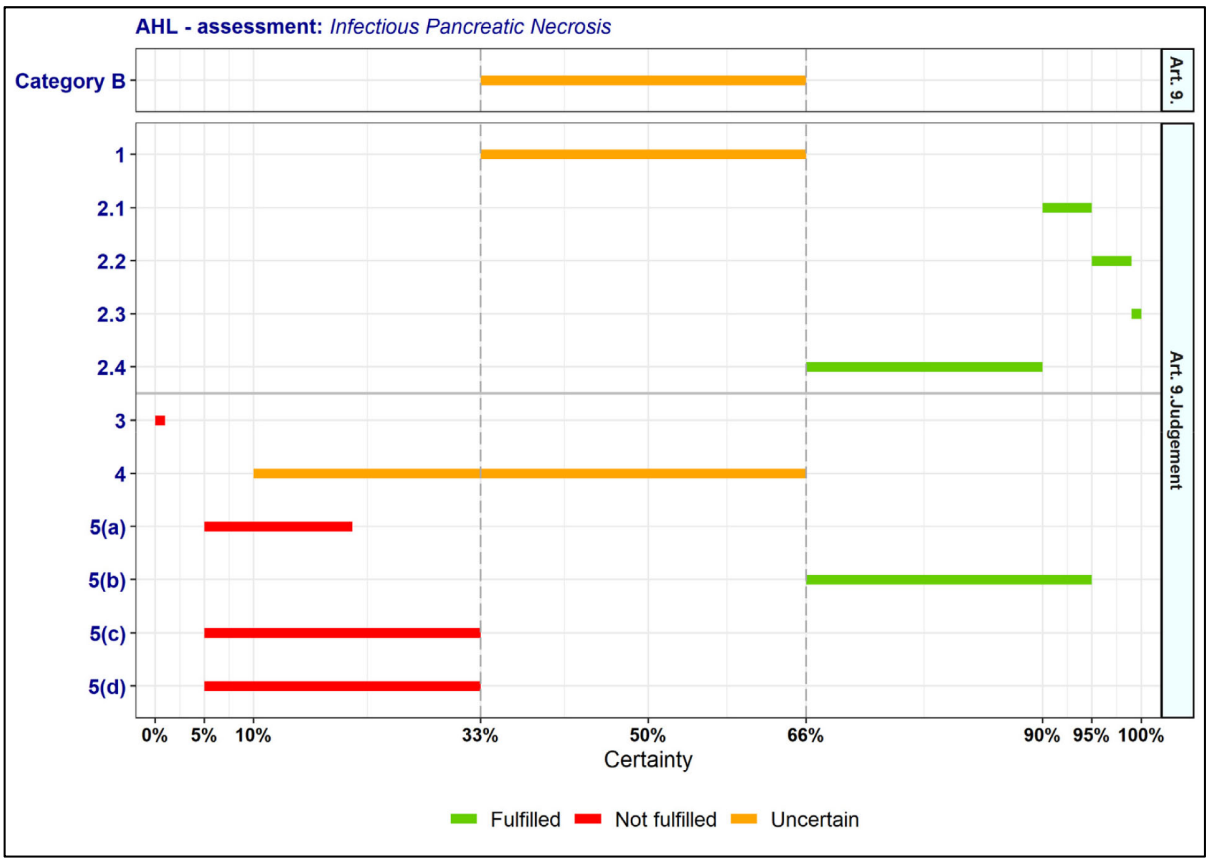
- The mortality can be very high and thus contribute to the impact on the economy, particularly, at a local level.

### 3.3.2. Detailed outcome on Category B criteria

**Table 11:** Outcome of the expert judgement related to the criteria of Section 2 of Annex IV (Category B of Article 9)

| **Criteria to be met by the disease:** The disease needs to fulfil all of the following criteria | | **Outcome** | | | |
|---|---|---|---|---|---|
| | | **Median range (%)** | **Criterion fulfilment** | **Number of NA** | **Number of experts** |
| 1 | The disease is present in the whole or part of the Union territory with an endemic character and (at the same time) several Member States or zones of the Union are free of the disease | 33–66 | Uncertain | 1 | 15 |
| 2.1 | The disease is moderately to highly transmissible | 90–95 | Fulfilled | 0 | 15 |
| 2.2 | There are possibilities of airborne or waterborne or vector-borne spread | 95–99 | Fulfilled | 0 | 15 |
| 2.3 | The disease affects single or multiple species[(a)] | – | Fulfilled | 0 | 15 |
| 2.4 | The disease may result in high morbidity with in general low mortality | 66–90 | Fulfilled | 0 | 15 |
| **At least one criterion to be met by the disease**: In addition to the criteria set out above at point 1–2.4, the disease needs to fulfil at least one of the following criteria | | | | | |
| 3 | The disease has a zoonotic potential with significant consequences for public health, including epidemic potential or possible significant threats to food safety | 0–1 | Not fulfilled | 1 | 15 |
| 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 | 15 |
| 5(a) | The disease has a significant impact on society, with in particular an impact on labour markets | 5–20 | Not fulfilled | 0 | 15 |
| 5(b) | the disease has a significant impact on animal welfare, by causing suffering of large numbers of animals | 66–95 | Fulfilled | 0 | 15 |
| 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 | 15 |
| 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 | 15 |

NA: not applicable. Green is used for fulfilled, red for not fulfilled and orange for uncertain.
(a): This is always fulfilled.




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 and overall probability of the infectious pancreatic necrosis to be fitting in Category B of Article 9

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

**Criterion 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):

- Since 2005, IPN is not a WOAH-listed disease, and therefore, the reporting of IPN cases has decreased. Consequently, it is difficult to assess whether some countries or zones are free of IPNV or not. However, IPNV has been reported in the literature in at least 17 countries in the Union in the period 2014–2021, and three additional countries in Europe.
- Sweden and partially Finland (zones) are free from IPNV genotype 5 but not for all other genotypes. Denmark has IPN-free compartments and farms (broodstock farms) where high biosecurity is in place and the absence of IPN infection is very well documented (bi-annual testing for > 50 years).
- Although IPN is known to be endemic to salmonid farming in many areas around the world including Europe, and the disease is considered likely endemic in the parts of the Union not listed above, the current distribution of IPNV is not very clear.

**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):

- There is no evidence in the literature about the IPN impact on the economy of the Union to quantify the costs on animal health and production. In addition, there is gap of knowledge on the impact of IPN on the aquaculture sector in the Union.

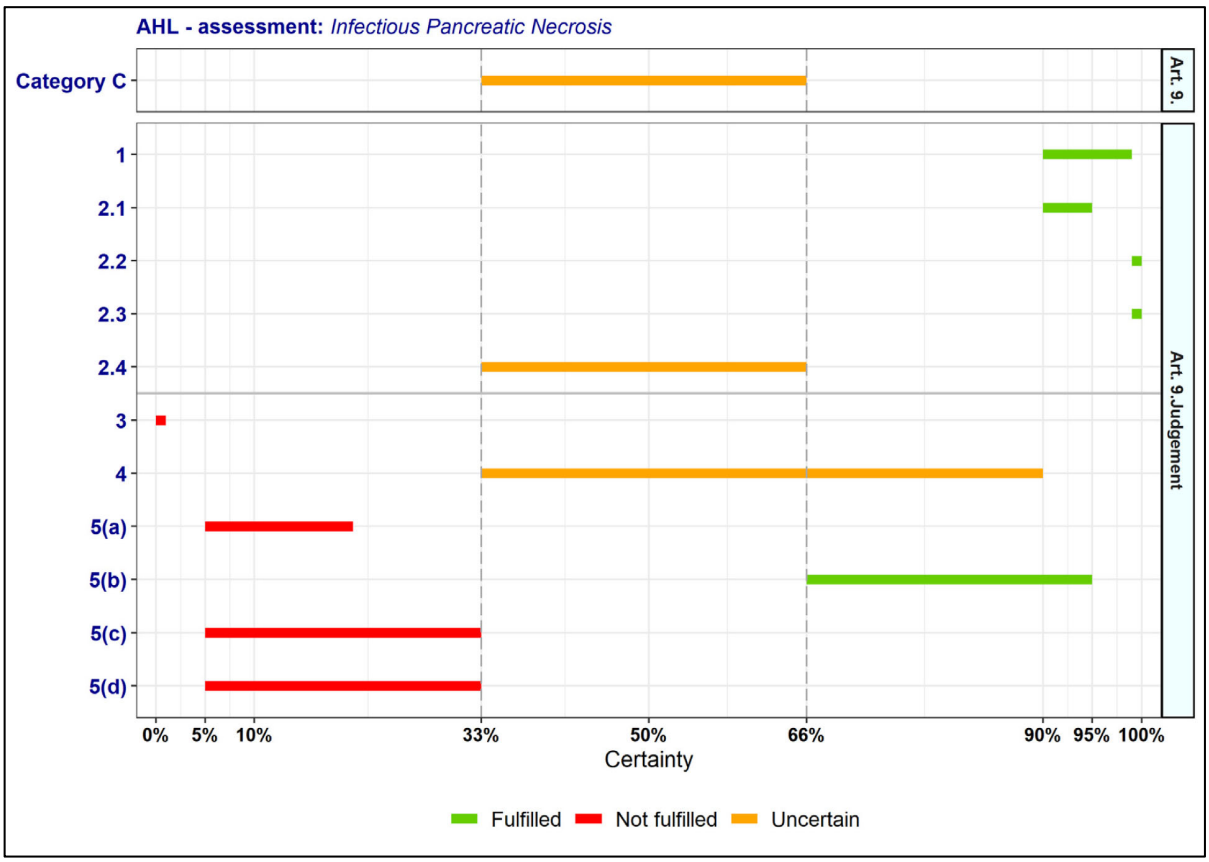
- For the countries where IPN occurs, and aquaculture is a significant economic sector the financial impact can be considered significant. Nevertheless, this impact may vary based on the aquatic animal species, the implementation of vaccination and the use of resistant to IPN breeds (IPN-QTL).

### 3.3.3. Detailed outcome on Category C criteria

**Table 12:** Outcome of the expert judgement related to the criteria of Section 3 of Annex IV (Category C of Article 9)

| **Criteria to be met by the disease:** The disease needs to fulfil all of the following criteria | | **Outcome** | | | |
|---|---|---|---|---|---|
| | | **Median range (%)** | **Criterion fulfilment** | **Number of NA** | **Number of experts** |
| 1 | The disease is present in the whole OR part of the Union territory with an endemic character OR in **aquatic animals** several Member States or zones of the Union are free of the disease | 90–99 | Fulfilled | 0 | 15 |
| 2.1 | The disease is moderately to highly transmissible | 90–95 | Fulfilled | 0 | 15 |
| 2.2 | The disease is transmitted mainly by direct or indirect transmission[(a)] | – | Fulfilled | 0 | 15 |
| 2.3 | The disease affects single or multiple species[(a)] | – | Fulfilled | 0 | 15 |
| 2.4 | The disease may result in high morbidity and usually low mortality and often the most observed effect of the disease is production loss? | 33–66 | Uncertain | 0 | 15 |
| **At least one criterion to be met by the disease**: In addition to the criteria set out above at point 1–2.4, the disease needs to fulfil at least one of the following criteria | | | | | |
| 3 | The disease has a zoonotic potential with significant consequences for public health or possible significant threats to food safety | 0–1 | Not fulfilled | 1 | 15 |
| 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 | 15 |
| 5(a) | The disease has a significant impact on society, with in particular an impact on labour markets | 5–20 | Not fulfilled | 0 | 14 |
| 5(b) | The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals | 66–95 | Fulfilled | 0 | 15 |
| 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 | 15 |
| 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 | 15 |

NA: not applicable. Green is used for fulfilled, red for not fulfilled and orange for uncertain.
(a): This is always fulfilled.




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 and overall probability of IPN to be fitting in Category C of Article 9

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

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

- The mortality ranges at farm level from 10% to 20% and can reach 70% in some cages. It is considered by the experts as significant and not low.
- There is uncertainty about the impact of IPN on production due to lack of scientific evidence. The impact on production is related to a range of different indicators in animal health and animal welfare. In the past, in infected farms, loss of production and low growth rates have not been assessed and there are no studies to estimate and quantify the impact of IPN.

**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):

- The impact to fish production varies depending on the type of the aquatic animals, the aquaculture practices, the implementation of vaccination or the use of resistant to IPN breeds (IPN-QTL).
- Major mortality rates have been observed, and the culling of large numbers of potentially infected fish has also been required.

### 3.3.4. Detailed outcome on Category D criteria

**Table 13:** Outcome of the expert judgement related to the criteria of Section 4 of Annex IV (Category D of Article 9)

| Diseases in Category D **need to fulfil criteria of Sections 1, 2, 3 or 5 of Annex IV** of the AHL **and the following:** | | Outcome | | | |
|---|---|---|---|---|---|
| | | **Median range (%)** | **Criterion fulfilment** | **Number of NA** | **Number of experts** |
| D | The risk posed by the disease can be effectively and proportionately mitigated by measures concerning movements of animals and products in order to prevent or limit its occurrence and spread | 66–95 | Fulfilled | 0 | 15 |

NA: not applicable. Green is used for fulfilled, red for not fulfilled and orange for uncertain.

### 3.3.5. Detailed outcome on Category E criteria (Table 14)

**Table 14:** Outcome of the expert judgement related to the criteria of Section 5 of Annex IV (Category E of Article 9)

| Diseases in Category E **need to fulfil criteria of Sections 1, 2 or 3 of Annex IV** of the AHL **and/or the following:** | | Outcome | |
|---|---|---|---|
| | | **Median range (%)** | **Fulfilment** |
| E | Surveillance of the disease is necessary for reasons related to animal health, animal welfare, human health, the economy, society or the environment<br>(If a disease fulfils the criteria as in Article 5, thus being eligible to be listed, consequently Category E would apply.) | 50–90 | Uncertain |

Green is used for fulfilled, red for not fulfilled and orange for 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 10–14. 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 Infectious Pancreatic Necrosis as in Article 9, is presented in Table 15 and Figure 6.

**Table 15:** Outcome of the assessment on criteria in Annex IV of the AHL for the purpose of categorisation as in Article 9

| | **Article 9 criteria** | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **1° set of criteria** | | | | | **2° set of criteria** | | | | | | **D** | |
| **Category** | **1** Geographical distribution | **2.1** Transmissibility | **2.2** Routes of transmission | **2.3** Multiple species | **2.4** Morbidity and mortality | **3** Zoonotic potential | **4** Impact on economy | **5(a)** Impact on society | **5(b)** Impact on animal welfare | **5(c)** Impact on environment | **5(d)** Impact on biodiversity | | **Art 5** |
| A | 0–1 | 33–66 | 95–99 | 95–100 | 90–95 | 0–1 | 10–66 | 5–20 | 66–95 | 5–33 | 5–33 | | |
| B | 33–66 | 90–95 | 95–99 | – | 66–90 | 0–1 | 10–66 | 5–20 | 66–95 | 5–33 | 5–33 | | |
| C | 90–99 | 90–95 | – | – | 33–66 | 0–1 | 33–90 | 5–20 | 66–95 | 5–33 | 5–33 | | |
| D | | | | | | | | | | | | 66–95 | |
| E | | | | | | | | | | | | | 50–90 |

Green is used for fulfilled, red for not fulfilled and orange for uncertain.

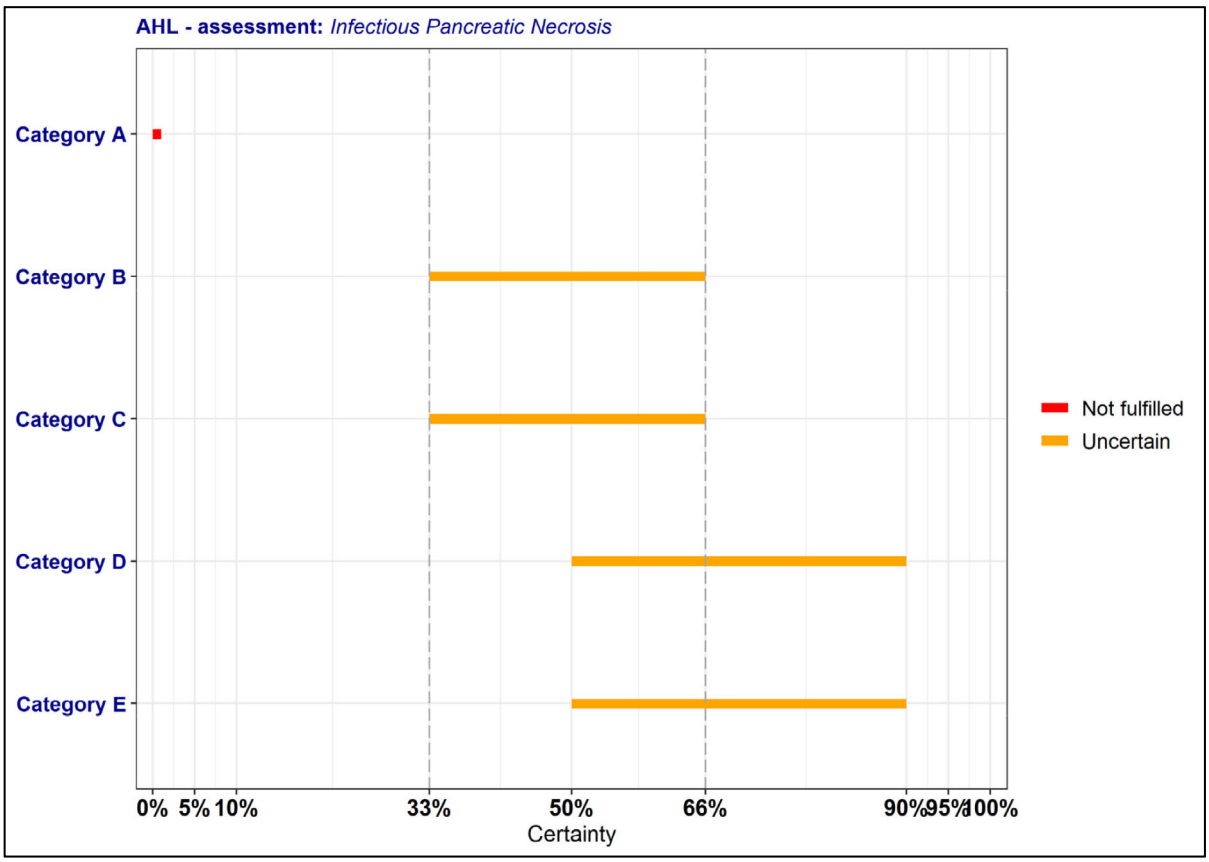



**Figure 6:** Outcome of the expert judgement on criteria in Annex IV and overall probabilities for categorisation of IPN in accordance with Article 9

According to the assessment here performed, IPN 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, IPN complies only with four out of five criteria (2.1, 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 IPN complies with 5 (b) criterion. Overall, it was assessed with 0–1% probability that IPN 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, IPN complies only with four out of five criteria; 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 IPN complies with 5 (b) criterion. Overall, it was assessed with 33–66% probability that IPN 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, IPN complies with four out of five criteria; 1, 2.1, 2.2 and 2.3). To be eligible for Category C, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5(a)–(d)) and IPN complies with 5 (b) criterion. Overall, it was assessed with 33–66% probability that IPN may be assigned to Category C according to criteria in Section 3 of Annex IV for the purpose of categorisation as in Article 9 of the AHL.
4) To be assigned to **Category D**, a disease needs to comply with criteria of Sections 1, 2, 3 or 5 of Annex IV of the AHL and with the specific criterion D of Section 4. IPN does not comply

with criteria of Sections 1, 2, 3 or 5 of Annex IV of the AHL but complies with 66–95% probability with criterion D.

5) To be assigned to **Category E**, a disease needs to comply with criteria of Sections 1, 2 or 3 of Annex IV of the AHL, and/or the surveillance of the disease is necessary for reasons related to animal health, animal welfare, human health, the economy, society or the environment. The latter is applicable if a disease fulfils the criteria as in Article 5, for which the assessment is uncertain with 50–90% probability.

## 3.4. Assessment of infectious pancreatic necrosis 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 infectious pancreatic necrosis are presented. The Article 8(3) criteria are about animal species to be listed, as it reads below:

*'3. Animal species or groups of animal species shall be added to the list if they are affected or if they pose a risk for the spread of a specific listed disease because*:

*a) they are susceptible to a specific listed disease, or scientific evidence indicates that such susceptibility is likely; or*

*b) they are vector species or reservoirs for that disease, or scientific evidence indicates that such role is likely.'*

For this reason, the assessment on Article 8 criteria is based on the evidence as extrapolated from the relevant criteria of Article 7, i.e. the ones related to susceptible, vectors and reservoir species or routes of transmission, which cover also the possible role of biological or mechanical vectors.

According to the mapping, as presented in Table 5, Section 3.2, of the Scientific Opinion on the ad hoc methodology (EFSA AHAW Panel, 2017a), the animal species to be listed for infectious pancreatic necrosis according to the criteria of Article 8(3) of the AHL are as displayed in Table 16 (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 infectious pancreatic necrosis has been described, but also those animal species from which only the infectious pancreatic necrosis virus itself has been isolated. The latter makes susceptibility to IPNV likely.

**Table 16:** Animal species to be listed for infectious pancreatic necrosis according to the criteria of Article 8

| Type | Class | Order | Family | Genus/species | References |
|---|---|---|---|---|---|
| **Susceptible** | Actinopterygii | Anabantiformes | Channidae | *Channa striata* | Wattanavijarn et al. (1988) |
| | | Anguilliformes | Anguillidae | *Anguilla anguilla* | Hudson et al. (1981) |
| | | | | *Anguilla japonica* | Kim and Oh (2014) |
| | | Clupeiformes | Clupeidae | *Brevoortia tyrannus* | Stephens et al. (1980), Nicholson and Caswell (1982) |
| | | Cypriniformes | Cyprinidae | *Danio rerio* | Rud et al. (2020) |
| | | Exociformes | Esocidae | *Esox lucius* | Ahne (1978), Hill and Way (1995) |
| | | Gadiformes | Merlucciidae | *Merluccius merluccius* | Wallace et al. (2005) |
| | | | Gadidae | *Gadus morhua* | Duan et al. (2021), Jensen et al. (2009), Urquhart et al. (2009), Duan et al. (2021) |
| | | Perciformes | Anarhichadidae | *Anarhichas minor* | Sommer et al. (2004) |
| | | | Moronidae | *Morone saxatilis* | Schutz et al. (1984) |
| | | | Moronidae | *Dicentrarchus labrax* | Bonami et al. (1983) |
| | | | Labridae | *Ctenolabrus rupestris* | Gibson et al. (1998) |
| | | Pleuronectiformes | Pleuronectidae | *Limanda limanda* | Diamant et al. (1988), Munro et al. (2004), Wallace et al. (2008) |
| | | | Pleuronectidae | *Microstomus kitt* | Maj-Paluch et al. (2020) |
| | | | Pleuronectidae | *Pleuronectes platessa* | Wallace et al. (2008) |
| | | | Pleuronectidae | *Hippoglossus hippoglossus* | Biering et al. (1994), Rodger and Frerichs (1997) |
| | | | Scophthalmidae | *Scophthalmus maximus* | Novoa et al. (1993) |
| | | Salmoniformes | Salmonidae | *Coregonus lavaretus* | Castric et al. (1987), Mortensen et al. (1993), Duan et al. (2021) |
| | | | | *Oncorhynchus clarkii* | Blake et al. (2001) |
| | | | | *Oncorhynchus gorbuscha* | Hill and Way (1995) |
| | | | | *Oncorhynchus keta* | Jeon et al. (2011) |
| | | | | *Oncorhynchus kisutch* | Lopez-Lastra et al. (1994), Eissler et al. (2011) |
| | | | | *Oncorhynchus mykiss* | Blake et al. (2001), Bebak and McAllister (2009) |
| | | | | *Oncorhynchus rhodurus* | Jung et al. (1999), Zhang and Suzuki (2003) |
| | | | | *Oncorhynchus tshawytscha* | Davies et al. (2010) |
| | | | | *Salmo salar* | Blake et al. (2001), Cutrín et al. (2004), Shivappa et al. (2004) |
| | | | | *Salmo trutta* | Rexhepi et al. (2011), Ulrich et al. (2018) |
| | | | | *Salvelinus alpinus* | Blake et al. (2001) |
| | | | | *Salvelinus fontinalis* | Bootland et al. (1991); Blake et al. (2001) |

| Type | Class | Order | Family | Genus/species | References |
|---|---|---|---|---|---|
| | | | | *Salvelinus namaycush* | Maj-Paluch et al. (2020) |
| **Vector** | Branchiopoda | Diplostraca | Daphniidae | *Daphnia magna* | Mortensen et al. (1993) |
| | Copepoda | Siphonostomatoida | Caligidae | *Lepeophtheirus salmonis* | Johnson et al. (2004) |
| | Malacostraca | Decapoda | Astacidae | *Astacus astacus* | Halder and Ahne (1988) |
| | | | Penaeidae | *Penaeus japonicus* | Mortensen et al. (1993) |
| | | | Carcinidae | *Carcinus maenas* | Mortensen et al. (1993) |
| | Bivalvia | Mytilida | Mytilidae | *Mytilus edulis* | Molloy et al. (2013) |
| | IPNV has been isolated from piscivorous bird species that frequent fish farms for feeding e.g. *Ardea cinerea*, *Chroicocephalus ridibundus*, Mink may be a possible vector (Sonstegard and McDermott, 1972), as IPNV can be recovered from mink faeces 1 week after experimental infection. | | | | |
| Reservoir | Actinopterygii | Carangiformes | Carangidae | *Seriola dumerili* | Kusuda et al. (1993) |
| | | | | *Seriola quinqueradiata* | Sorimachi and Hara (1985) |
| | | | | *Seriola lalandi* | Kusuda et al. (1993) |
| | | Cypriniformes | Cyprinidae | *Abramis brama* | Adair and Ferguson (1981) |
| | | | | *Carassius auratus* | Adair and Ferguson (1981) |
| | | | | *Luciobarbus graellsii* | Ortega (1993) |
| | | Gadiformes | Gadidae | Merlangius merlangus | Possible reservoirs Wallace et al. (2008) |
| | | | | *Pollachius virens* | Possible reservoirs Wallace et al. (2008) |
| | | Perciformes | Cichlidae | *Oreochromis mossambicus* | Mulei et al. (2018) |
| | | | | *Symphysodon discus* | Adair and Ferguson (1981) |
| | | | Sparidae | *Pagrus pagrus* | Lopez-Jimena et al. (2010) |
| | | Pleuronectiformes | Pleuronectidae | *Hippoglossoides platessoides* | Possible reservoirs Wallace et al. (2008) |
| | | | | *Platichthys flesus* | Possible reservoirs Wallace et al. (2008) |
| | | | Soleidae | *Solea senegalensis* | Rodríguez et al. (1997) |
| | | | | *Solea solea* | Hill and Way (1995) |
| | | Salmoniformes | Salmonidae | *Hucho hucho* | IPNV isolation from asymptomatic Ahne (1980), Hill and Way (1995) |
| | | | | *Thymallus thymallus* | IPNV isolation from asymptomatic Ahne (1980), Hill and Way (1995) |
| | | Scorpaeniformes | Triglidae | *Eutrigla gurnardus* | Possible reservoirs Wallace et al. (2008) |
| | Bivalvia | Unionida | Unionidae | *Anodonta cygnea* | Rud et al. (2020) |

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

## 4. Conclusions

The AHAW Panel emphasises that the assessment of impacts, as well as prevention and control measures, related to IPN using the criteria as laid down in Articles 5 and 9 of the AHL is particularly challenging in.

**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*;

It is uncertain 50–90% probability (from "about as likely as not" to "likely") whether IPN 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 0–1% probability ('almost impossible') that IPN meets the criteria as in Section 1 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in point (a) of Article 9(1) of the AHL.
- The AHAW Panel was uncertain (33–66% probability, 'about as likely as not') whether IPN meets the criteria as in Section 2 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in point (b) of Article 9(1) of the AHL.
- The AHAW Panel was uncertain (33–66% probability, 'about as likely as not') whether IPN meets the criteria as in Section 3 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in point (c) of Article 9(1) of the AHL.
- The AHAW Panel was uncertain (50–90% probability; from 'about as likely as not' to 'likely') whether IPN meets the criteria as in Section 4 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in point (d) of Article 9(1) of the AHL.
- The AHAW Panel was uncertain (50–90% probability; from 'about as likely as not' to 'likely') whether IPN meets the criteria as in Section 5 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in point (e) of Article 9(1) of the AHL.

**TOR 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 IPN according to Article 8(3) of the AHL are reported in Table 16 in Section 3.4 of the present document.

The AHAW Panel highlights that even though the assessment on IPN is inconclusive regarding its eligibility to be listed for Union intervention, specific activities and initiatives should be considered based on the epidemiological situation such as:

i) surveillance activities to provide information on the geographical distribution of the IPNV
ii) research to enlighten areas where there is knowledge gaps or limitations and help to better understand the impact of IPNV on animal health and welfare in EU.

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## Abbreviations

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|---|---|
| AHAW | Animal Health and Welfare |
| AHL | Animal Health Law |
| CI | current impact |
| IPN | infectious pancreatic necrosis |
| IPNV | infectious pancreatic necrosis virus |
| MS | Member State |
| MSs | Member States |
| OIE | Office International des Épizooties (World Organisation For Animal Health) |
| PCR | polymerase chain reaction |
| PI | potential impact |
| QTL | quantitative trait loci |
| Se | sensitivity |
| Sp | specificity |
| ToR | terms of reference |
| WOAH | World Organisation for Animal Health |

# Appendix A – Expert judgement plotted by question

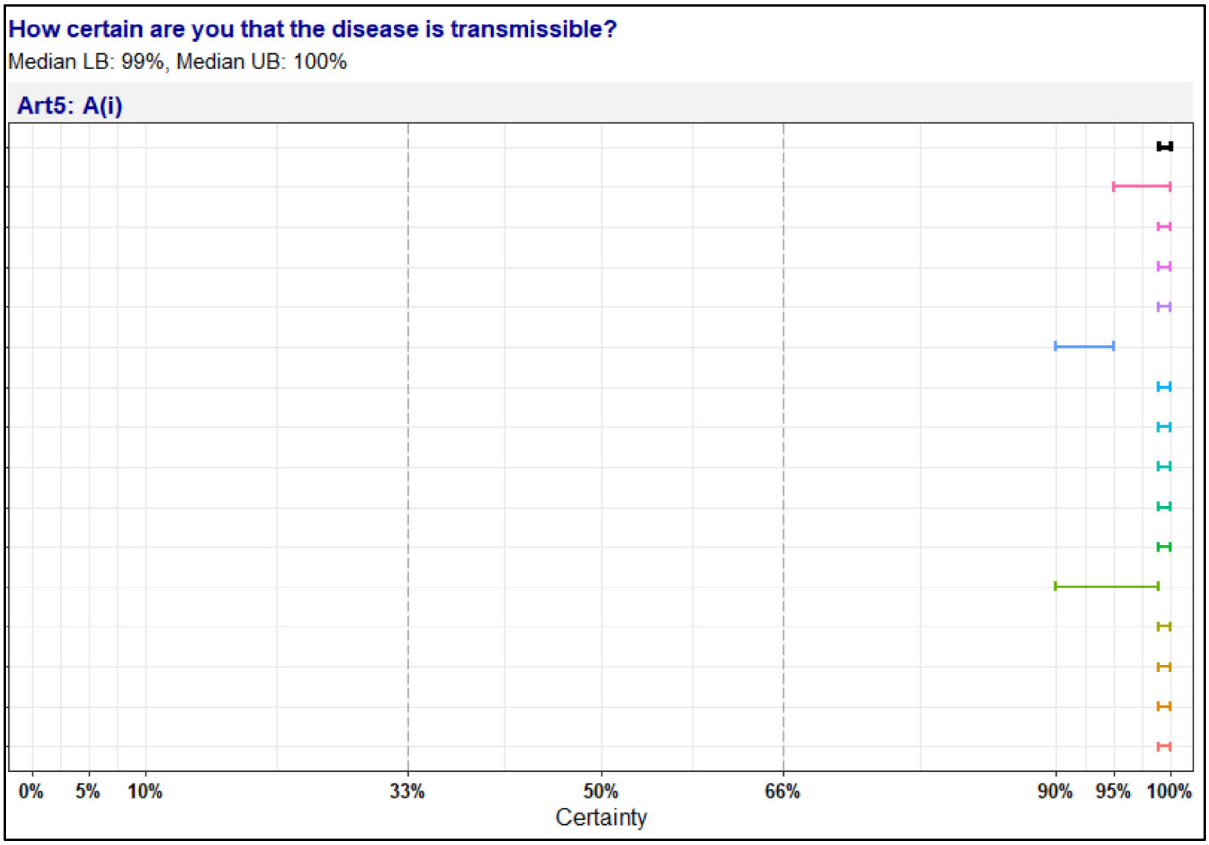


**Figure A.1:** Individual probability ranges, after the collective judgement, reflecting fulfilment of criterion A(i) (the disease is transmissible). Black dotted line on the top indicates the median

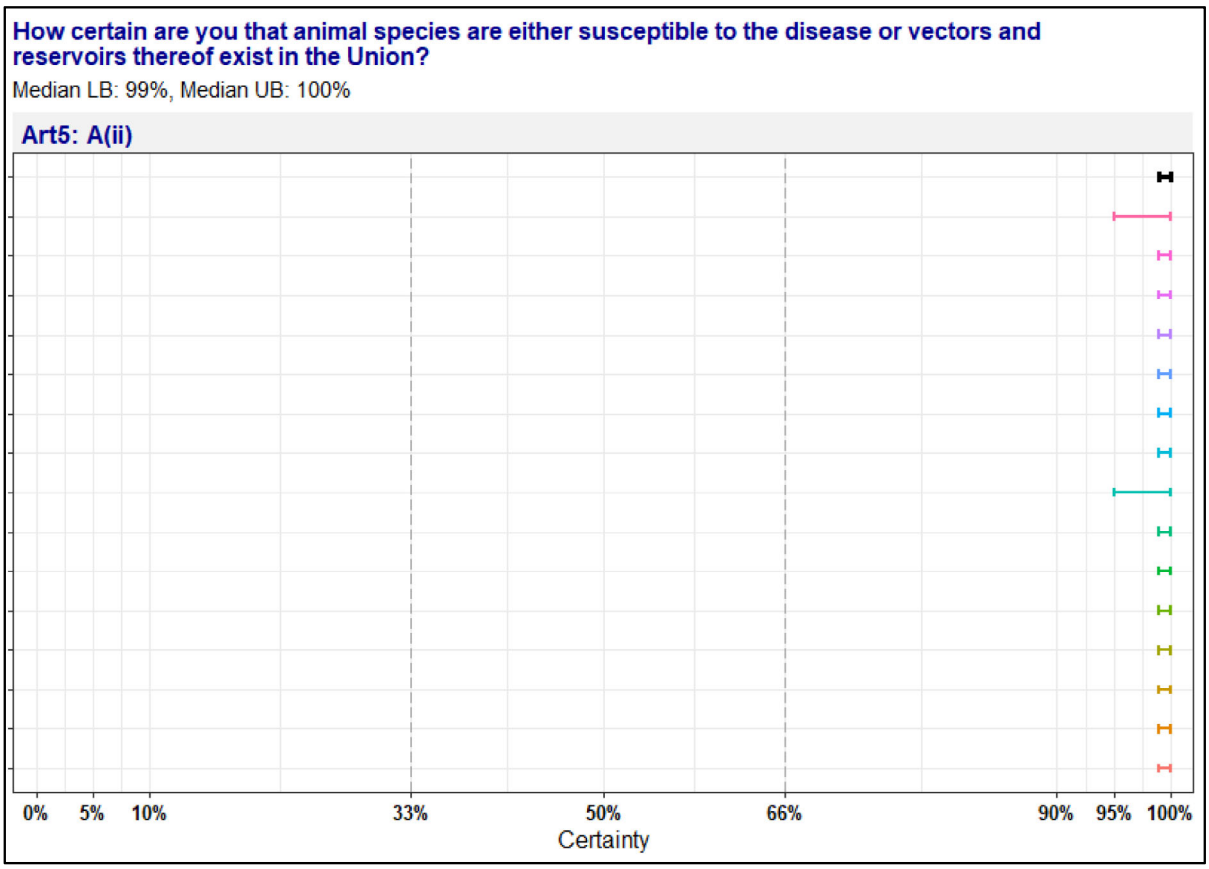


**Figure A.2:** Individual probability ranges, after the collective judgement, reflecting fulfilment of criterion A (ii) (animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union). Black dotted line on the top indicates the median

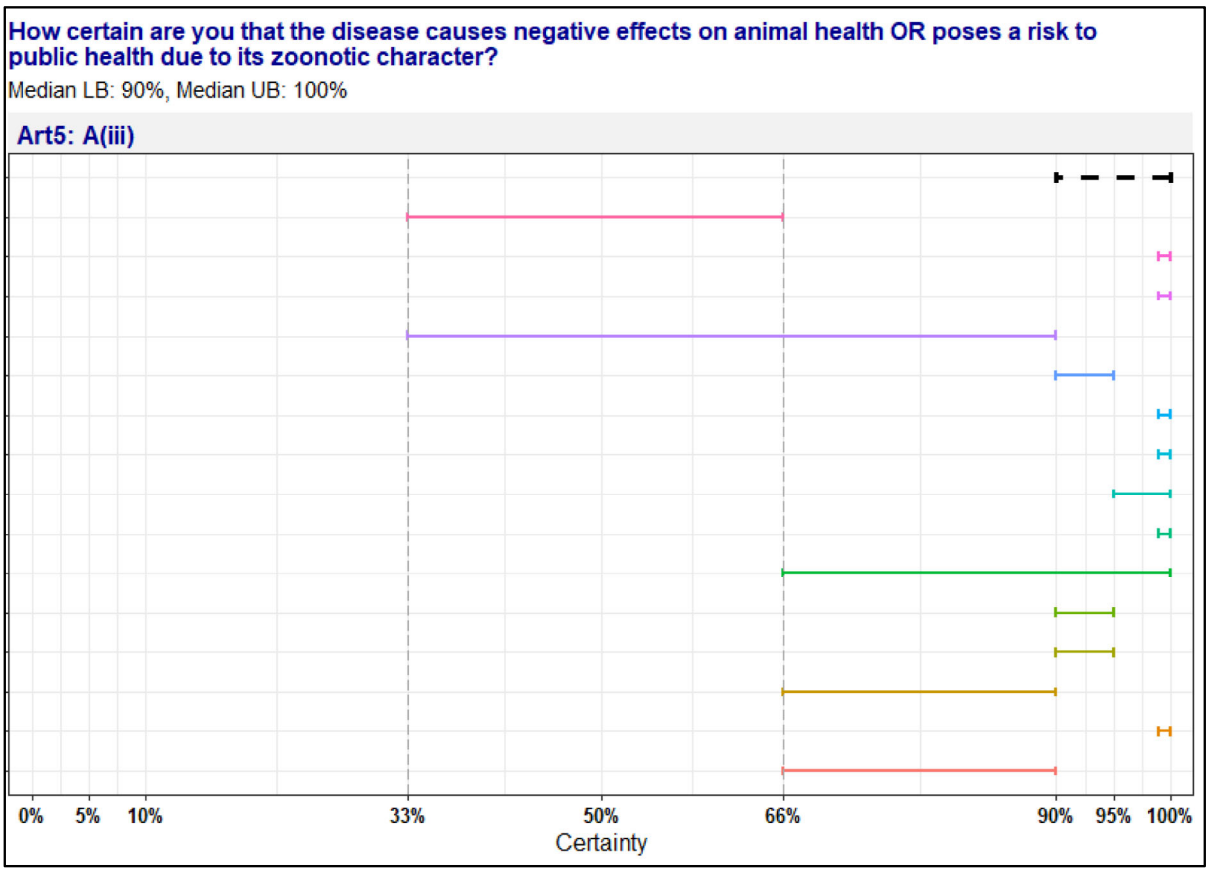


**Figure A.3:** Individual probability ranges, after the collective judgement, reflecting fulfilment of criterion A(iii) (the disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character). Black dotted line on the top indicates the median

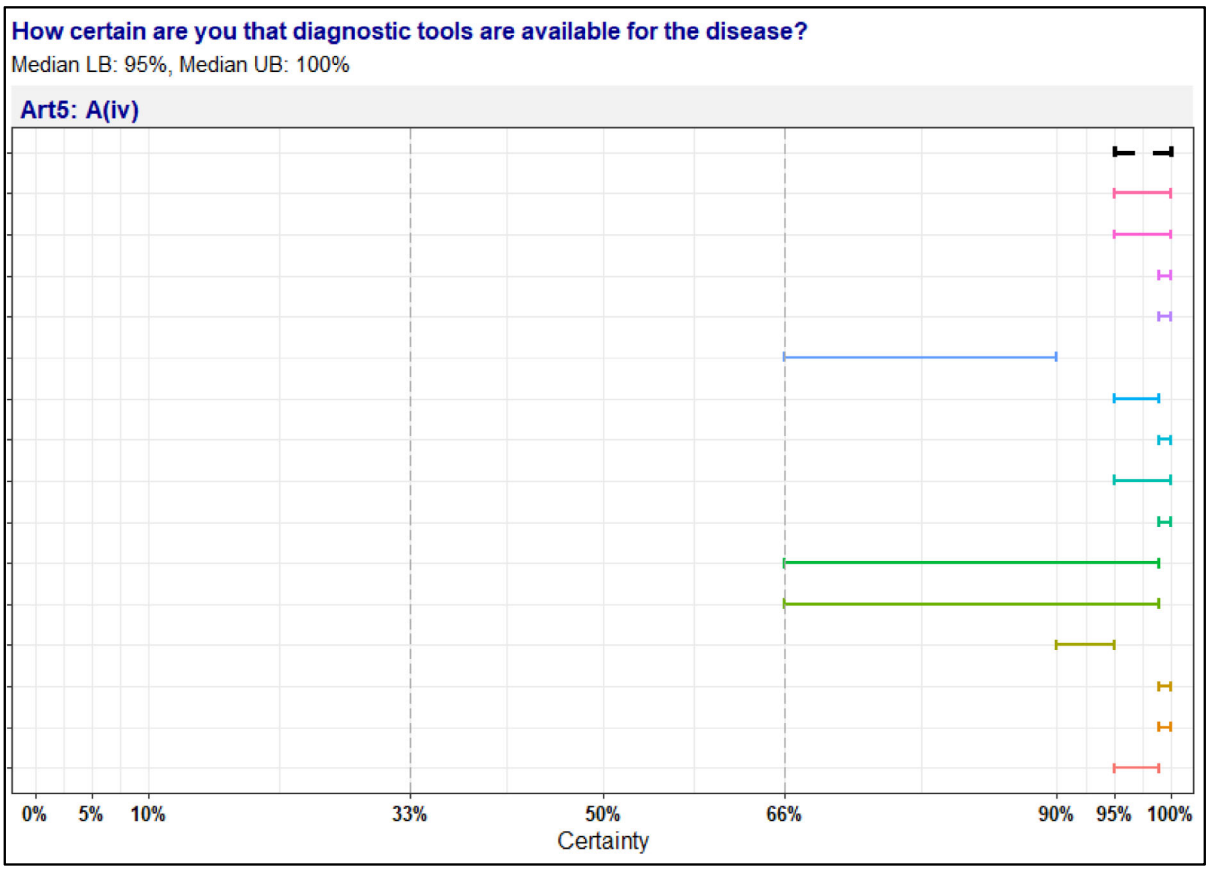


**Figure A.4:** Individual probability ranges, after the collective judgement, reflecting fulfilment of criterion A(iv) (diagnostic tools are available for the disease). Black dotted line on the top indicates the median

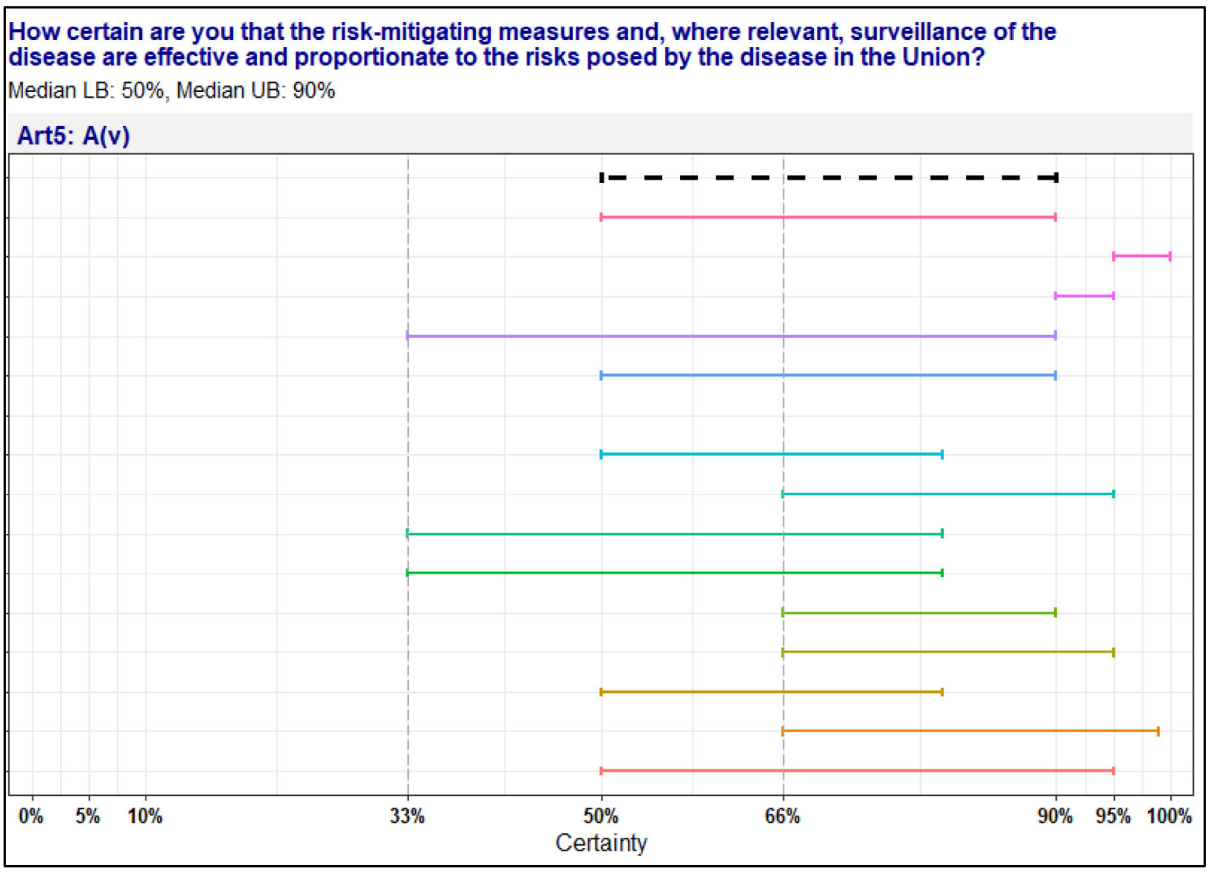


**Figure A.5:** Individual probability ranges, after the collective judgement, reflecting uncertain outcome on criterion A(v) (risk-mitigating measures and, where relevant, surveillance of the disease are effective and proportionate to the risks posed by the disease in the Union). Black dotted line on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

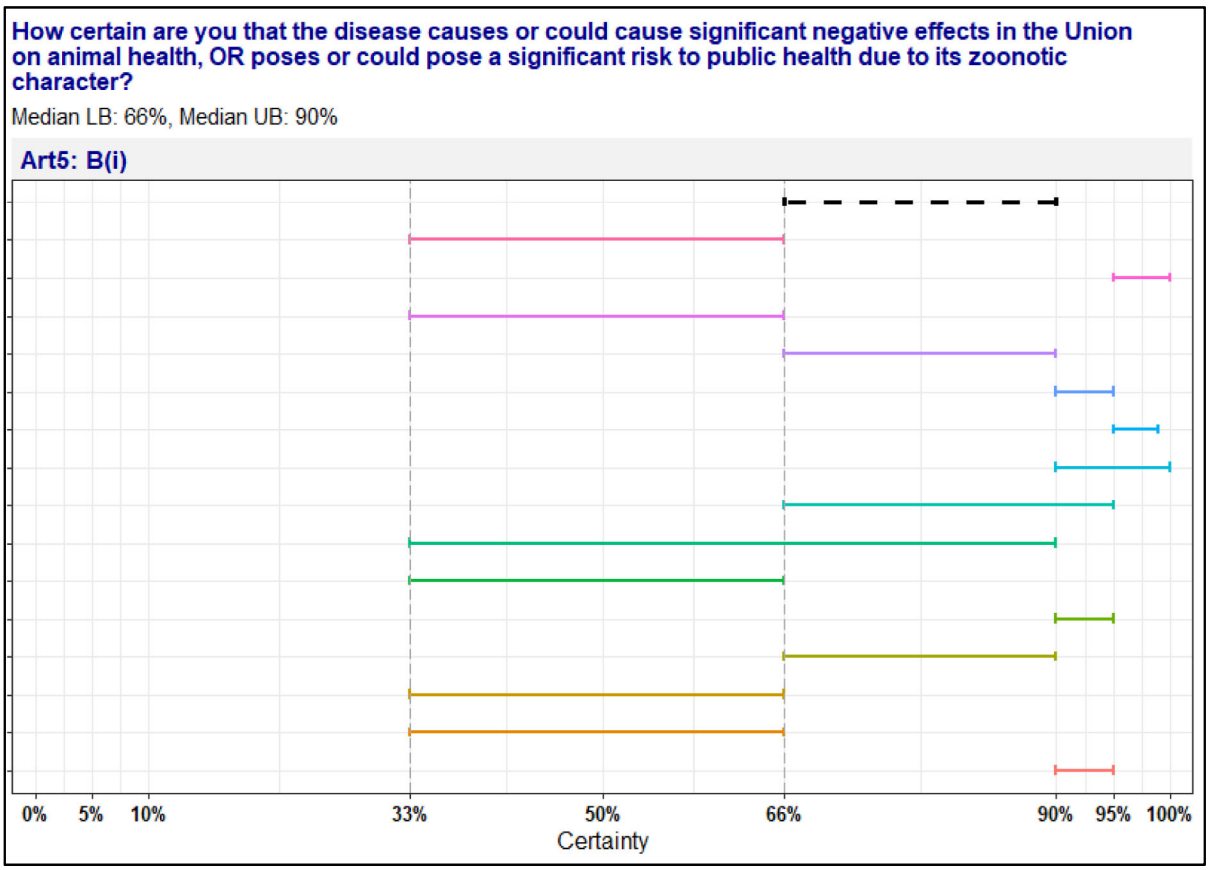


**Figure A.6:** Individual probability ranges, after the collective judgement, reflecting fulfilment of criterion B(i) (the disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic character).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

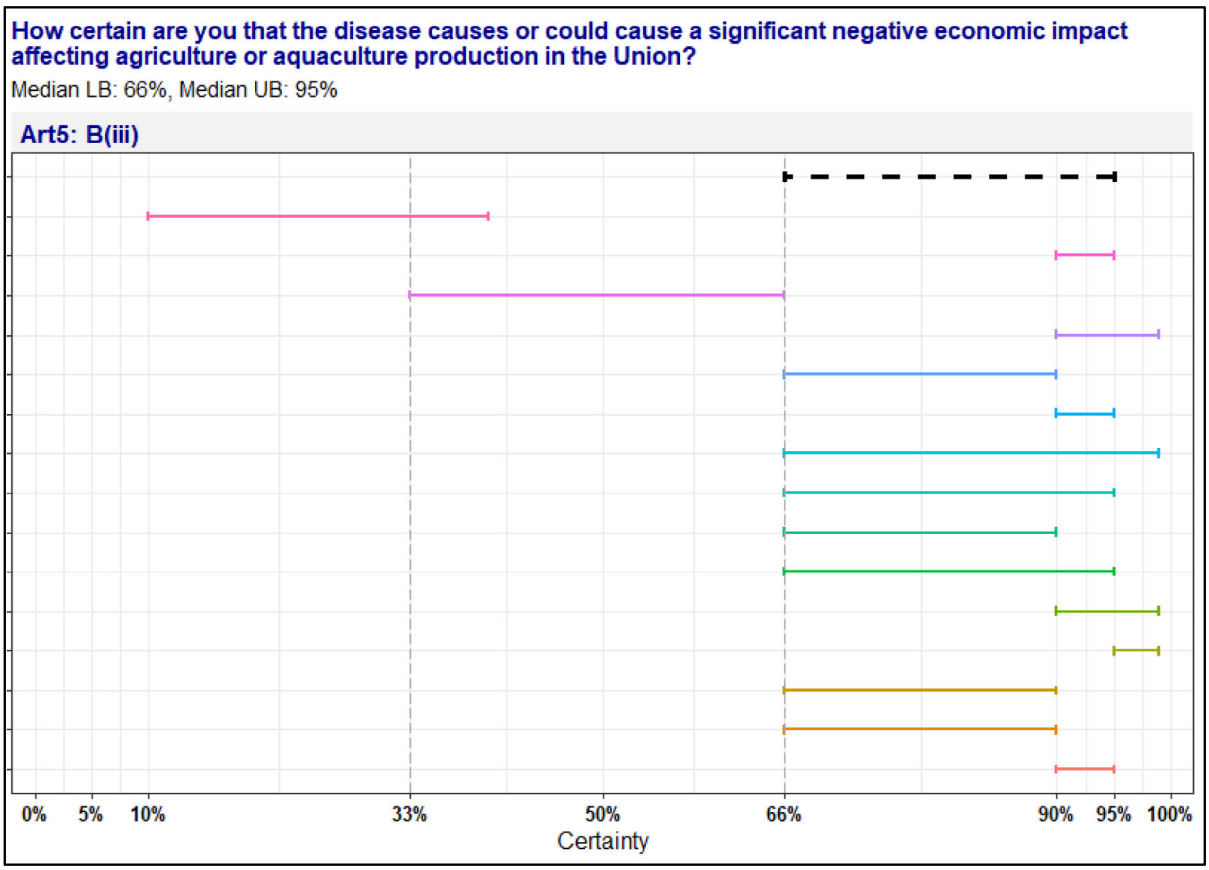


**Figure A.7:** Individual probability ranges, after the collective judgement, reflecting fulfilment of criterion B(iii) (the disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union). Black dotted line on the top indicates the median

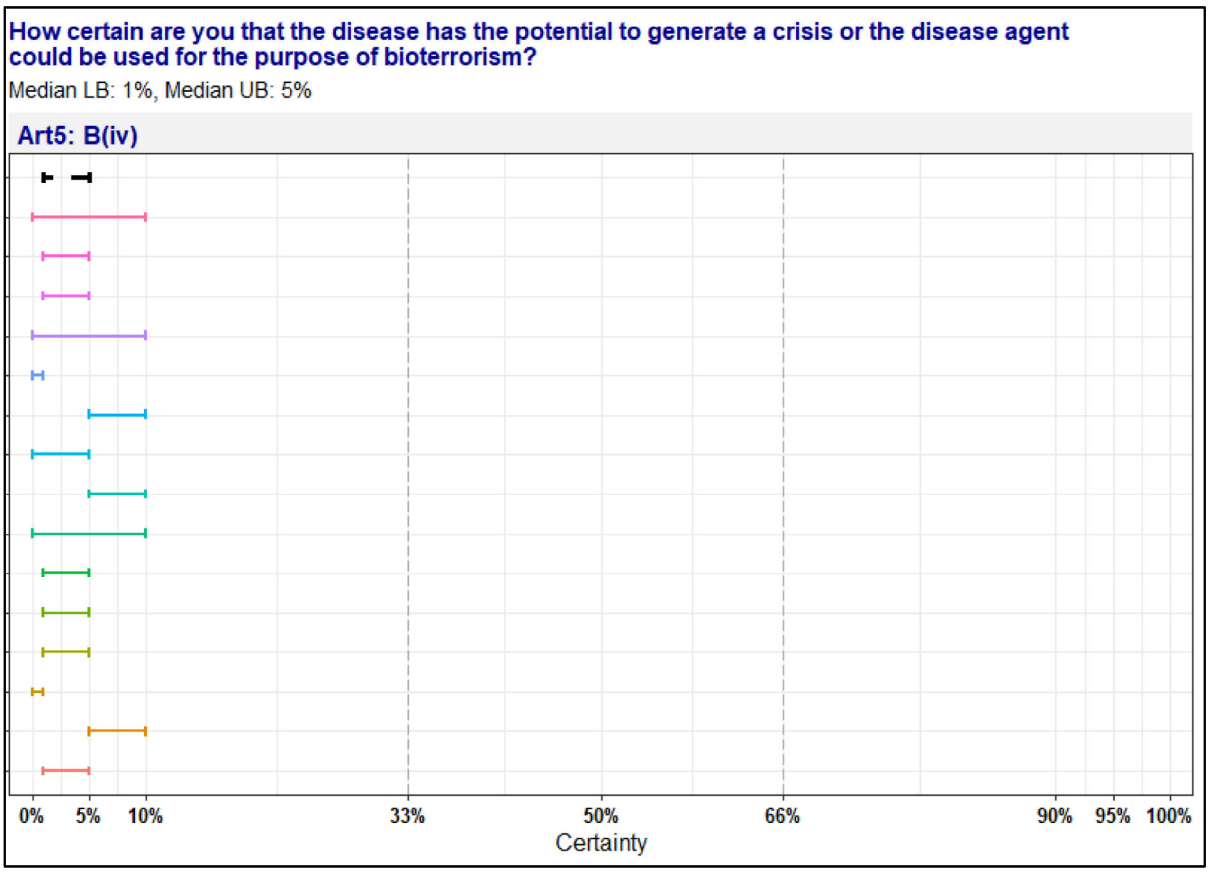


**Figure A.8:** Individual probability ranges, after the collective judgement, reflecting non-fulfilment of criterion B(iv) (the disease has the potential to generate a crisis, or the disease agent could be used for the purpose of bioterrorism). Black dotted line on the top indicates the median

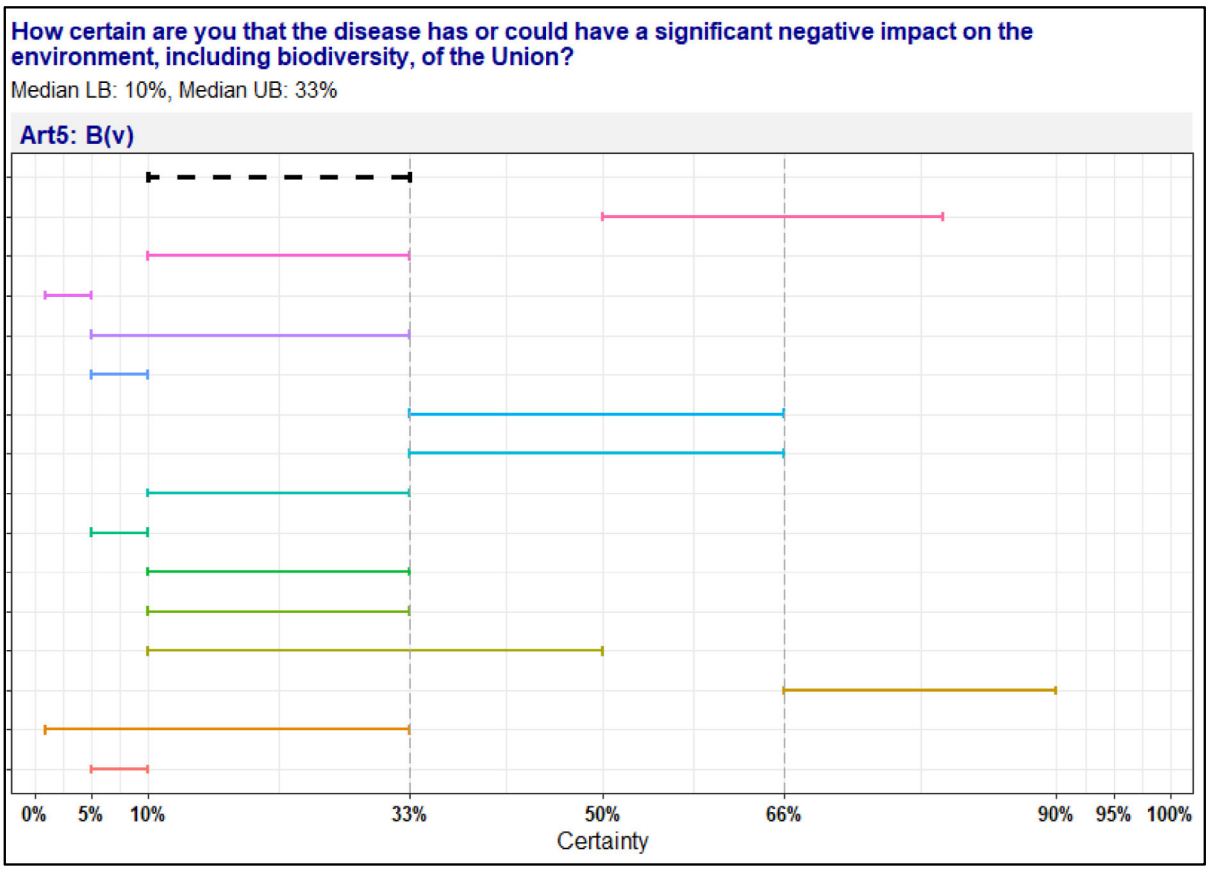


**Figure A.9:** Individual probability ranges, after the collective judgement, reflecting non-fulfilment of criterion B(v) (the disease has or could have a significant negative impact on the environment, including biodiversity, of the Union). Black dotted line on the top indicates the median

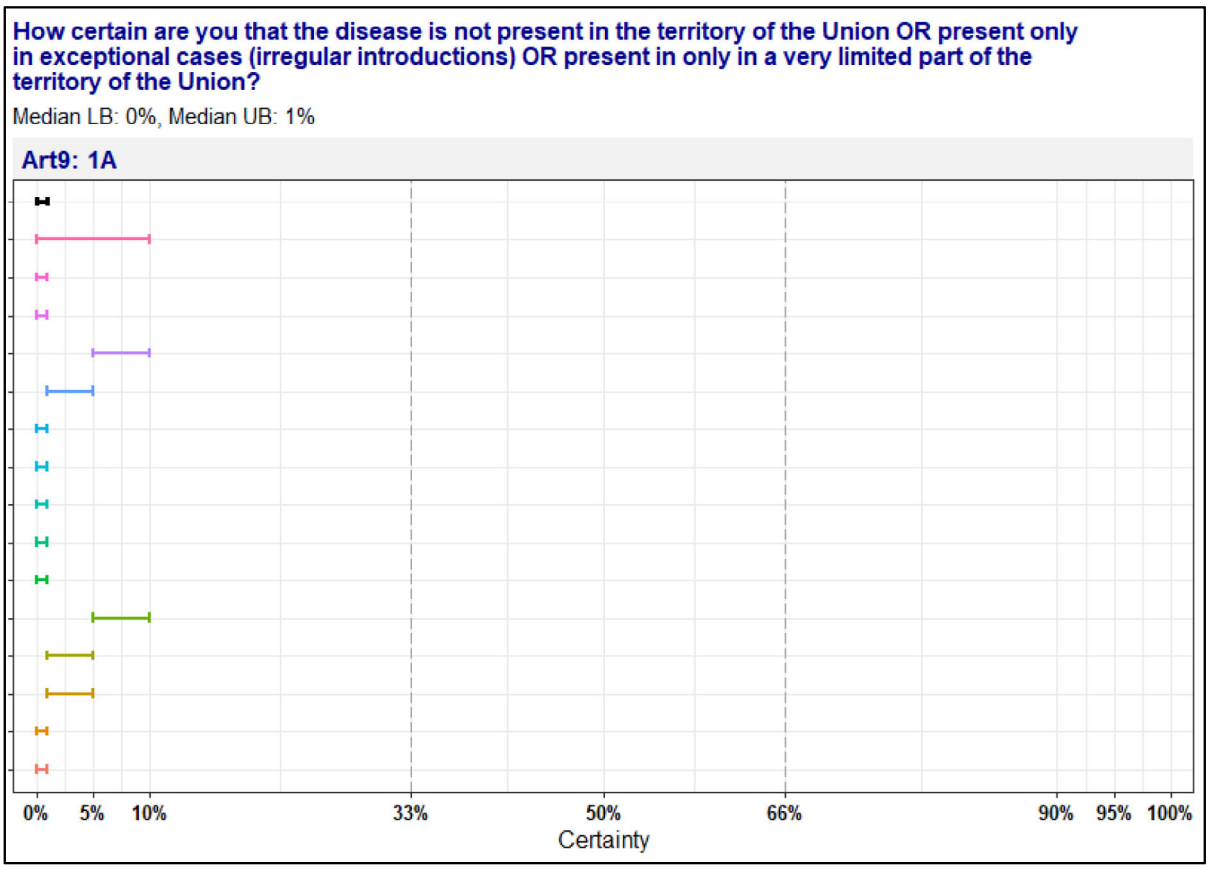


**Figure A.10:** Individual probability ranges, after the collective judgement, reflecting non-fulfilment of criterion 1A (the disease is not present in the territory of the Union or present only in exceptional cases (irregular introductions) or present only in a very limited part of the territory of the Union). Black dotted line on the top indicates the median

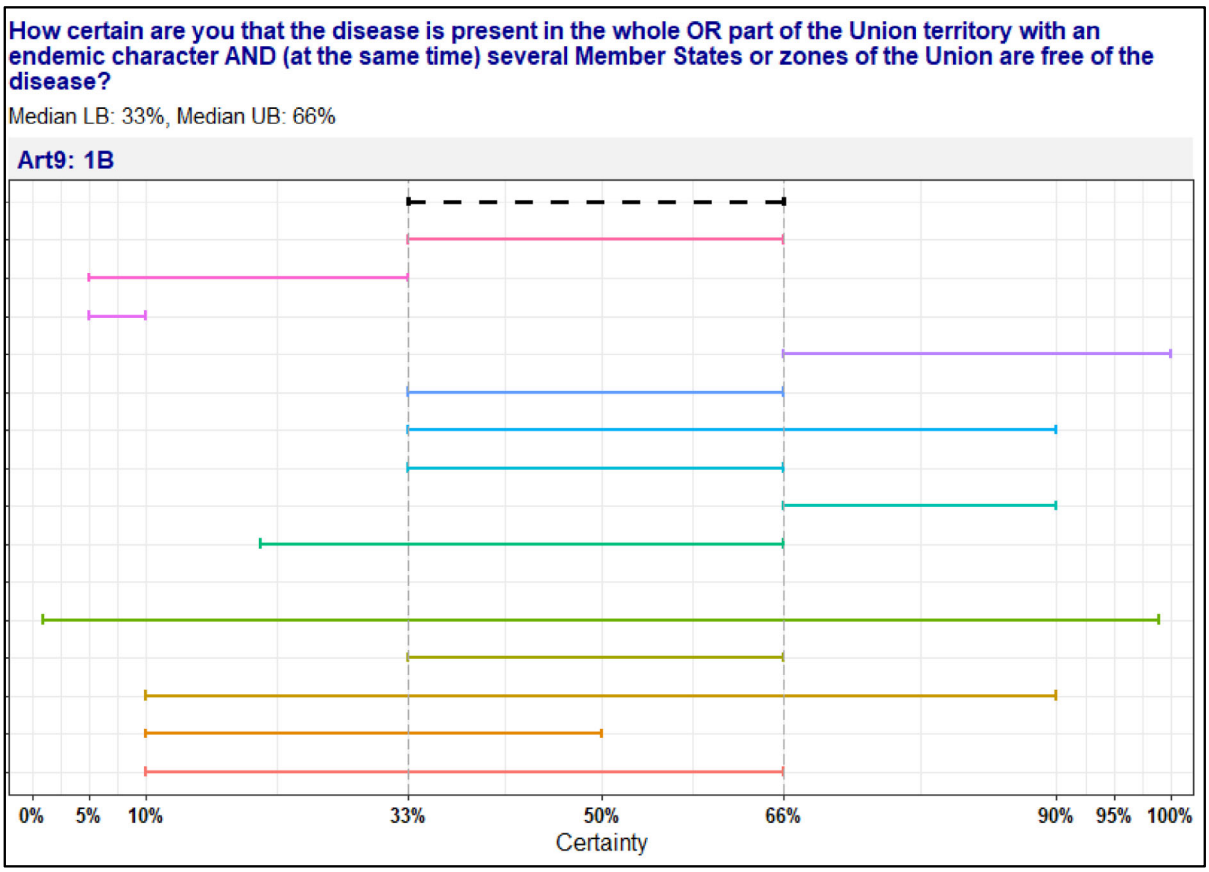


**Figure A.11:** Individual probability ranges, after the collective judgement, reflecting the uncertainty on criterion 1B (the disease is present in the whole or part of the Union territory with an endemic character and (at the same time) several Member States or zones of the Union are free of the disease). Black dotted line on the top indicates the median)

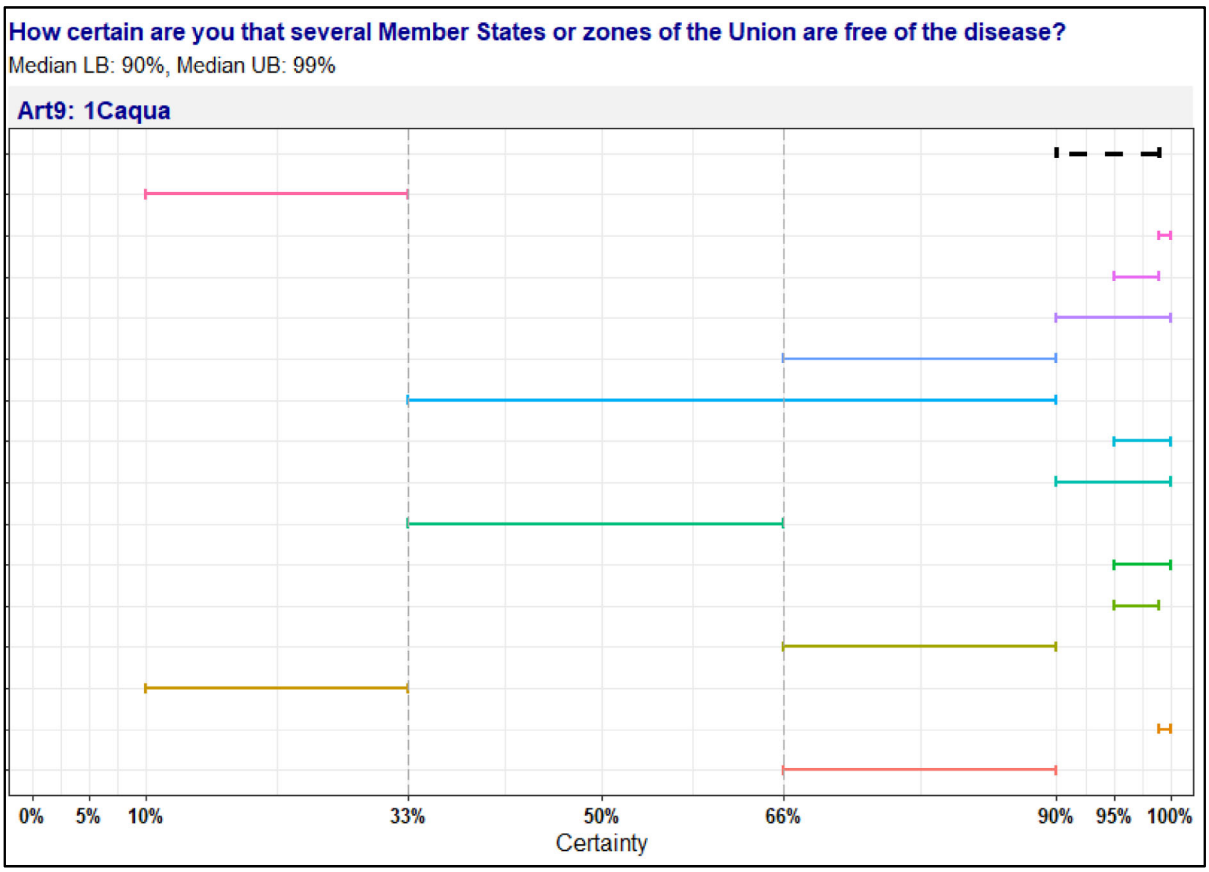


**Figure A.12:** Individual probability ranges, after the collective judgement, reflecting fulfilment of criterion 1Caqua (the disease is present in the whole or part of the Union territory with an endemic character). Black dotted line on the top indicates the median

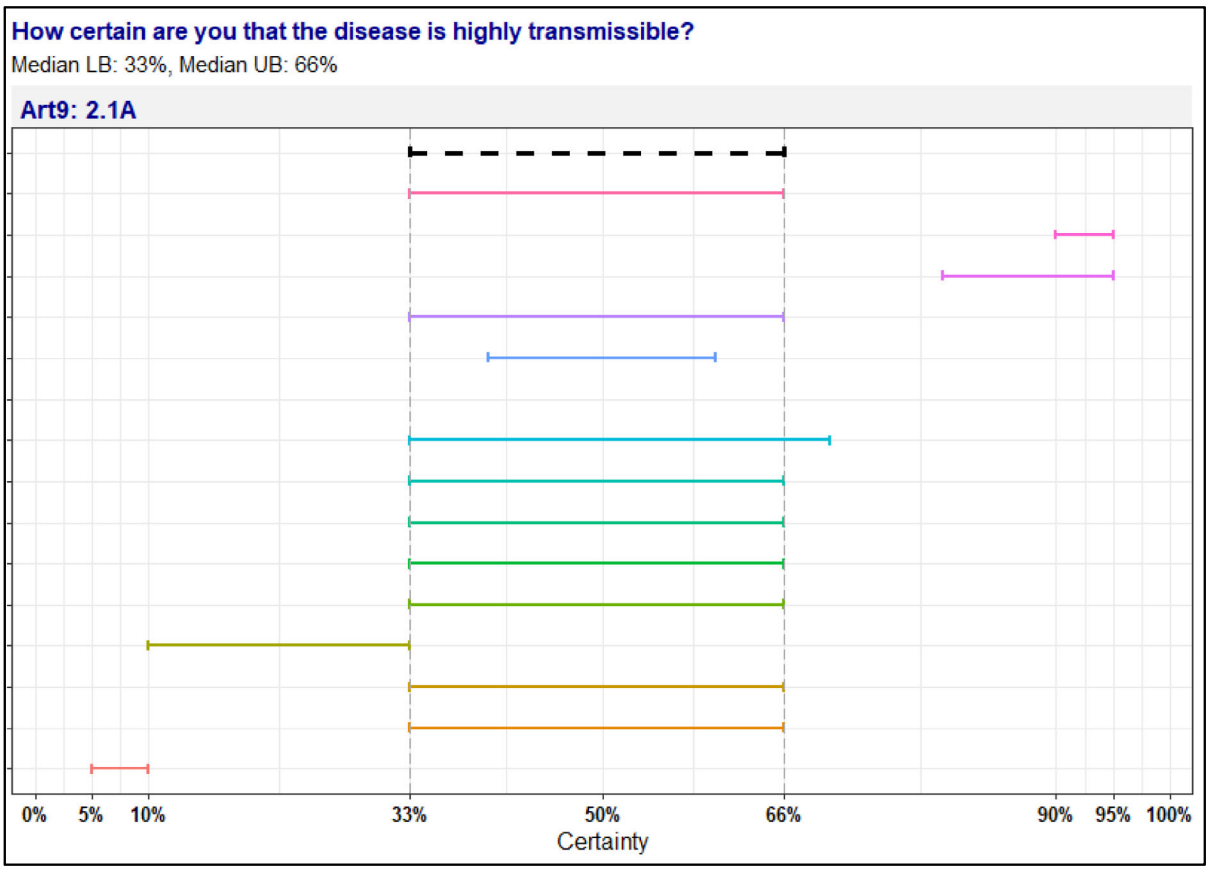


**Figure A.13:** Individual probability ranges, after the collective judgement, reflecting the uncertainty on criterion 2.1A (the disease is highly transmissible). Black dotted line on the top indicates the median

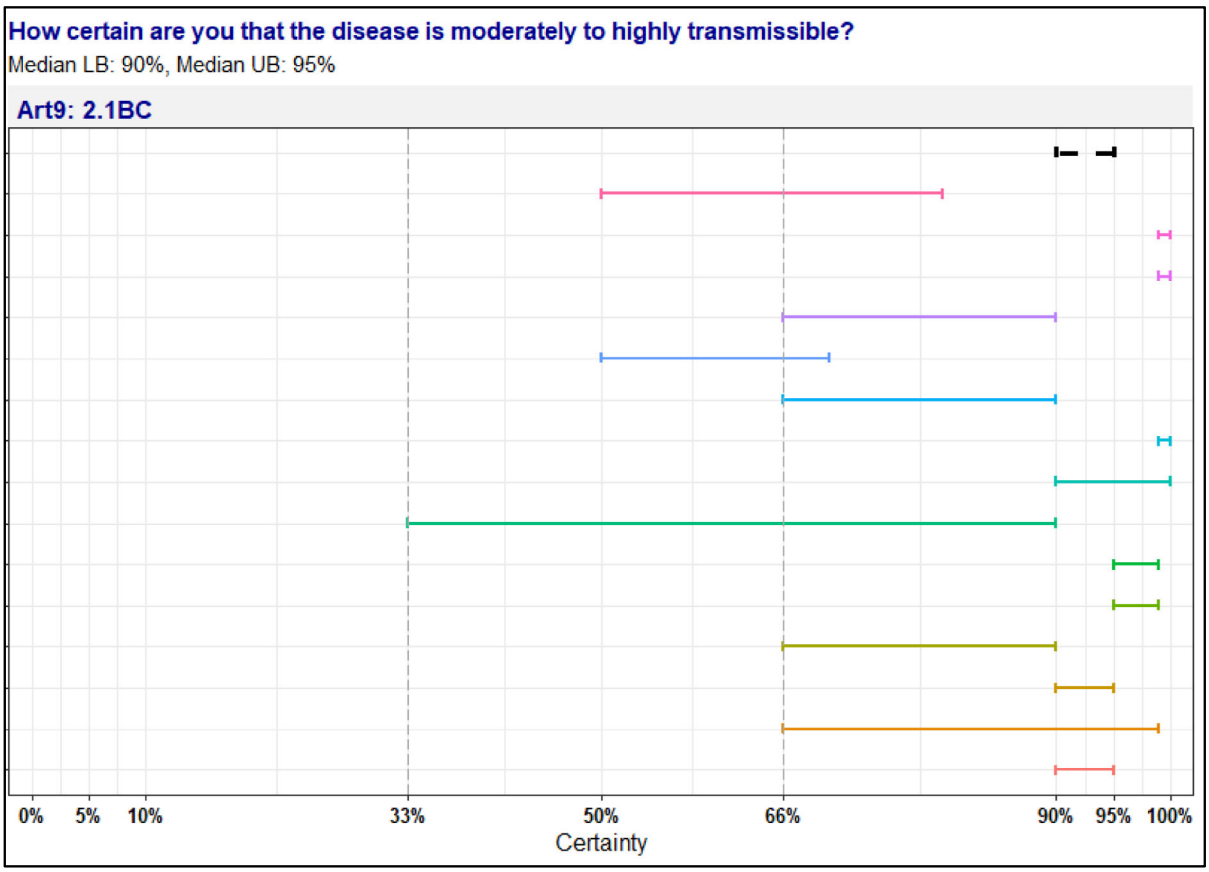


**Figure A.14:** Individual probability ranges, after the collective judgement, reflecting the fulfilment of criterion 2.1BC (the disease is moderately to highly transmissible). Black dotted line on the top indicates the median

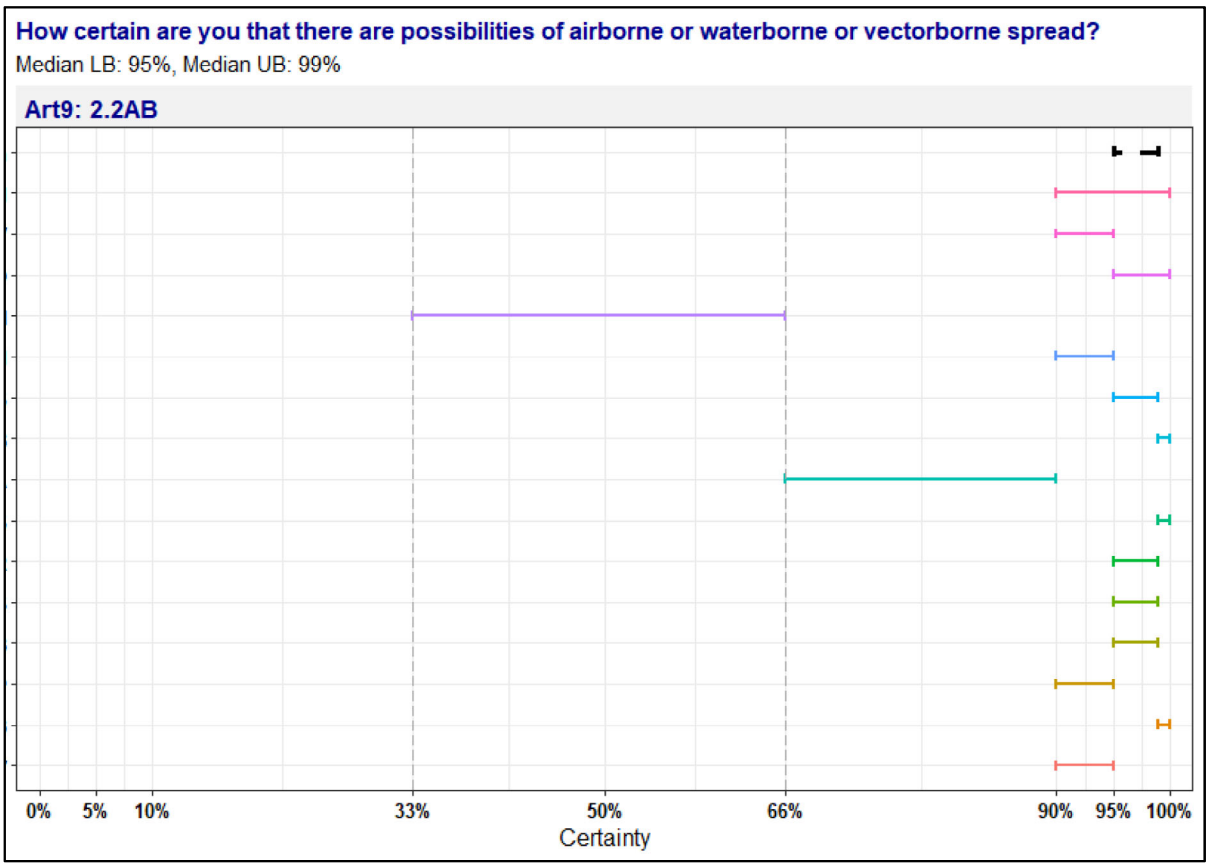


**Figure A.15:** Individual probability ranges, after the collective judgement, reflecting the fulfilment of criterion 2.2AB (there are possibilities of airborne or waterborne or vector-borne spread). Black dotted line on the top indicates the median

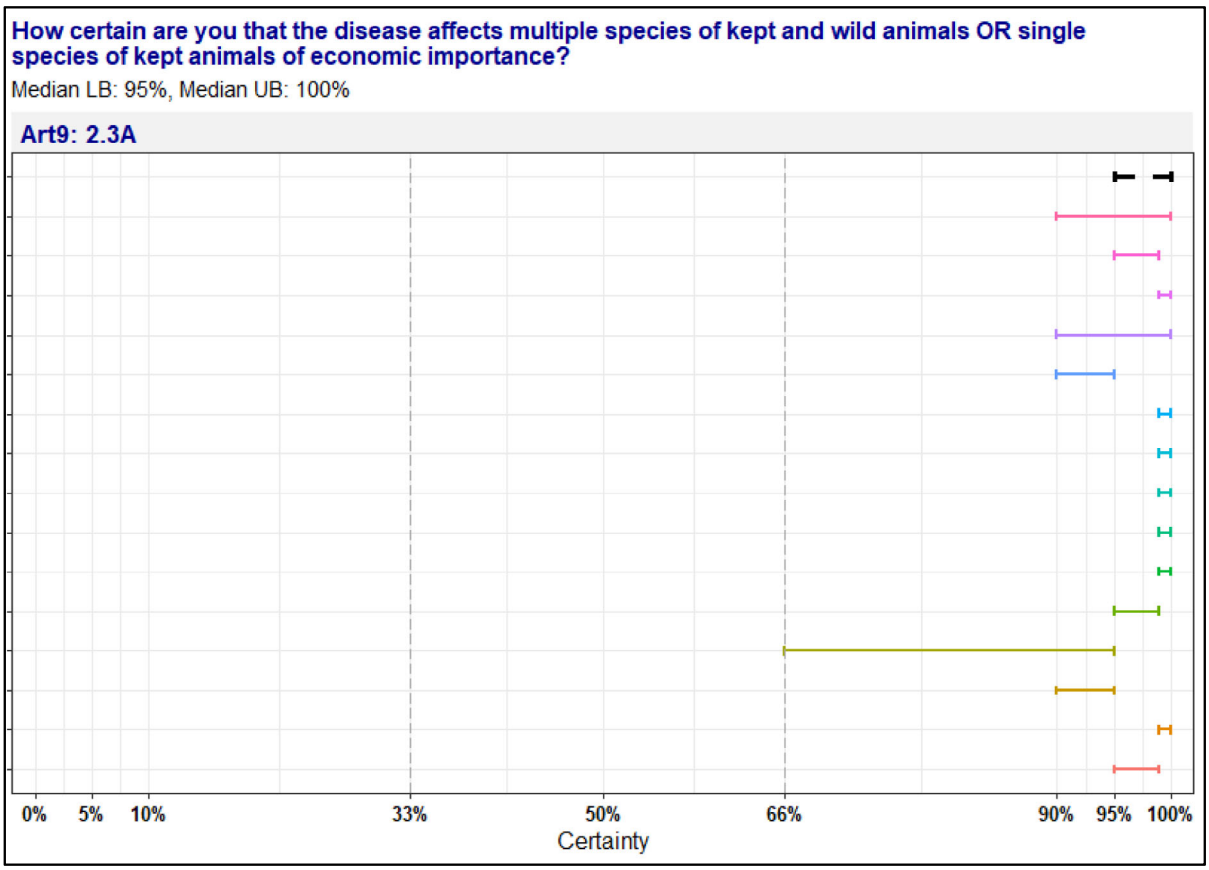


**Figure A.16:** Individual probability ranges, after the collective judgement, reflecting fulfilment of criterion 2.3A (the disease affects multiple species of kept and wild animals or single species of kept animals of economic importance). Black dotted line on the top indicates the median

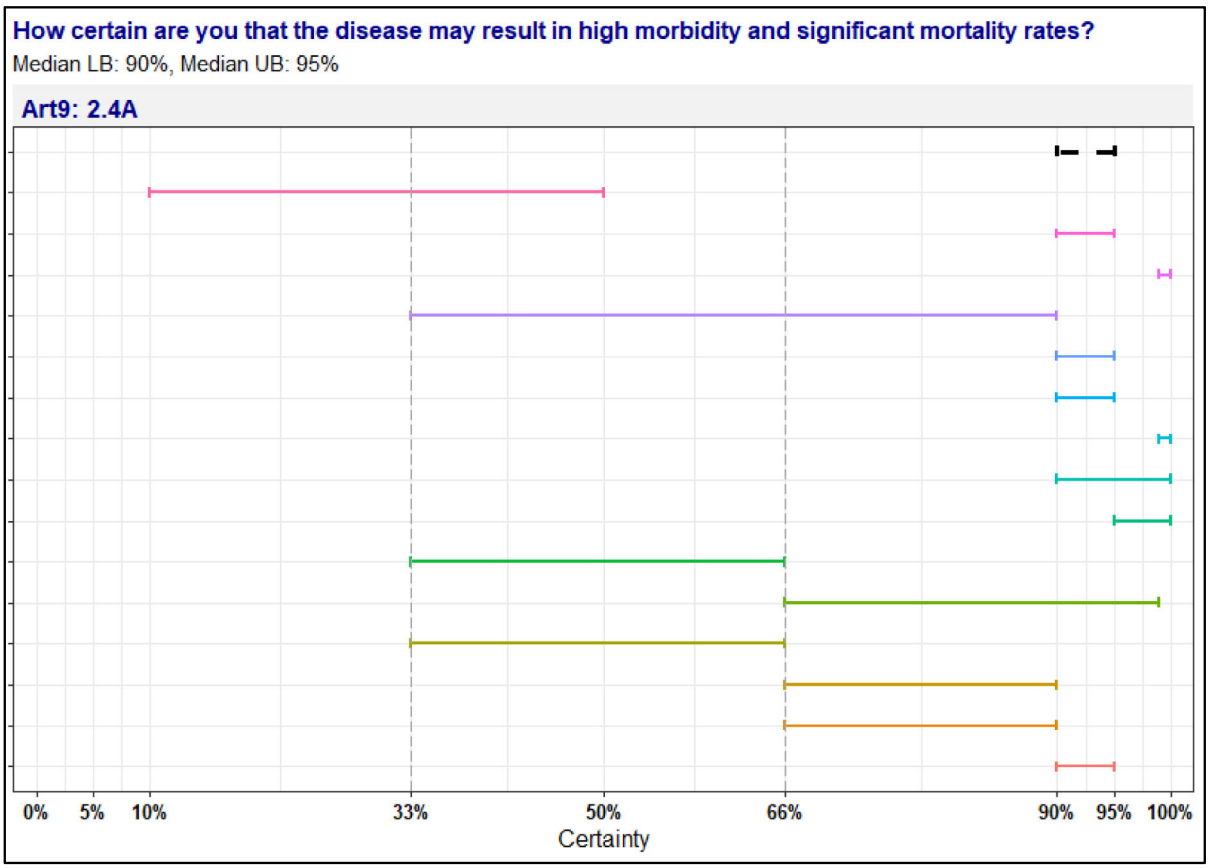


**Figure A.17:** Individual probability ranges, after the collective judgement, reflecting fulfilment of criterion 2.4A (the disease may result in high morbidity and significant mortality rates). Black dotted line on the top indicates the median

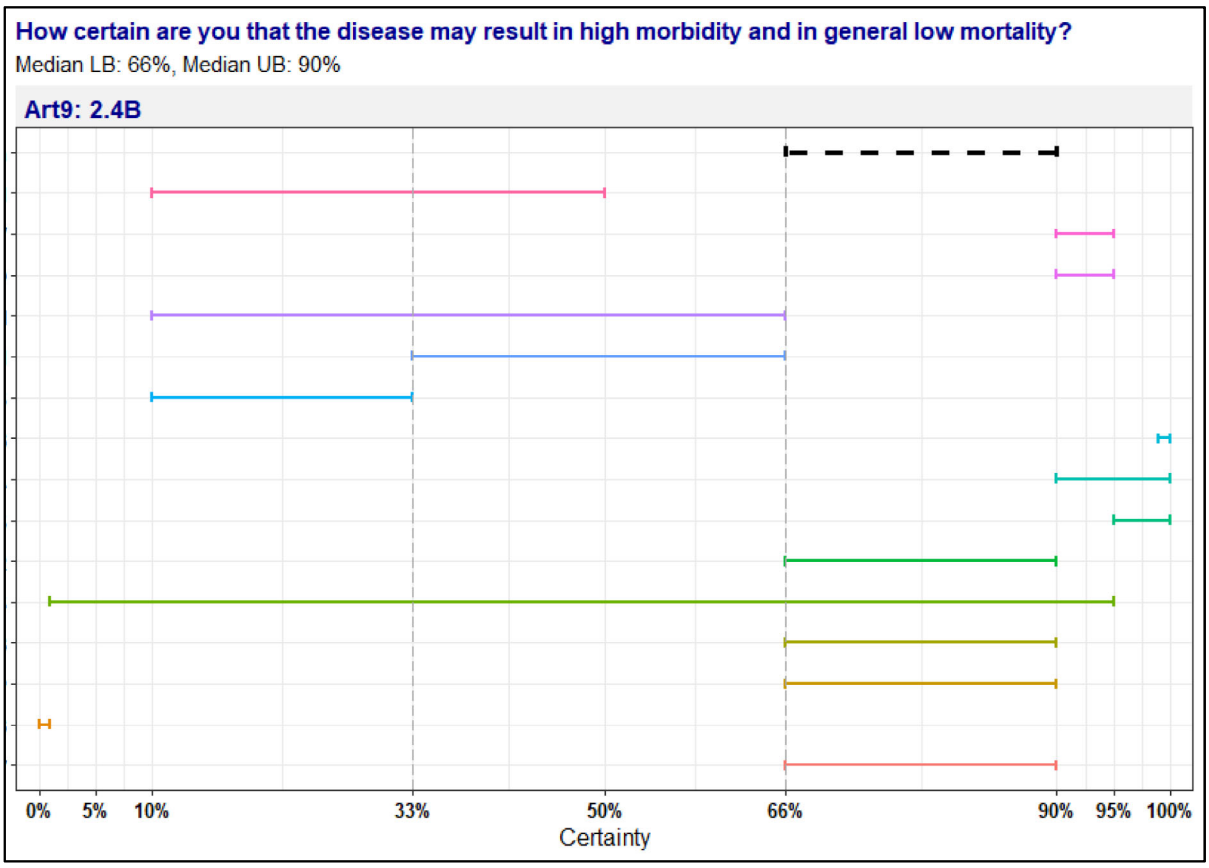


**Figure A.18:** Individual probability ranges, after the collective judgement, reflecting fulfilment of criterion 2.4B (the disease may result in high morbidity with in general low mortality). Black dotted line on the top indicates the median

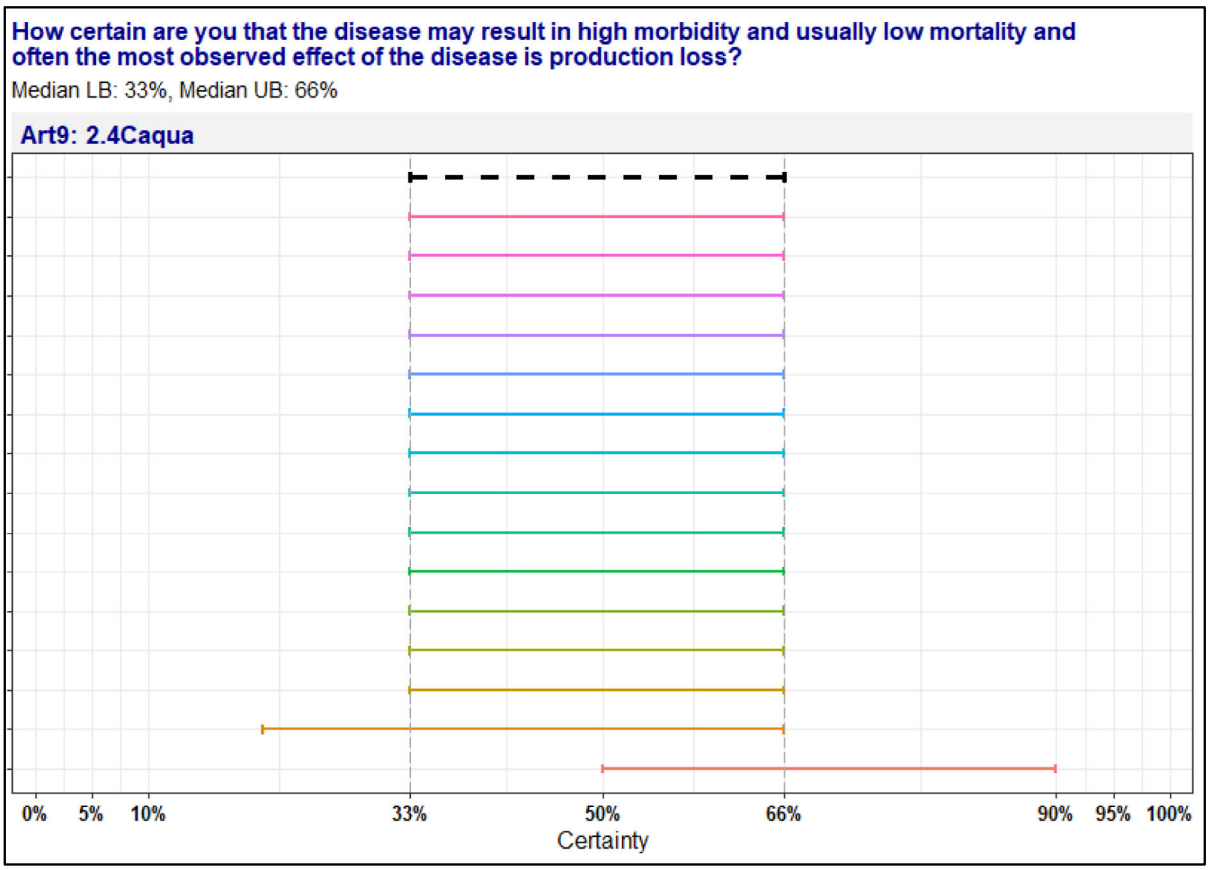


**Figure A.19:** Individual probability ranges, after the collective judgement, reflecting fulfilment of criterion 2.4Caqua (the disease usually does not result in high morbidity and has negligible or no mortality and often the most observed effect of the disease is production loss). Black dotted line on the top indicates the median

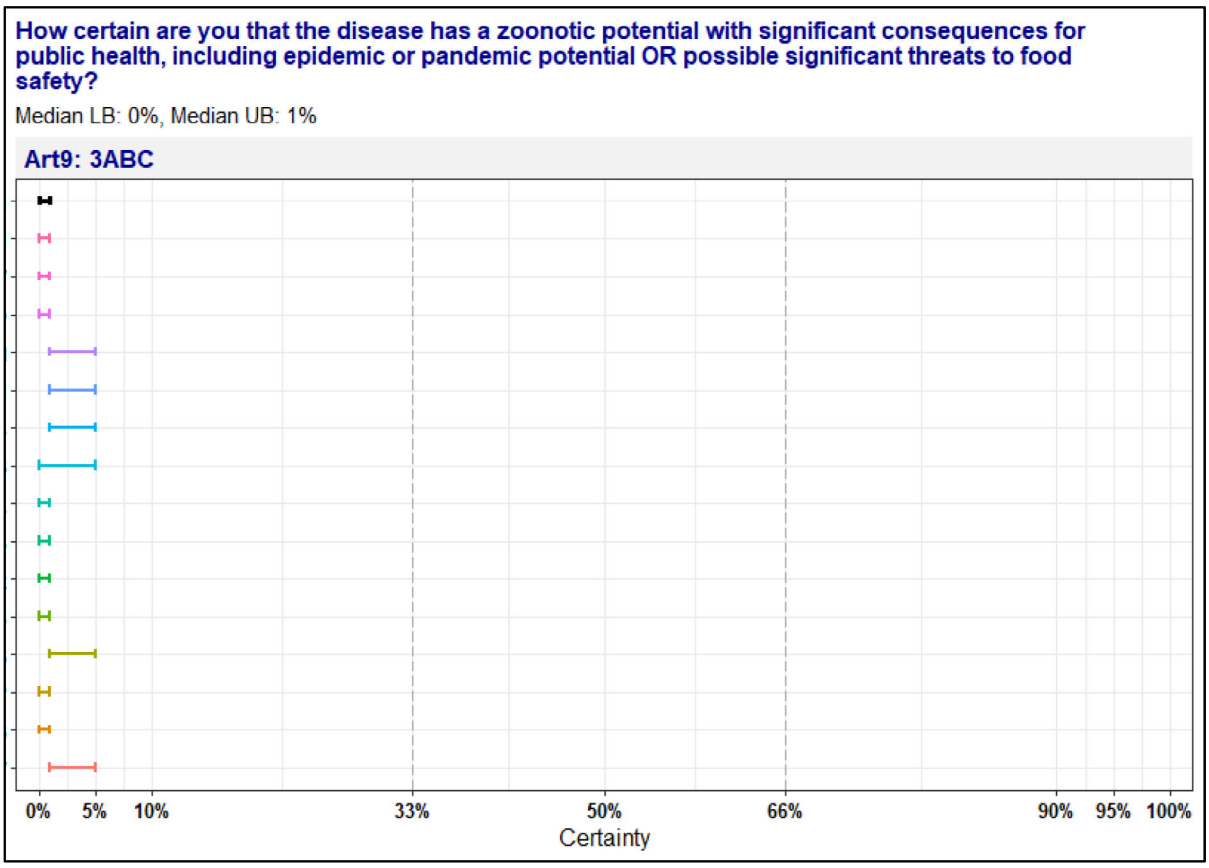


**Figure A.20:** Individual probability ranges, after the collective judgement, reflecting non-fulfilment of criterion 3ABC (the disease has a zoonotic potential with significant consequences for public health or possible significant threats to food safety). Black dotted line on the top indicates the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

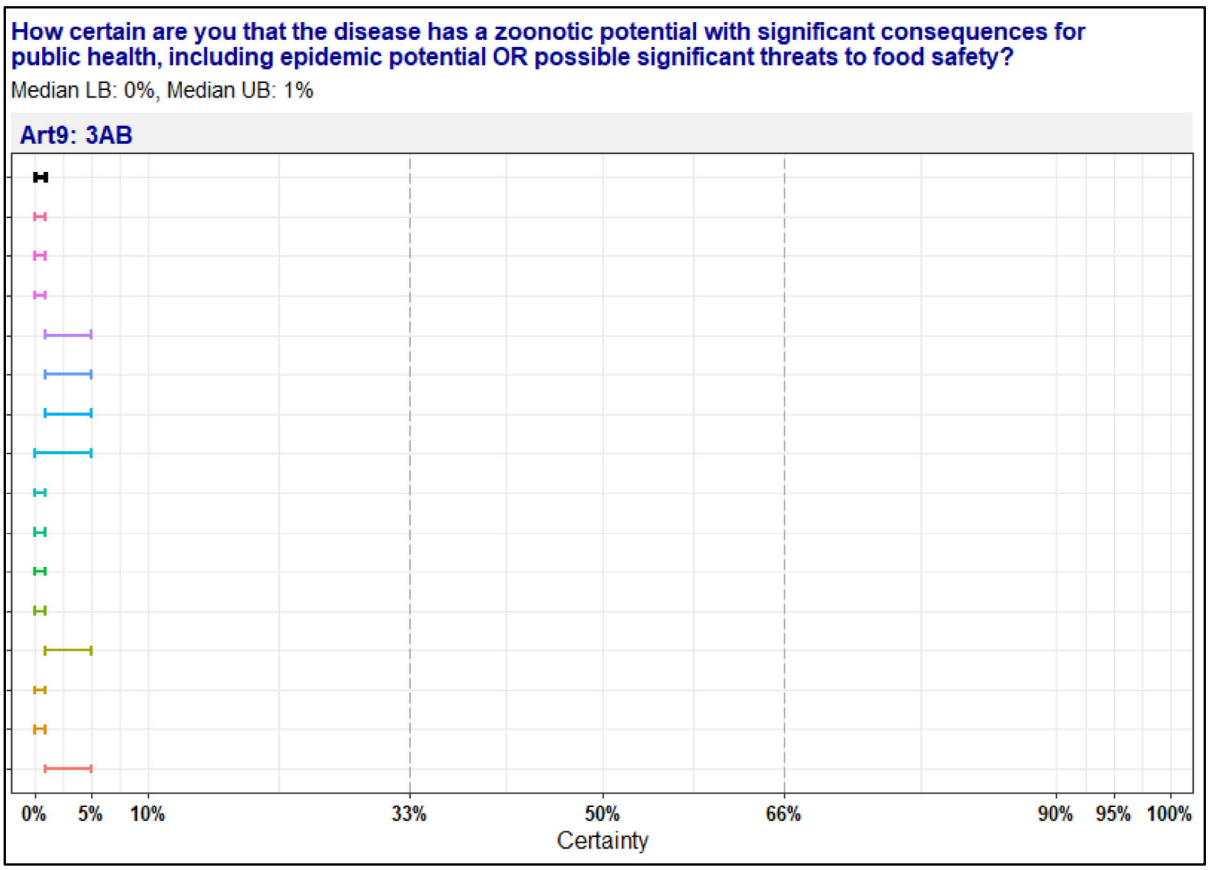


**Figure A.21:** Individual probability ranges, after the collective judgement, reflecting non-fulfilment of criterion 3AB (the disease has a zoonotic potential with significant consequences for public health, including epidemic potential or possible significant threats to food safety). Black dotted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

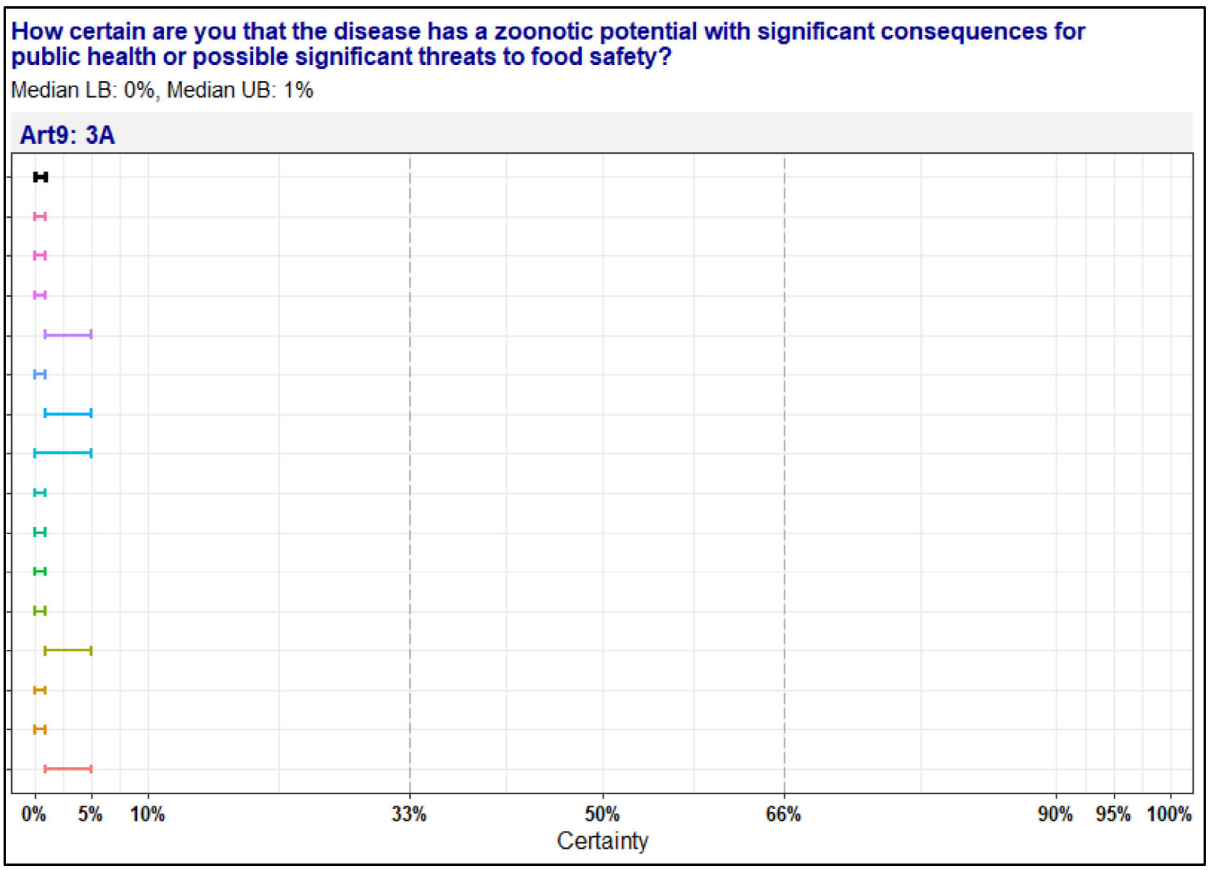


**Figure A.22:** Individual probability ranges, after the collective judgement, reflecting non-fulfilment of criterion 3A (the disease has a zoonotic potential with significant consequences for public health, including epidemic or pandemic potential or possible significant threats to food safety). Black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

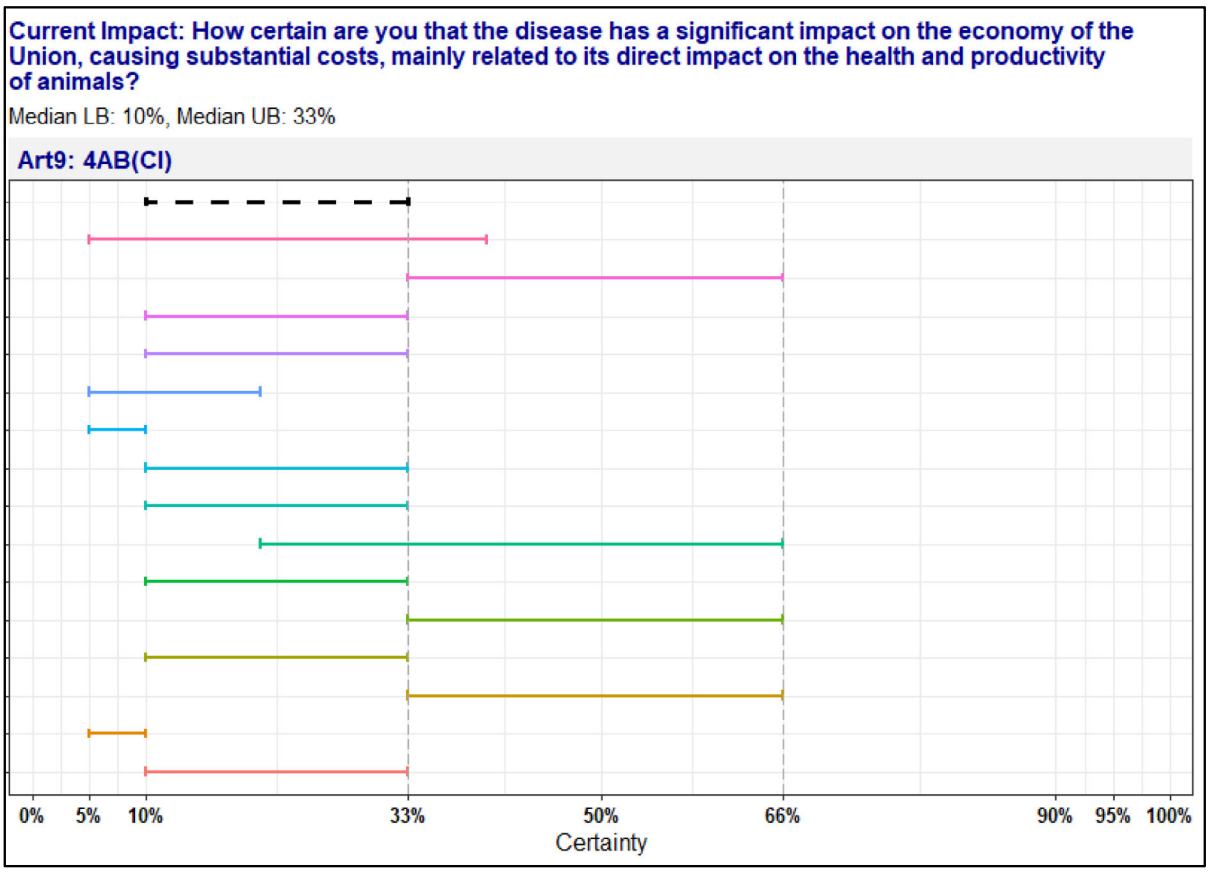


**Figure A.23:** Individual probability ranges, after the collective judgement, reflecting non-fulfilment of criterion 4AB (current impact) (the disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals). Black dotted line on the top indicates the median

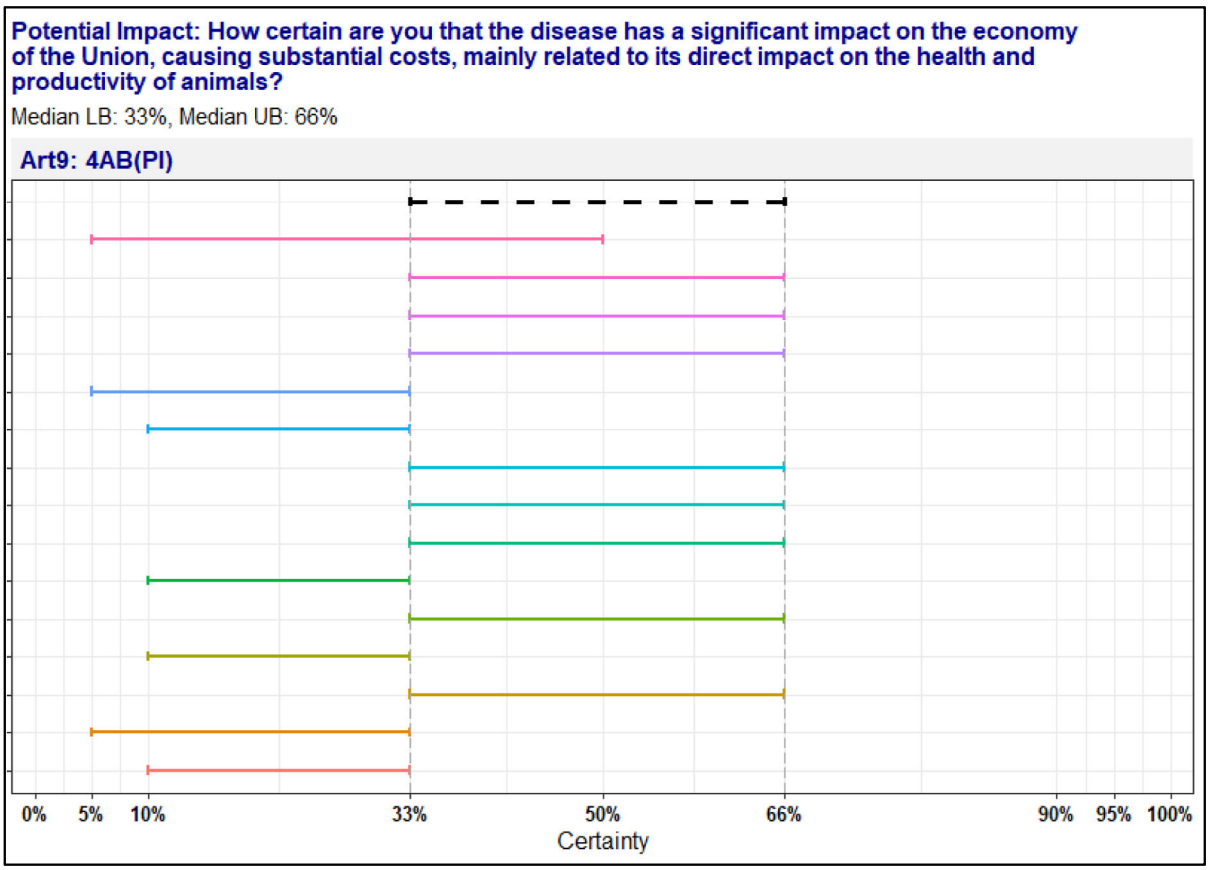


**Figure A.24:** Individual probability ranges, after the collective judgement, reflecting uncertainty on criterion 4AB (potential impact) (the disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of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

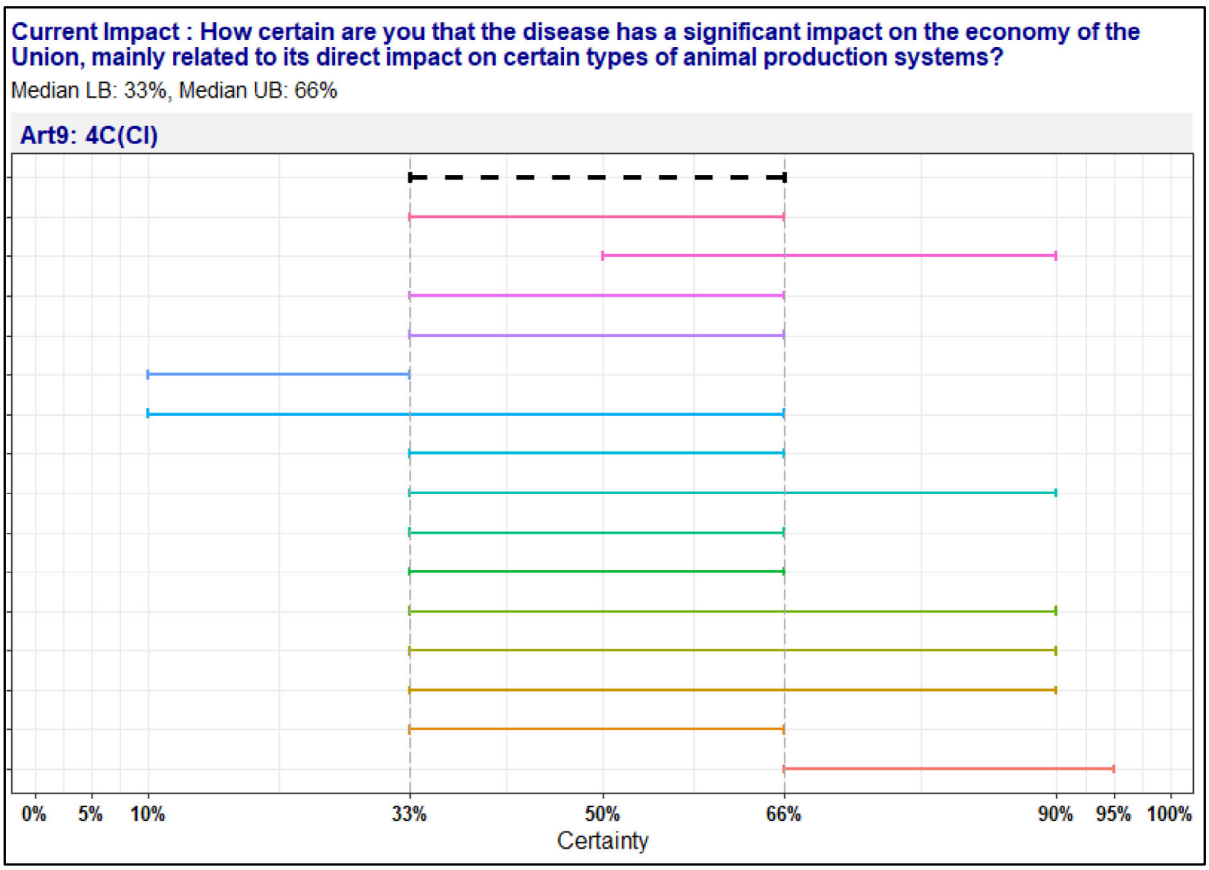


**Figure A.25:** Individual probability ranges, after the collective judgement, reflecting non-fulfilment of criterion 4C (current impact) (the disease has a significant impact on the economy of the Union, mainly related to its direct impact on certain types of animal production systems). Black dotted line on the top indicates the median

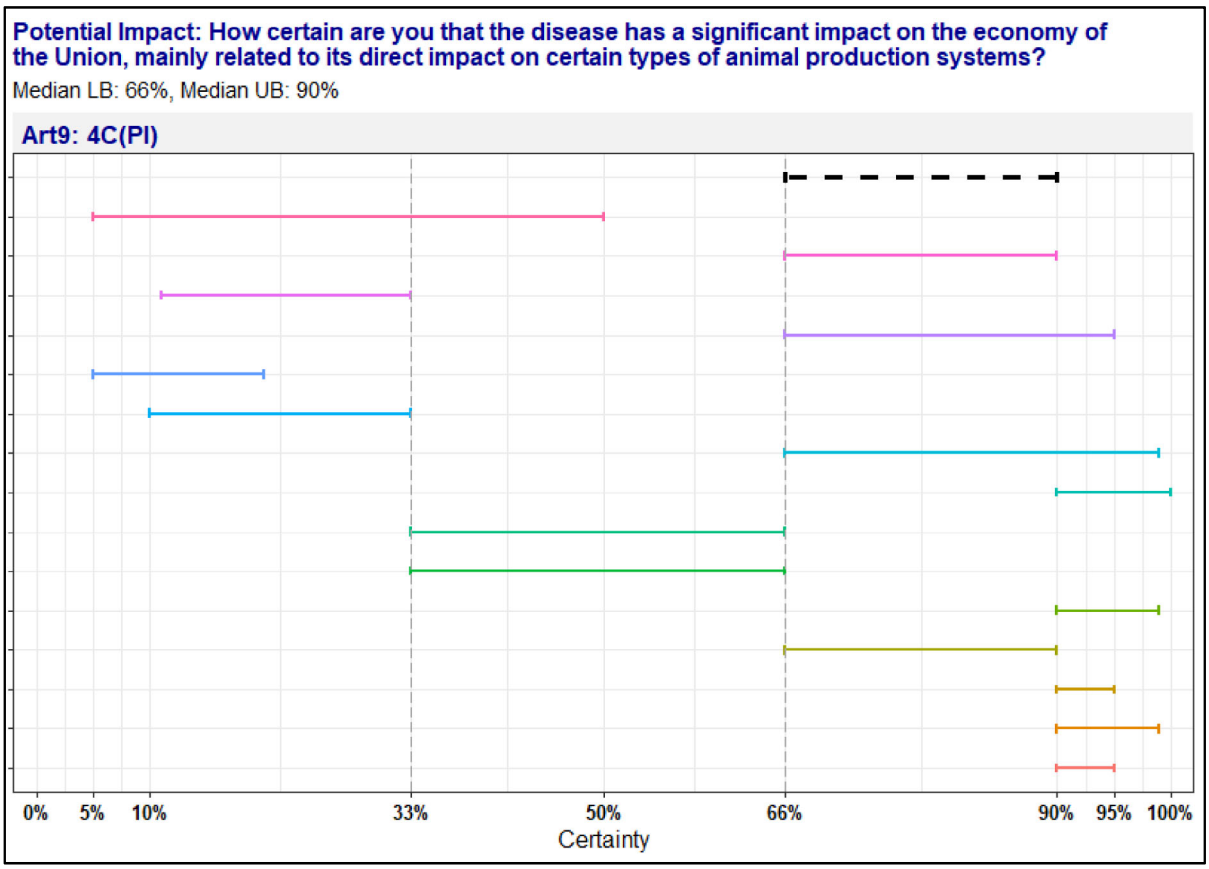


**Figure A.26:** Individual probability ranges, after the collective judgement, reflecting non-fulfilment of criterion 4C (potential impact) (the disease has a significant impact on the economy of the Union, mainly related to its direct impact on certain types of animal production systems). Black dotted line on the top indicates the median

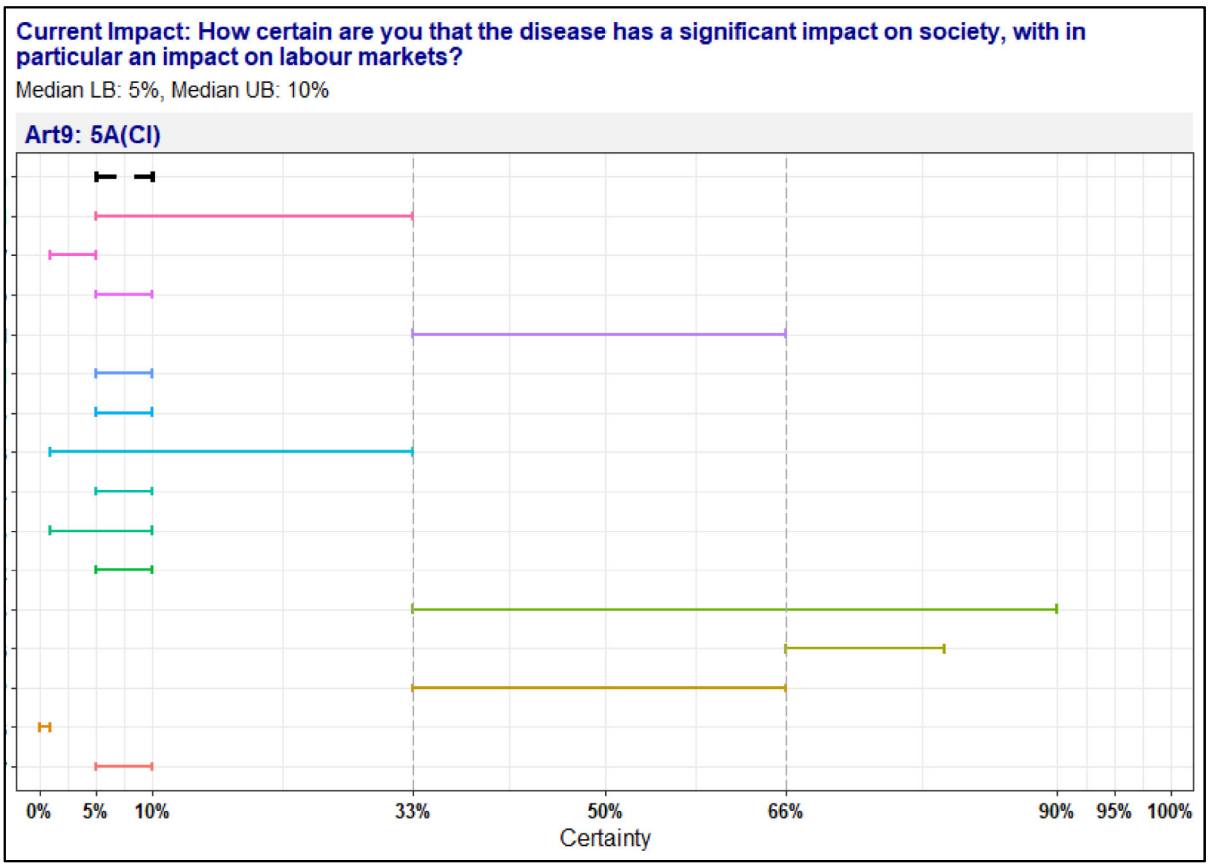


**Figure A.27:** Individual probability ranges, after the collective judgement, reflecting non-fulfilment of criterion 5(a) (current impact) (the disease has a significant impact on society, with in particular an impact on labour markets). Black dotted line on the top indicates the median

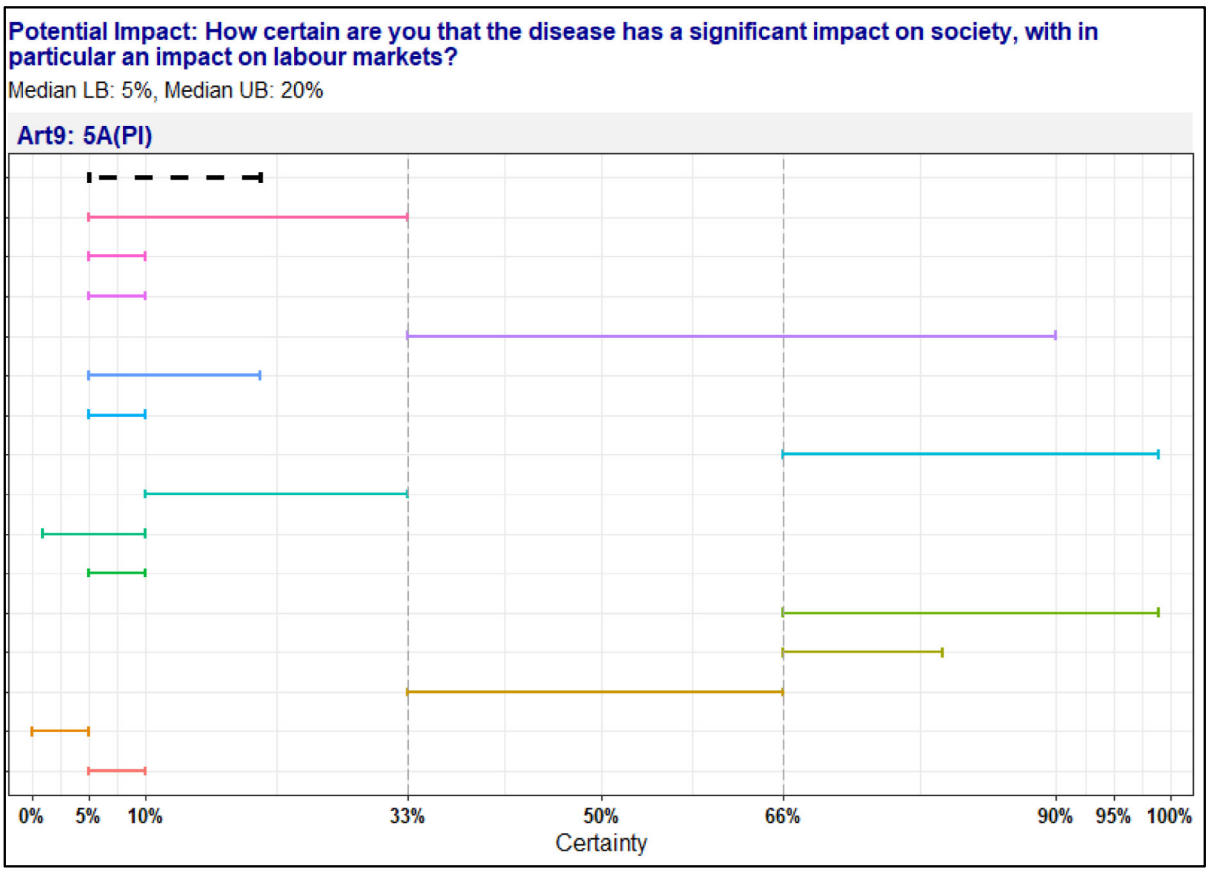


**Figure A.28:** Individual probability ranges, after the collective judgement, reflecting non-fulfilment of criterion 5(a) (potential impact) (the disease has a significant impact on society, with in particular an impact on labour markets). Black dotted line on the top indicates the median

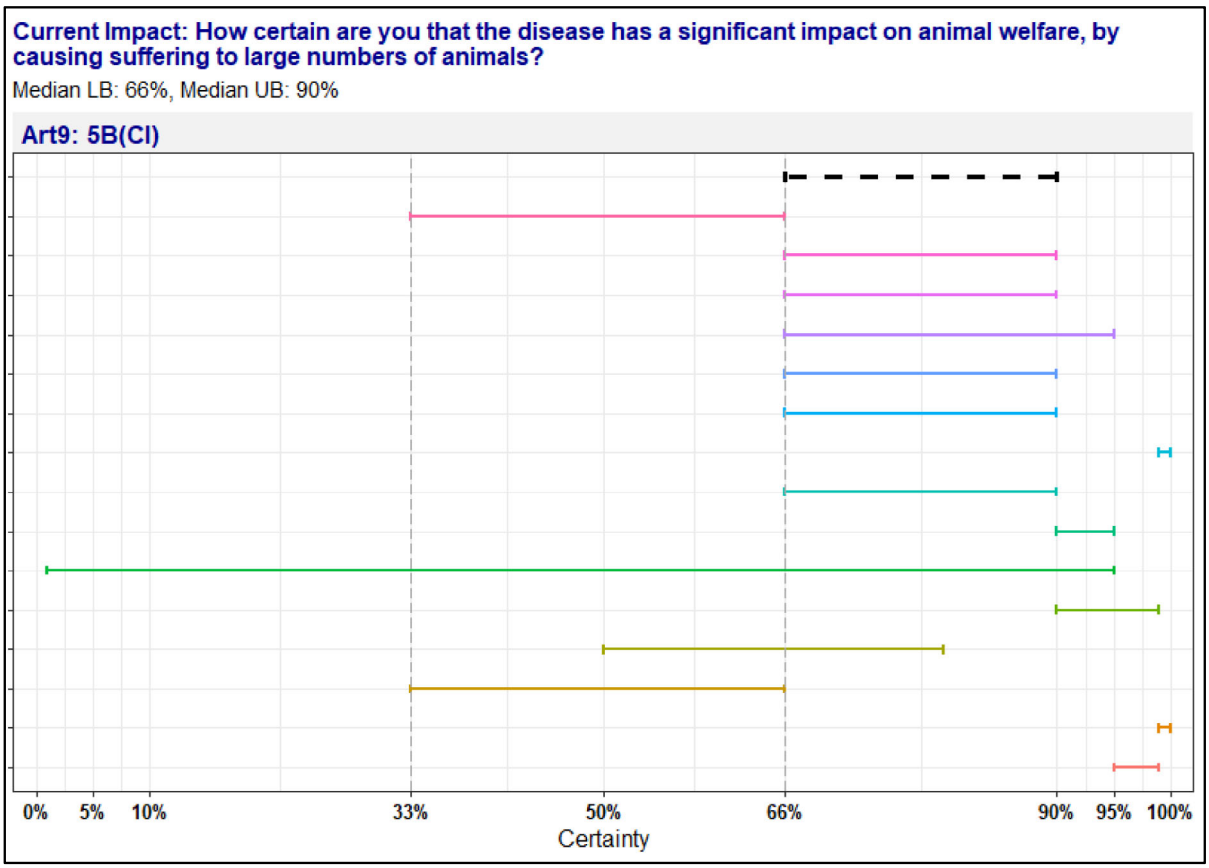


**Figure A.29:** Individual probability ranges, after the collective judgement, reflecting non-fulfilment of criterion 5(b) (current impact) (the disease has a significant impact on animal welfare, by causing suffering of large numbers of animals). Black dotted line on the top indicates the median

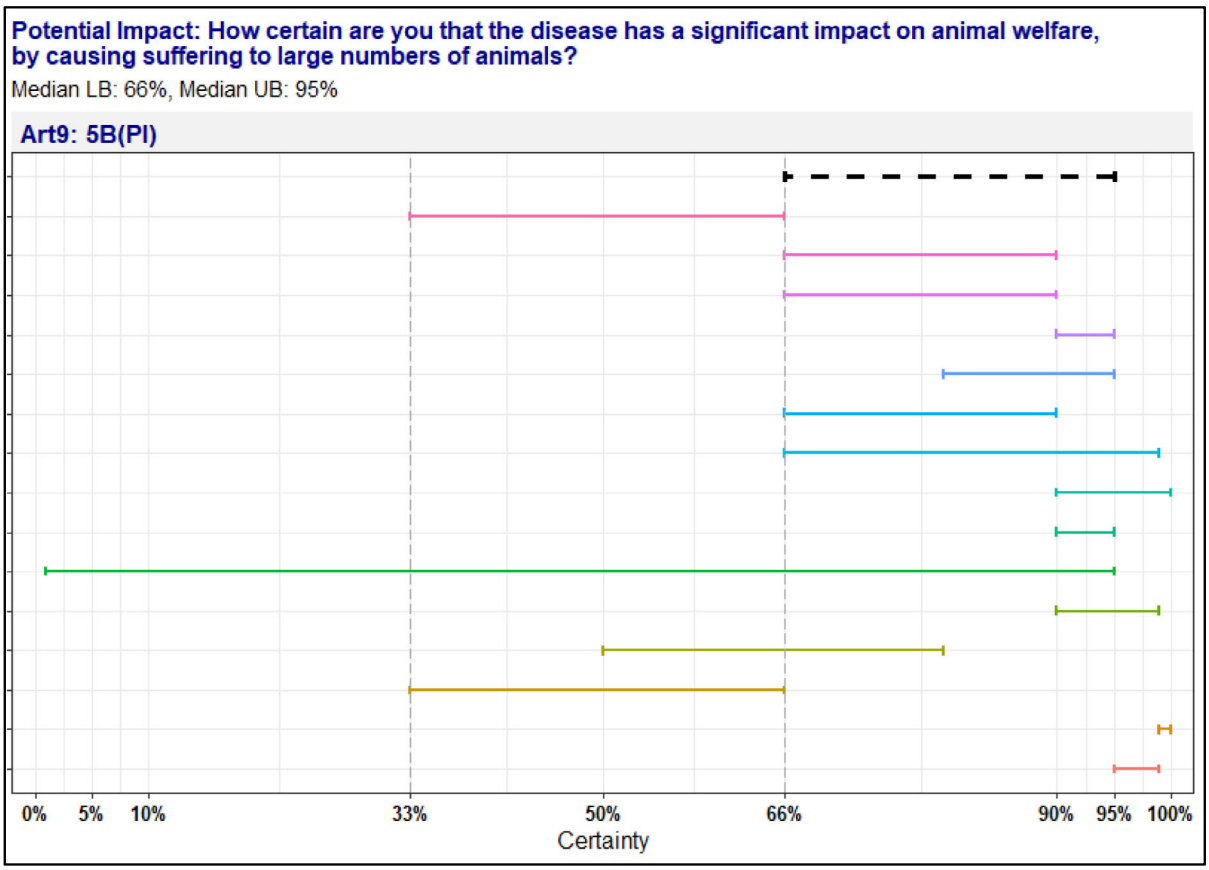


**Figure A.30:** Individual probability ranges, after the collective judgement, reflecting uncertain outcome on criterion 5(b) (potential impact) (the disease has a significant impact on animal welfare, by causing suffering of large numbers of animals). Black dotted line on the top indicates the median

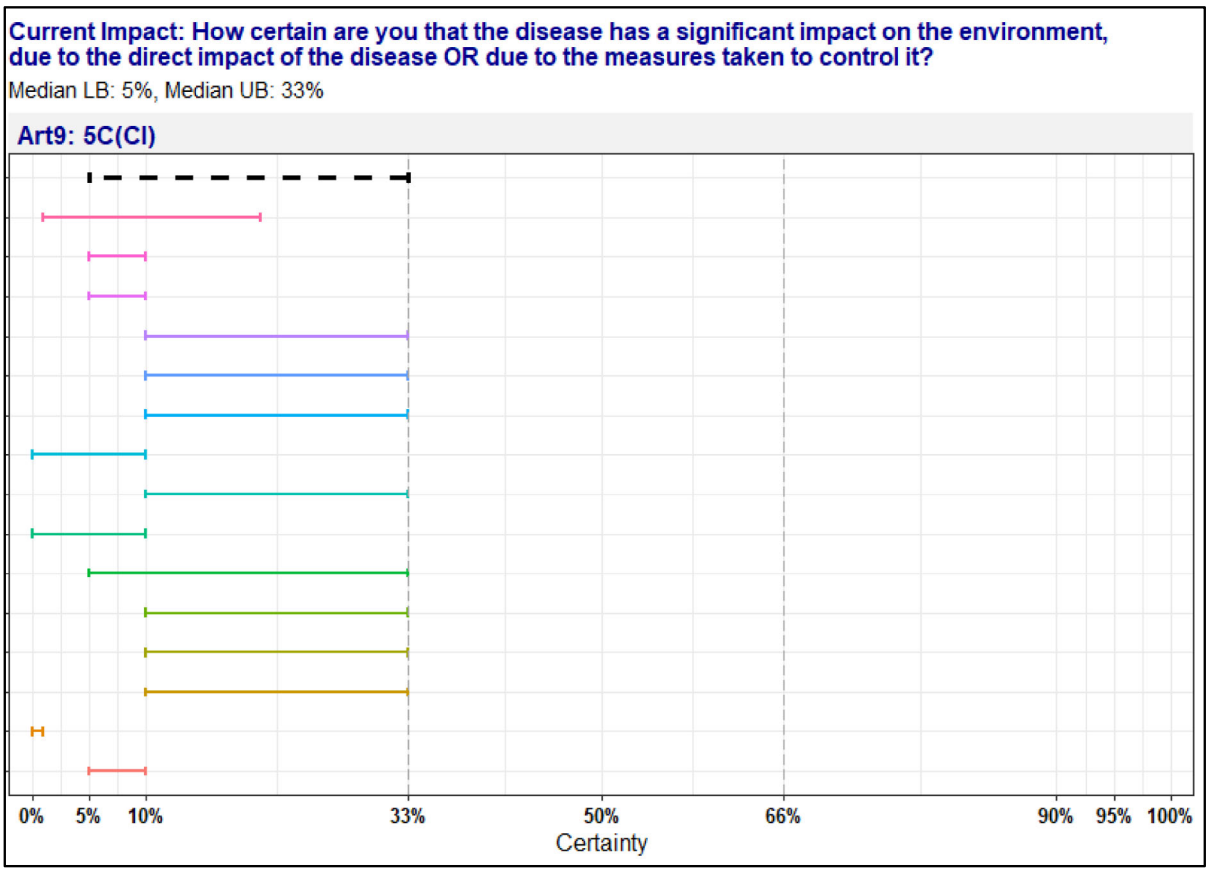


**Figure A.31:** Individual probability ranges, after the collective judgement, reflecting non-fulfilment of criterion 5(c) (current impact) (the disease has a significant impact on the environment, due to the direct impact of the disease or due to the measures taken to control it). Black dotted line on the top indicates the median

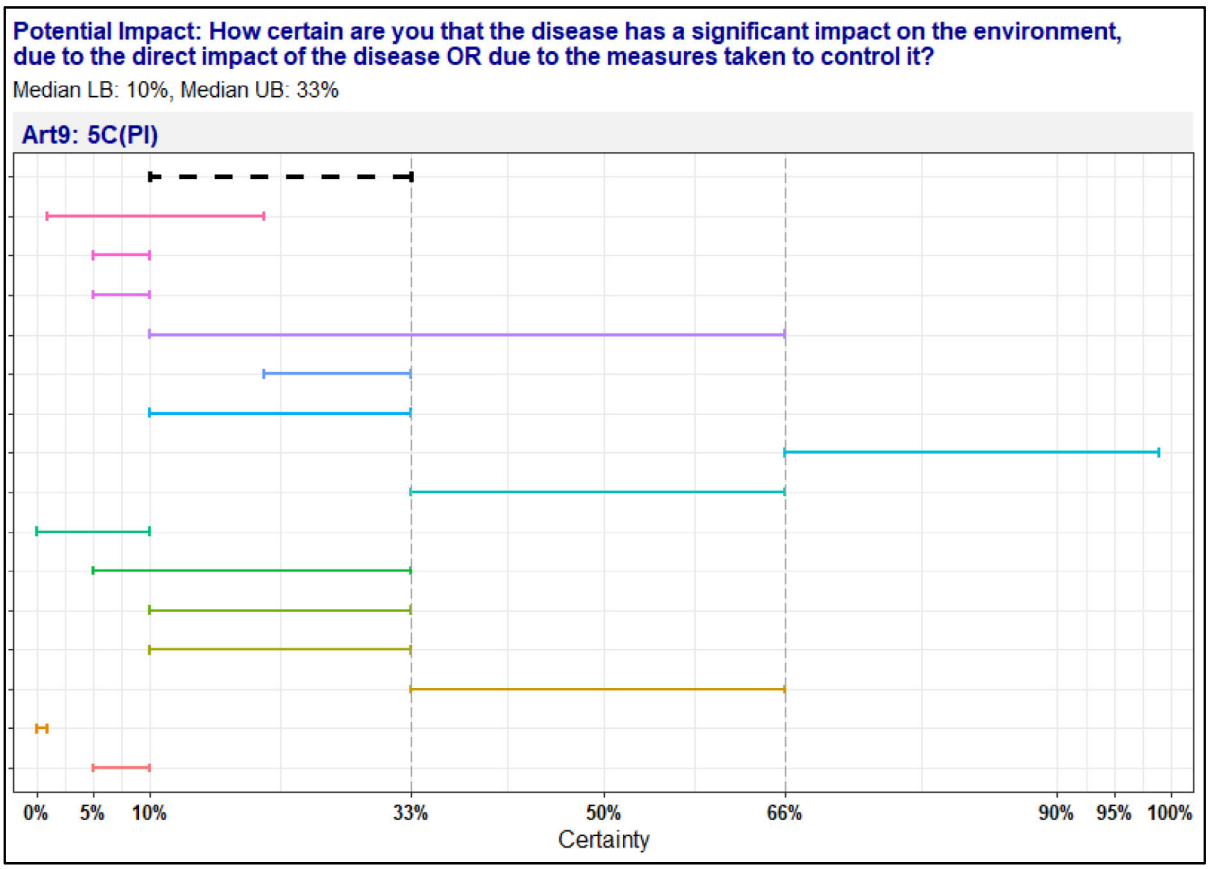


**Figure A.32:** Individual probability ranges, after the collective judgement, reflecting non-fulfilment of criterion 5(c) (potential impact) (the disease has a significant impact on the environment, due to the direct impact of the disease or due to the measures taken to control it). Black dotted line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

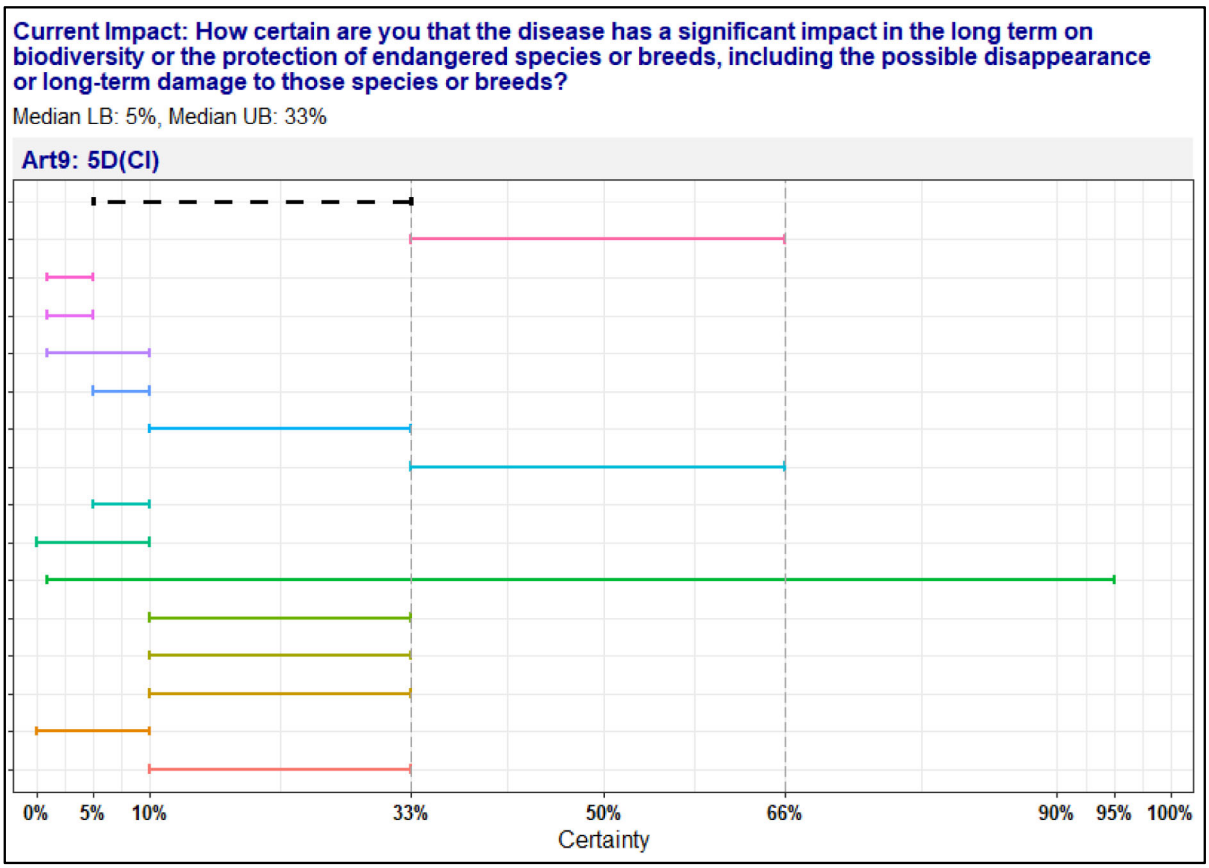


**Figure A.33:** Individual probability ranges, after the collective judgement, reflecting non-fulfilment of criterion 5(d) (current impact) (the disease has a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds). Black dotted line on the top indicates the median

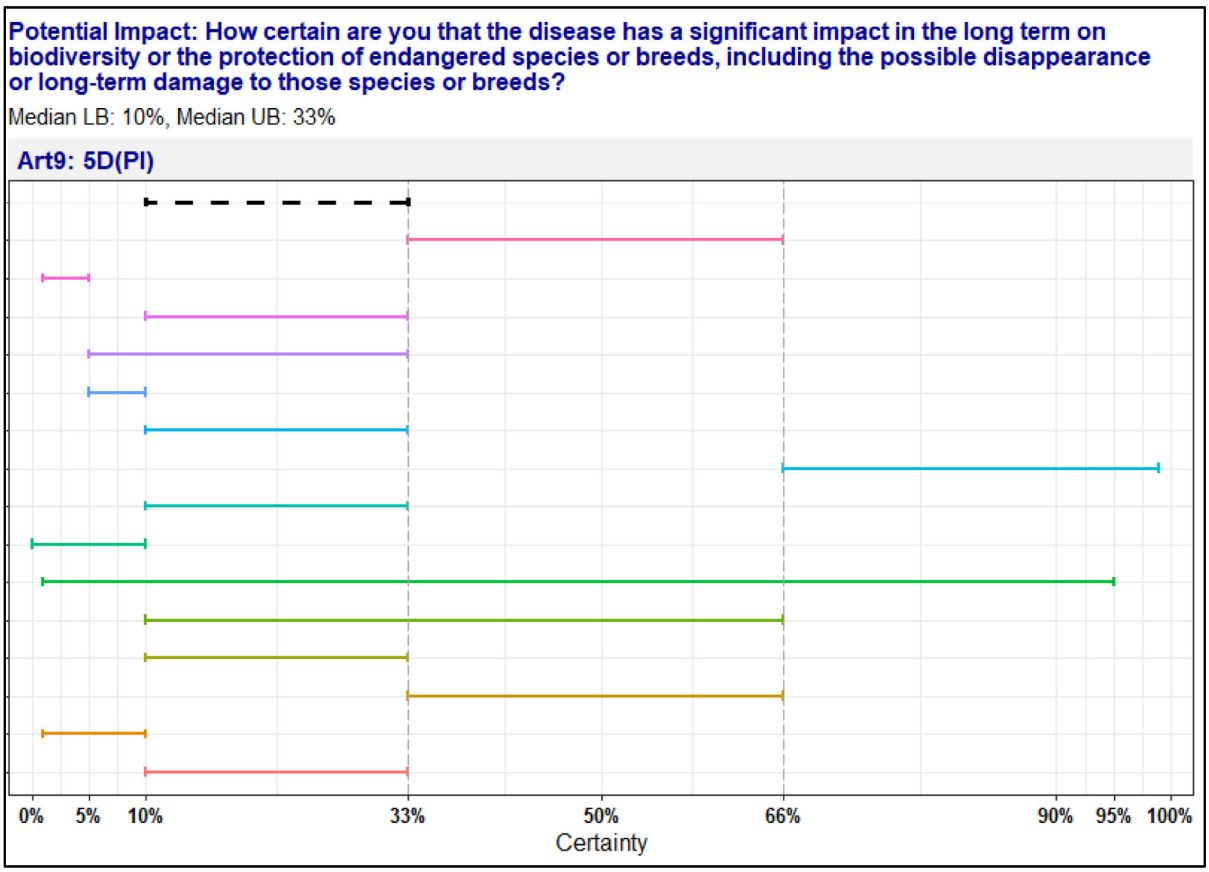


**Figure A.34:** Individual probability ranges, after the collective judgement, reflecting non-fulfilment of criterion 5(d) (potential impact) (the disease has a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance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

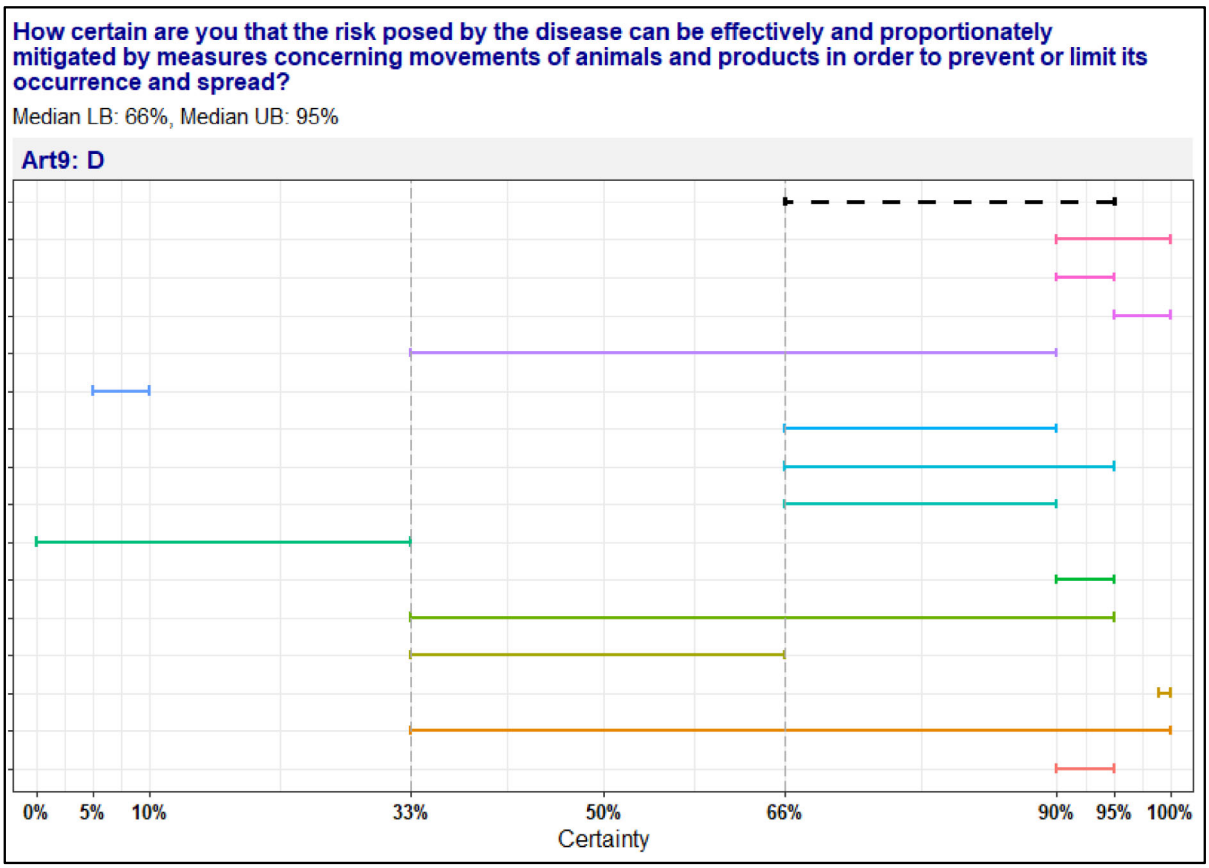


**Figure A.35:** Individual probability ranges, after the collective judgement, reflecting non-fulfilment of criterion D (the risk posed by the disease can be effectively and proportionately mitigated by measures concerning movements of animals and products in order to prevent or limit its occurrence and spread). Black dotted line on the top indicates the median

## Appendix B – Expert judgement: medians for all questions

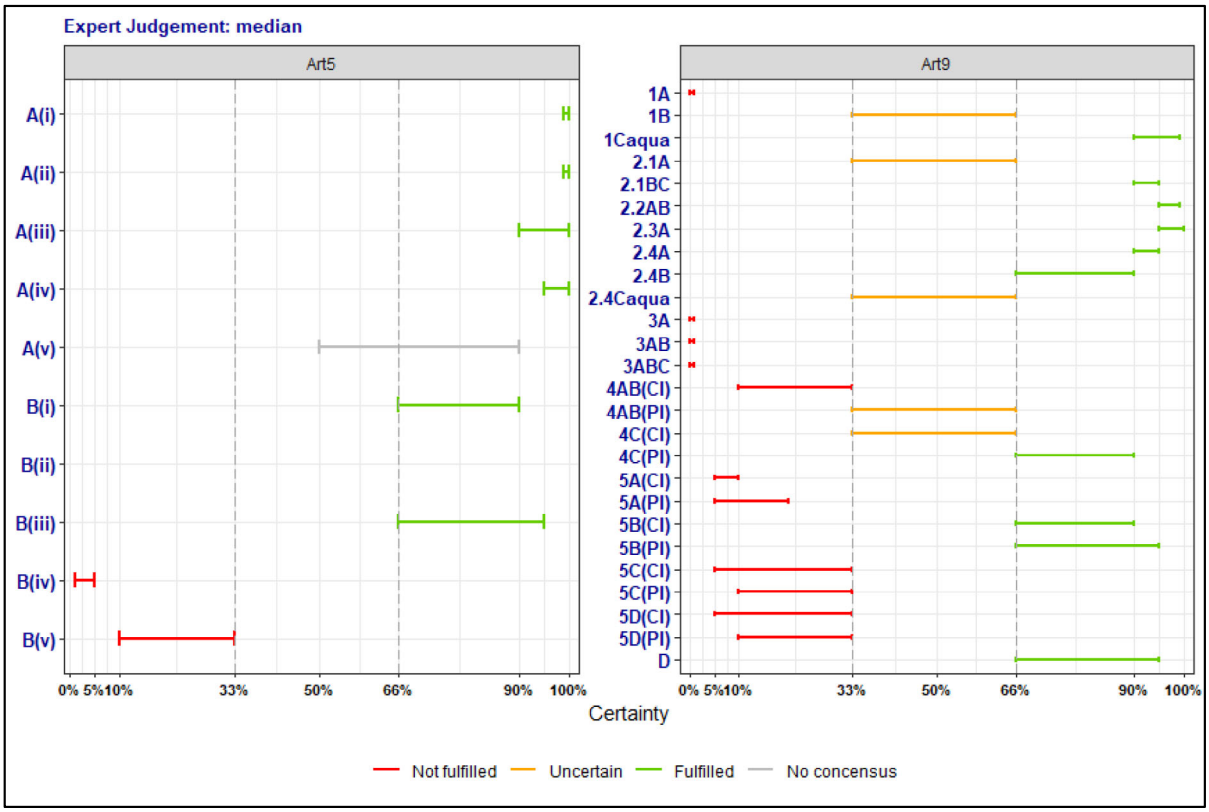


**Figure B.1:** Medians of the judgement replies in questions related to article 5 (left side) and article 9 (right side)