SCIENTIFIC OPINION

efsa JOURNAL

ADOPTED: 27 September 2023

doi: 10.2903/j.efsa.2023.8325

Assessment of listing and categorisation of animal diseases within the framework of the Animal Health Law (Regulation (EU) 2016/429): infection with *Gyrodactylus salaris* (GS)

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Abstract

Infection with *Gyrodactylus salaris* was assessed according to the criteria of the Animal Health Law (AHL), in particular, the criteria of Article 7 on disease profile and impacts, Article 5 on its eligibility to be listed, Annex IV for its categorisation according to disease prevention and control rules as laid down in Article 9 and Article 8 for listing animal species related to infection with *G. salaris*. The assessment was performed following the ad hoc method for data collection and assessment previously developed by AHAW panel and already published. The outcome reported is the median of the probability ranges provided by the experts, which indicates whether each criterion is fulfilled (lower bound ≥ 66%) or not (upper bound ≤ 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 infection with *G. salaris* can be considered eligible to be listed for Union intervention according to Article 5 of the AHL (33–70% probability). According to the criteria in Annex IV, for the purpose of categorisation related to the level of prevention and control as in Article 9 of the AHL, the AHAW Panel concluded that Infection with *G. salaris* does not meet the criteria in Section 1 and 3 (Category A and C; 1–5% and 10–33% probability of fulfilling the criteria, respectively) and it is uncertain whether it meets the criteria in Sections 2, 4 and 5 (Categories B, D and E; 33–80%, 33–66% and 33–80% probability of meeting the criteria, respectively). The animal species to be listed for infection with *G. salaris* according to Article 8 criteria are provided.

Keywords: aquatic animals, Animal Health Law, *Gyrodactylus salaris*, *G. salaris*, listing, categorisation, impact

Requestor: European Commission

Question number: EFSA-Q-2023-00063

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

Acknowledgements: The AHAW Panel wishes to acknowledge the expert Dr Spiridoula Athanasiadou selected through the Individual Scientific Advisor schema (ISA expert; EOI/EFSA/SCIENCE/2022/01 – CT 04 BIOHAW contract) for conducting the literature review on the disease profile and the parameters of the criteria of Article 7 of AHL and drafting the fact sheet.

Suggested citation: EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare), Nielsen, S. S., Alvarez, J., Calistri, P., Canali, E., Drewe, J. A., Garin-Bastuji, B., Gonzales Rojas, J. L., Gortázar, C., Herskin, M. S., Michel, V., Miranda Chueca, M. A., Padalino, B., Roberts, H. C., Spoolder, H., Ståhl, K., Velarde, A., Viltrop, A., Winckler, C., . . . Bicout, D. J. (2023). Assessment of listing and categorisation of animal diseases within the framework of the Animal Health Law (Regulation (EU) 2016/429): infection with *Gyrodactylus salaris* (GS). *EFSA Journal*, *21*(10), 1–81. https://doi.org/10.2903/j.efsa.2023.8325

ISSN: 1831-4732

efsa EUROPEAN FOOD SAFETY AUTHORITY

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

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1. Introduction

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

1.1.1. Background

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

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

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

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

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

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

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

1.1.2. Disease specific information

(a) Spring viraemia of carp (SVC)

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

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

(b) Bacterial kidney disease (BKD)

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

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

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

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

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

(c) Infectious pancreatic necrosis (IPN)

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

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

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

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

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

(e) Infection with salmonid alphavirus (SAV)

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

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

1.1.3. Terms of Reference

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

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

1.2. Interpretation of the Terms of Reference

The interpretation of the ToRs is as in Section 1.2 of the scientific opinion on the ad hoc method to be followed for the assessment on listing and categorisation of animal diseases within the AHL framework (EFSA AHAW Panel, 2017a).

The present document reports the results of the assessment on the infection with *G. salaris* (GS) according to the criteria of the AHL articles as follows:

- Article 7: infection with *G. salaris* profile and impacts;
- Article 5: eligibility of infection with *G. salaris* to be listed;
- Article 9: categorisation of infection with *G. salaris* according to disease prevention and control rules as in Annex IV. Each category foresees the application of certain disease prevention and

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

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

- Article 8: list of animal species related to infection with *G. salaris*.

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

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

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

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

The Section 3.1 below includes the information of the fact sheet on the disease profile and the parameters of the criteria of Article 7 of AHL and has been drafted by the selected expert through the

Individual Scientific Advisor schema (ISA expert; EOI/EFSA/SCIENCE/2022/01 – CT 04 BIOHAW contract) and reviewed by the EFSA working group of experts.

3. Assessment

3.1. Assessment according to Article 7 criteria

This Section presents the assessment of infection with *Gyrodactylus salaris* 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 fact sheet on the disease profile and the parameters of the criteria of Article 7 of AHL (see Section 2.1 of the Scientific Opinion on the ad hoc methodology).

3.1.1. Article 7(a) Disease Profile

Gyrodactylosis is a disease caused by species belonging to the genus *Gyrodactylus* (Olstad et al., 2009), whose members are viviparous ectoparasites belonging to the Family Gyrodactylidae and Class Monogenea (Phylum Platyhelminthes). *G. salaris* is among the best characterised of the species, causing severe gyrodactylosis, with the most susceptible host being Atlantic salmon (*Salmo salar*), but other hosts such as trout species and Arctic charr can also be affected. The severity of clinical signs depends on the host species and stage of life, but also upon the infection intensity and mortality may be high in the susceptible host. For example, wild Atlantic salmon with low-infection intensities usually do not exhibit any clinical signs, whereas heavy infection can lead to increased flashing, increased mucus production and erosion of the fins. The most reliable diagnostic procedure is the morphological identification combined with molecular diagnostics, such as PCR. If *G. salaris* is identified in a population, biocides such as rotenone can be used, which kills the host species, as well as the parasite. Other chemicals such as aluminium sulphate ($[Al_2(SO_4)_3]$)and low doses of chlorine can be used, as they are less toxic to fish and other aquatic life than to *G. salaris*.

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

Susceptible animal species

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

G. salaris, commonly known as salmon fluke, can be responsible for gyrodactylosis in a range of hosts. It is an ectoparasite of the phylum Platyhelminths, class Monogenea and the host species that fulfil the criteria for listing as susceptible to infection are: Arctic charr (*Salvelinus alpinus*), Atlantic salmon (*S. salar*), brown trout, (*S. trutta*), grayling (*Thymallus thymallus*), North American brook trout (*Salvelinus fontinalis*) and rainbow trout (*Oncorhynchus mykiss*) (Paladini et al., 2021). It is notable that Paladini et al. (2021) reported that available data suggest synonymising of the species *G. salaris* and *Gyrodactylus thymalli*, despite the fact that the latter is considered restricted to grayling (*T. thymallus*) while the former has never been recorded from wild grayling (WOAH, 2021).

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

The naturally susceptible aquatic species (wild and farmed) are presented in Table 2.

Table 2: Naturally susceptible aquatic species (wild and farmed)

Fish species [common name (scientific name)]	Wild/farmed	Reference
Arctic charr (*Salvelinus alpinus*)	Wild	Paladini et al. (2021)
Atlantic salmon (*Salmo salar*)	Wild/farmed	Paladini et al. (2021)
Brook trout (*Salvelinus fontinalis*)	Wild/farmed	Hansen et al. (2016) Paladini et al. (2021)
Brown trout (*Salmo trutta*)	Wild/farmed	Hansen et al. (2016) Paladini et al. (2021)
Grayling (*Thymallus thymallus*)	Wild	Paladini et al. (2021)
Rainbow trout (*Oncorhynchus mykiss*)	Wild/farmed	Hansen et al. (2016) Paladini et al. (2009)

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

High susceptibility following experimental infection was evidenced in Arctic charr (*S. alpinus*) (Winger et al., 2008). Evidence for some susceptibility following experimental infection has been shown in brown trout (*S. trutta*) (Jansen and Bakke, 1995) (and grayling (*T. thymallus*) (Soleng and Bakke, 2001); but experimental infections have not been sustained for long in these species; for example, in grayling, the experimental infection was cleared within 25 days post infection at 13°C in most of the fish. In another research by Sterud et al. (2002), *G. salaris* was reported to still be present on a single grayling after 143 days post infection challenge. North American lake trout (*Salvelinus namaycush*) have also been successfully infected through experimental challenge (Bakke et al., 1992).

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

The experimentally infected domestic/farmed species are presented in Table 3.

Table 3: Experimentally infected species wild or farmed

Fish species	Wild/ farmed	Experiment setting	Reference
Arctic charr (*Salvelinus alpinus*)	Wild	Fry were exposed to a dead infected *S. alpinus* parr suspended on a string in a tub.	Winger et al. (2008)
Brown trout (*Salmo trutta*)	Wild	Experimental trout cohabited with heavily infected *S. salar* for 5 days, and then either isolated and held individually or maintained as a group.	Jansen and Bakke (1995)
Grayling (*Thymallus thymallus*)	Wild	Grayling was exposed to heavily infected salmon fins for 24 h in boxes	Soleng and Bakke (2001)
		Experimental fish were given a light parasite infection by cohabitation with fins cut from donor fish (salmon with *G. salaris*) in aerated 25 L tanks.	Sterud et al. (2002)
North American lake trout (*Salvelinus namaycush*)	Wild/ farmed	Protocol 1: Experimental fish were kept for 7 days with 11 heavily infected salmon (> 500 parasites per fish) in intermediate sized (27 × 38 × 15 cm) plastic aquaria. Protocol 2: 150 uninfected experimental fish were placed with 20 heavily infected salmon pan (> 500 parasites per fish) for 8 days in a volume of 200 1 water in plastic tanks (1.0 × 1.0 × 0.2 m).	Bakke et al. (1992)

Reservoir animal species

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

G. salaris parasites may attach themselves to any fish species not considered a susceptible species, for short periods of time. The European eel (*Anguilla anguilla*) was shown to carry and transfer *G. salaris* to target host population (Bakke et al., 1991). Epidemiologically, Atlantic salmon × brown trout hybrids may also act as a reservoir for *G. salaris* (Bakke et al., 1992). Wild salmonids that are less susceptible to *G. salaris* than Atlantic salmon may act as reservoirs of the parasite and transfer it to susceptible hosts, particularly in river systems that have a reproducing Atlantic salmon population (Koski and Heinimaa, 2001). Wild caught alpine bullhead (*Cottus poecilopus*) may function as transport host or reservoir for *G. salaris*, depending on the environmental temperature (Bakke et al., 2019). Three-spined stickleback (*Gasterosteus aculeatus*), nine-spined stickle back (*Pungitius pungitius*) and flounder (*Platichthys flesus*) are innately resistant to *G. salaris*, but experimental studies have shown that the parasites can be attached to the fish, so they can play a role as transport hosts for *G. salaris* (Soleng and Bakke, 1998). Additional fish species where *G. salaris* has been shown to survive and be carried are summarised by Peeler et al. (2006) and include brook lamprey (*Lampetra planeri*), perch (*Perca fluviatilis*), minnows (*Phoxinus phoxinus*), roach (*Rutilus rutilus*).

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

Any of the above species, if farmed, could act as reservoirs for *G. salaris*. No specific studies were identified.

Vector animal species

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

G. salaris may attach themselves to any fish species inhabiting freshwater or brackish environments (extrapolating from salinity work by Soleng and Bakke (1997)), which are not considered a susceptible species, for short periods of time. However, there is no evidence from the published literature that fish vectors have transmitted *G. salaris* to other susceptible species.

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

The same as the Parameter 7 above.

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

Morbidity

Parameter 1 – Prevalence or Incidence

There appears to be a significant knowledge gap in terms of prevalence and incidence information at the national level. Some experimental data are available on transmission; these report prevalence after exposure to *G. salaris*. In Norway, prevalence data from a case study in the early 1990s showed variation, but *G. salaris* was present at almost up to 100% of Atlantic salmon in all year classes throughout the study period, except for a marked decline in winter and spring of 1992 (Appleby and Mo, 1997). Prevalence in other susceptible species, such as brown trout (*S. trutta*) and grayling (*T. thymallus*), is generally lower and can be below 10%, however, this is not always the case (WOAH, 2021).

In a case study in Russia, almost 100% prevalence in a rainbow trout farm was reported (Ieshko et al., 2016). Similarly, in Danish rainbow trout farms prevalence was as 100% for the majority (9/11) of farms studied and the overall farm mean intensity was 152.3 parasites per infected fish (Nielsen and Buchmann, 2001), whereas in Atlantic salmon in Danish rivers, the prevalence was variable, from 0%–100% (Jørgensen et al., 2008). Similarly, *G. salaris* monthly prevalence varied between 93% and 100% in field studies in Atlantic salmon, as published by Jansen and Bakke (1995), at the River Glitra area in Southeast Norway.

Data are also available to show how temperature affects parasite intensity and prevalence; for example, parasite intensity shows an autumn high and a spring low in the Arctic charr in Norway, although this seasonal pattern variation is not always consistent (Winger et al., 2008). Prevalence and the intensity of infections was generally low in farms in Romania but neither of them was quantified (Hansen et al., 2016).

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

A significant knowledge gap is also evident in determining case-morbidity rate. Reports from WOAH mention that morbidity in farmed Atlantic salmon fry and parr can be 100% if not treated (WOAH, 2021).

Parameter 3 – Case-fatality rate

Mortality in wild Atlantic salmon fry and parr in Norwegian rivers can be as high as 98%, with an average of about 85%. Mortality in other susceptible host species is usually low or not observed (WOAH, 2021).

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

Presence

Parameter 1 - Report of zoonotic human cases (anywhere)

Infection with *G. salaris* is not a zoonotic disease. There is no evidence in the literature that *G. salaris* 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

There is not much information available in the literature on the resistance of *G. salaris* to substances used for treatment. *G. salaris* is sensitive to the most commonly used chemicals for bath treatment of farmed salmon parr and salmon eggs (e.g. high salinity salt water, formaldehyde and compounds containing chlorine and iodine). Furthermore, *G. salaris* is sensitive to acidic solutions (pH 5.0–6.0) of aluminium sulphate (WOAH, 2021).

Various anthelmintics that belong to different pharmacological groups, such as ivermectins, levamisole and praziquantel have been used both *in vitro* and *in vivo* with variable efficacy against *G. salaris* infecting rainbow trout (Santamarina et al., 1991). It is unclear if this variation in efficacy is attributed to anthelmintic resistance or lack of specificity.

Removal of *G. salaris* from affected river systems has been achieved through the use of the plant-derived compound rotenone, aiming to achieve concentrations of 0.033 mg L^{-1} (Sandodden, 2018) and to date, no formal reports of resistance to this biocide have been reported.

3.1.1.5. Article 7(a)(v) The persistence of the disease in an animal population or the environment

Animal population

Parameter 1 – Duration of infectious period in animals

Some *S. salar* populations can control their infection level relatively quickly by 7–14 days post infection, whereas other fish showed a peak intensity at up to 35 days post infection, after which the parasite population declined (Nielsen and Buchmann, 2001; Bakke et al., 2004a; Bakke et al., 2004b). In experimentally infected Scottish and Norwegian stocks of salmon *G. salaris* has been reported to remain present up to 50 days post infection (Bakke and MacKenzie, 1993).

G. salaris tends to persist longer on starved than on fed trout, where the maximum persistence was 50 days; it was assumed that parasite reproduction occurred during the 50 days (Jansen and Bakke, 1995). Parasite reproduction also occurred among grouped grayling as judged from the duration of infection of more than 50 days (Soleng and Bakke, 2001). Persistence in the fish population in the field is sometimes achieved when fish avoid the treatment; for example, Arctic charr can avoid rotenone treatment if in small streams and they can be the source of re-infection of a particular river in Northern Norway (Winger et al., 2007; Winger et al., 2008). In susceptible individually isolated grayling, parasite reproduction can last for more than 35 days (Soleng and Bakke, 2001). There are differences in susceptibility between anadromous and resident stocks of Arctic resident charr (Kcharjoen stock) exposed to heavily infected salmon, which were considered innately resistant as they lost their infections within 21 days when individually isolated. Isolated anadromous charr (Hammechart stock) remained infected for up to 150 days, although most infections disappeared within 30–50 days (Bakke et al., 1996).

Parameter 2 – Presence and duration of latent infection period

G. salaris is an obligate viviparous parasite with a direct life cycle. *G. salaris* contains a fully grown daughter *in utero* which in turn encloses a developing embryo, boxed inside one another like 'Russian dolls' (Cable and Harris, 2002). They give birth to free-swimming larvae containing a further generation of progeny at birth, and which migrate to the specific sites (e.g. gills etc.) where they attach to the host (Guo and Woo, 2009; WOAH, 2021).

Based on this information, there does not appear to be any significant latent infection period and hosts are likely to be infectious as soon as they get infected (Figure 1).

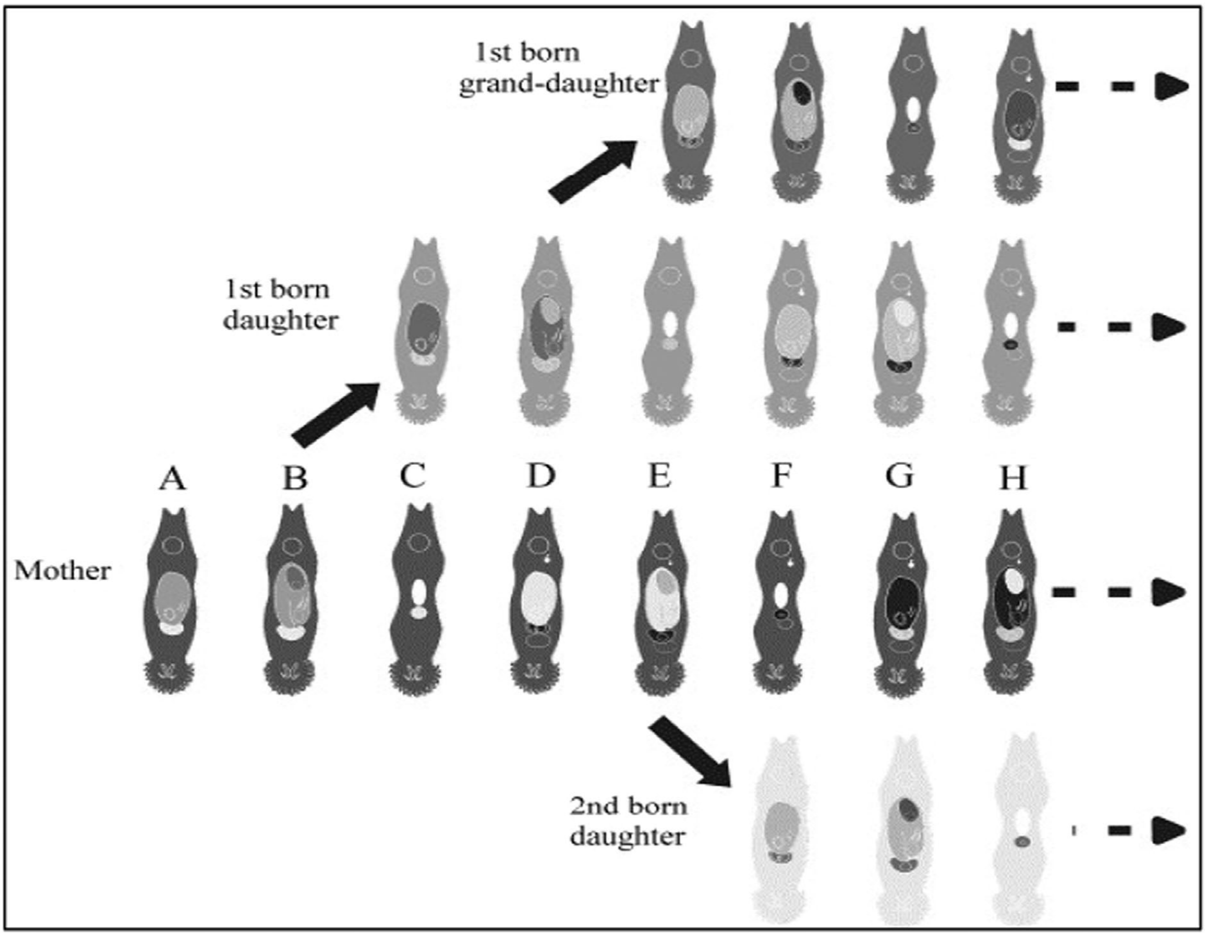


Figure 1: Reproductive modes of *Gyrodactylus* spp. A–H represent successive stages in the life cycle of a newborn parasite. At stages B and E, the mother gives birth. The male reproductive system is fully functional from stage D onwards. The first-born daughter develops asexually while its parent is still an embryo. The second-born daughter develops from an oocyte that commences development before the parent's male reproductive system is fully mature. Only selected births are shown for simplicity. © 2002 Australian Society for Parasitology Inc. Reproduced from (Cable and Harris, 2002) by modifying the drawing from (Kearn, 1994)

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

The presence and duration of the pathogen in healthy carriers appears to be associated with environmental temperature, water salinity and other environmental factors. *G. salaris* was present in the European eel (*A. anguilla*) for 8 days (Bakke et al., 1996). In alpine bullhead (*C. poecilopus*), 8 to 9 days post infection at high temperature (11.5°C), the infection of *G. salaris* was eliminated, whereas at low temperatures (6.5°C) infections persisted for 47–48 days (Bakke et al., 2019). Following an experimental infection study in brown trout (*Salmo trutta*), *G. salaris* was present for up to 50 days post infection (Jansen and Bakke, 1995).

Environment

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

Survival of detached parasites is temperature dependent. At 18°C, survival off the host was 1 day, but at 3°C parasites survived for 4 days (Olstad et al., 2006). At 10°C, detached parasites survived up to 89 h *in vitro* (Cable et al., 2002). Salinity was shown to be the key environmental determinant of parasite survival; at 25‰ the parasite survives for ~ 22 h (at 1.4°C, temperature at which parasite survival is longest) (Peeler et al., 2006).

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)

Horizontal transmission between fish by physical contact can be instantaneous in crowded environments (direct transmission) or when the parasites have detached from their hosts and are present in the water seeking for a new host (indirect transmission) (Ramírez et al., 2015). Environmental factors are important – transmission of the parasites is very low from seawater sites where salinity is greater than 25‰ (Peeler et al., 2006).

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

G. salaris can transfer via direct contact with live and dead hosts. Indirect transmission is in principle possible via detached parasites present in the water or fishing equipment. Transmission to humans has not been reported.

Speed of transmission

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

No available data or published studies document a reliable time series of prevalence change in natural infections; however, experimental/case studies suggest that as the pathogen is transmitted via direct and indirect contact, infection rates post introduction are high, particularly for the target species and lead to the majority of the population becoming infected over a short period of time; prevalence reached 100% within 1 month, whereas the mean intensity of the infections peaked at over 600 parasites within a couple of months in salmon in Norway (Jansen and Bakke, 1993). If *G. salaris* is introduced into a farm with Atlantic salmon, there is a high probability that all fish in the farm will become infected, depending on the layout of the farm (WOAH, 2021).

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

There are no published data to allow R_0 to be estimated; however, as stated above, most of the population of the target host appears to become infected over a few days, depending on the environmental conditions. Progeny are born carrying developing embryos and can hence rapidly expand the population on contact with a new host, prior to any sexual reproduction, i.e. one worm can start a new population. The ecological consequences of this reproductive strategy are well studied: viviparity allows explosive population growth, especially when transmission is favoured under culture conditions (Cable et al., 2000). No transmission from fish to humans has been recorded and the parasite is not thought to have any zoonotic potential.

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

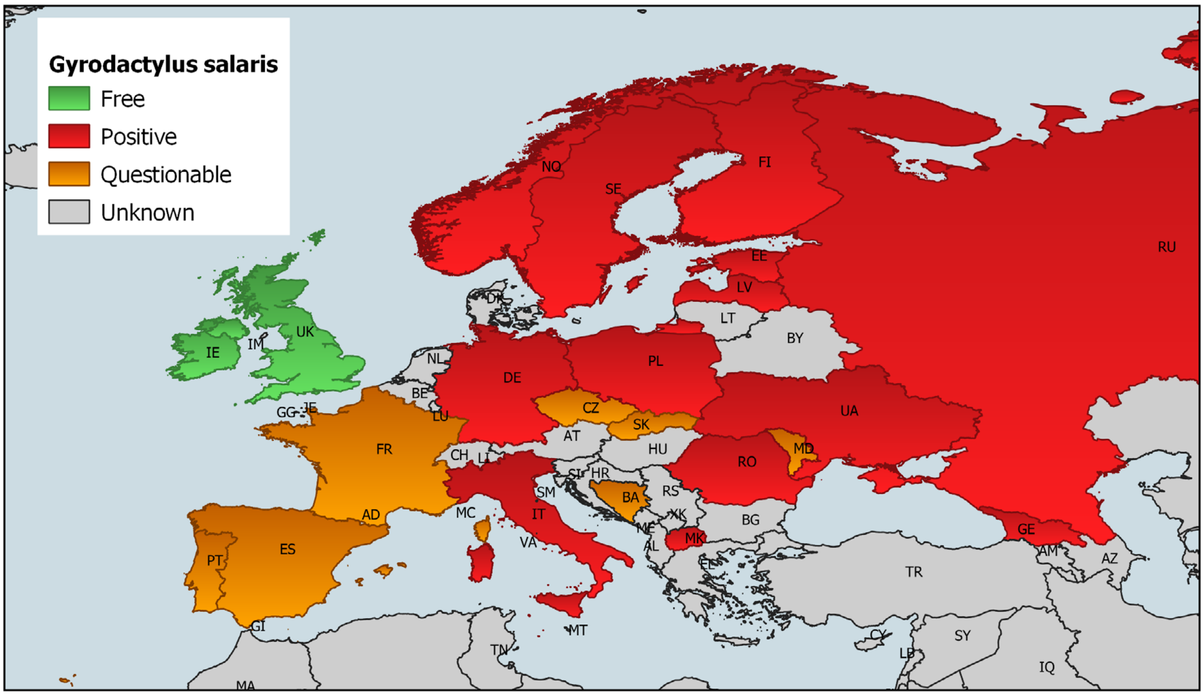
Presence and distribution

Parameter 1 – Map where the disease is present in EU

No map was available from WOAH. A map from a recent publication is included Figure 2. *G. salaris* is a WOAH listed parasitic pathogen (Malmberg, 1957; cited in [Paladini et al., 2021]). Originally, it was distributed within the eastern parts of the Baltic area including the drainages of the Russian lakes Onega and Ladoga (Ergens, 1983; Malmberg and Malmberg, 1993). From these areas, the parasite has spread in both wild and farmed populations. The parasite has been found on wild salmonids, mainly Atlantic salmon parr, in rivers in Finland, Norway, Russia and Sweden and had until 2021 been reported in 19 countries across Europe, although some records may still require confirmation (Paladini et al., 2021). According to WOAH, it is restricted in its distribution to Europe; it has been recovered from farmed Atlantic salmon or farmed rainbow trout in several (mainly northern) European countries. In the wild, the parasite has been found on wild salmonids, mainly Atlantic salmon parr, in rivers in Norway, Russia and Sweden. Infection with *G. salaris* is more common in farmed rainbow trout than previously thought and is likely to be present in more countries than those currently known. The

United Kingdom and Ireland have been demonstrated to be free of the parasite. A detailed list of countries in which *G. salaris* has been reported to occur in salmonids is provided in the recent publication by Paladini et al. (2021) and in Figure 2 from the same publication. As noted earlier in Section 3.1.1.1, it has been suggested that *G. salaris* and *G. thymalli* might be synonymised despite differences in host preference and apparent pathogenicity. However, WOAH suggests that the cytochrome I (COI) genotypes traditionally found on grayling and described as *G. thymalli* do not need to be reported as *G. salaris* and do not warrant the same control measures.

Recently, according to the European Union Reference Laboratory for Fish and Crustacean Diseases (EURL)[3] annual reports from 2014 to 2021, *G. salaris* has been identified in the following countries, among which 5 EU MSs: Finland, Latvia, Bosnia and Herzegovina, Hungary, Germany and Italy (EURL, 2014–2021).



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

Figure 2: Map highlighting *Gyrodactylus salaris* positive countries (red colour) in European Continent, as reported from 1951 to 2021 (Paladini et al., 2021) where yearly tests are performed for the presence of *G. salaris,* same as the free countries (green colour). This map is a modification of the one in Paladini et al. (2021). Please note that according to the Commission Implementing Decision 2021/260 and the EFTA Surveillance Authority Delegated Decision No 203/21/COL Ireland, United Kington (Northern Ireland) and certain water catchment areas in Finland and Norway are considered currently free from infection with *G. salaris*. The map produced through QGIS (free and open-source Geographic Information System)

According to Annex I to Commission Implementing Decision (EU) 2021/260[4] as amended, Ireland (whole territory), the United Kingdom (Northern Ireland) and certain water catchment areas of Finland are considered currently free from infection with *G. salaris*. In addition, according to Annex I to EFTA Surveillance Authority Delegated Decision No 203/21/COL[5] most of the catchment areas in Norway are considered free from infection with *G. salaris*.

[3] https://www.eurl-fish-crustacean.eu/
[4] Commission Implementing Decision (EU) 2021/260: https://eur-lex.europa.eu/eli/dec_impl/2021/260/oj
[5] EFTA Surveillance Authority Delegated Decision No 203/21/CO: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3AE2021C0203

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

G. salaris is endemic in Atlantic salmon east of the Baltic Sea but has spread outside these areas via transport and reservoir hosts and stocking of fish (Hansen et al., 2022). In Russia, it is endemic in wild salmon and rainbow trout farms. The parasite is endemic in western Sweden, northern Finland and northern Russia (Peeler and Thrush, 2004). It has been responsible for severe epidemics in Atlantic salmon in rivers draining into the North Atlantic Ocean and the White Sea since the 1980s when *G. salaris* was first found (Hansen et al., 2022).

Risk of introduction

Parameter 3 – Routes of possible introduction

Reservoir hosts, transport hosts and stocking fish are thought to be responsible for the spread of the parasite between countries (Paladini et al., 2014). *G. salaris* has spread between rivers and farms mainly by the translocation of live fish. Fish migrating through brackish water can also spread the parasite between rivers. Populations located near infected rivers are at great risk of infection if they are located within the same brackish water system. Given the reproduction model of *G. salaris,* if the parasite is introduced into a farm with Atlantic salmon, there is a high possibility that all fish in the farm will become infected, depending on the layout of the farm (WOAH, 2021).

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

The main route of transmission is the movement of live animals, although dead fish can also contribute to the distribution of the parasites. The movement and trade of live *G. salaris* susceptible species occurs mostly for aquaculture and a food commodity. The trading patterns are complex (Peeler and Taylor, 2011); MSs should record imports and movements for the purpose of aquaculture and hold records of commodity trade; however, these records do not appear to be stored in a centralised repository and are therefore not readily available. This is a significant knowledge gap.

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

As previously discussed, the duration of the infectious period will depend on the host (e.g. more or less susceptible) and the environmental conditions (e.g. salinity level, temperature, etc.). Although the infectious period is variable, the maximum duration of parasites present on hosts (which would indicate infectivity) in published studies was 150 days post infection (Bakke et al., 1996). Evidence has shown that *G. salaris* has been reported to remain present in experimentally infected Scottish and Norwegian stocks of salmon up to 50 days post infection (Bakke and MacKenzie, 1993). *G. salaris* tends to persist longer on starved than on fed trout, where the maximum persistence was 50 days (Jansen and Bakke, 1995). Parasite reproduction also occurred among grouped grayling as judged from the duration of infection of more than 50 days (Soleng and Bakke, 2001). Persistence in the fish population is sometimes achieved when fish avoid the treatment; for example, Arctic charr can avoid rotenone treatment if in small streams and they can be the source of re-infection of a particular river in Northern Norway for 77 days post infection (Winger et al., 2008). In susceptible individually isolated grayling, parasite reproduction can last for more than 35 days (Soleng and Bakke, 2001).

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

Regulation (EU) 2016/429 (AHL)[6] prevents trade in fish species susceptible to listed diseases from a country, zone or compartment with a lower health status than the place of destination. Countries considered as free from *G. salaris*, such as Ireland should only receive fish from approved *G. salaris*-free countries or zones or compartments, other than when consignments comply with the conditions which are set out in paragraph 2 of Article 4 of Commission Implementing Decision (EU) 2021/260. Entry into the Union from non-EU Countries should occur through designated border control posts (BCP), where official veterinarians check that consignments of susceptible fish have a health certificate provided by the exporting country that confirms they originate from a disease-free country, zone or compartment. Stockists of fish within MS are obliged to adopt good biosecurity practices (such as quarantine).

[6] Animal Health Law: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32016R0429

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

Because of their reproductive model, there does not appear to be any significant latent infection period and hosts are likely to be infectious as soon as they get infected.

G. salaris parasites may attach themselves to any fish species inhabiting freshwater or brackish environments, which is considered a susceptible species, for short periods of time and be carried to infest susceptible fish (Soleng and Bakke, 1997). The presence and duration of the pathogen in healthy carriers appears to be associated with environmental temperature, water salinity and other environmental factors. For example, *G. salaris* was present in the European eel (*A. anguilla*) for 8 days (Bakke et al., 1996). In alpine bullhead (*C. poecilopus*) 8 to 9 days post infection at high temperature (11.5°C), the infection of *G. salaris* was eliminated, whereas at low temperatures (6.5°C) infections persisted for 47–48 days (Bakke et al., 2019). Following an experimental infection study in brown trout (*S. trutta*), *G. salaris* was present for up to 50 days post infection (Jansen and Bakke, 1995).

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

From a simulation study from the UK, which is one of the few European countries that are confirmed free of *G. salaris*, it was shown that the risk of introducing *G. salaris* by the importation of species other than live salmonids such as eels and non-salmonid fish is rather low. This is because the likelihood of infection is very low in these species and the parasite can only survive on these hosts for less than 50 days (Peeler and Thrush, 2004). The importation of rainbow trout (*O. mykiss)* carcasses from *G. salaris* infected freshwater sites might introduce the parasite in the establishment and is only likely if carcasses are processed on a salmonid farm in the UK. Among the various mechanical transmission routes that have been considered (e.g. angling equipment, canoes, ballast water) the movement of live fish transporters was considered the most important one (Peeler and Thrush, 2004). An older study from Norway showed that the probability of introduction of *G. salaris* to the Tana River via transfer of smolt to the existing salmon farm is extremely low, primarily due to the low probability that the transferred smolt become infected. The total risk was very sensitive to changes in the salinity of the water at the sea site (Paisley et al., 1999).

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

Diagnostic tools

Parameter 1- Existence of diagnostic tools

Usually, there are no clinical signs when fish are colonised by up to a few 10s of parasites. For heavier infections clinical and behavioural signs and gross pathology provide a diagnosis. Scrapings (wet mounts) from skin or fins can be used to detect *Gyrodactylus* spp. specimens on infected fish, but only in cases of heavy infections. While the use of stereo dissection microscopes can establish the presence of *Gyrodactylus* spp., species identification usually involves a combination of molecular approaches (PCR/sequencing) coupled with direct observation of the sclerites of the attachment organ (opisthaptor) using a compound light microscope, often following digestion to free the sclerites. Identification of *G. salaris* based on morphology and morphometry (Shinn et al., 2004) requires considerable expertise and is not able to distinguish between the different genotypes found on Atlantic salmon, grayling and rainbow trout. Importantly, co-infection of *G. salaris* with *G. derjavini*, *G. teuchis* or *G. truttae* on individual fish is very common and these species are almost 100% prevalent in wild Atlantic salmon, brown trout and rainbow trout demanding very intensive sampling and testing on single species level to rule out the presence of *G. salaris* (Jørgensen et al., 2008). Molecular techniques, including PCR and sequencing, can be used for definitive diagnosis, although morphological/morphometric confirmation is advised for critical decisions. WOAH recommends that for the surveillance of apparently healthy animals and the diagnosis of clinically affected animals, a combination of morphological examination and PCR (Real-time or conventional PCR) targeting the ITS1 region are required. Definitive confirmation of this diagnosis is achieved with conventional PCR and amplicon sequencing of a partial COI gene PCR product. The COI sequence allows for discrimination between the *G. salaris* and the *G. thymalli* genotypes found on salmon and trout and should be controlled and those genotypes found on grayling, which currently do not need to be controlled. The accession numbers of the nucleotide sequences for the different genotypes are provided in the WOAH manual. Some limited multi-centre testing and validation of available molecular, morphological and morphometric techniques was conducted by (Shinn et al., 2010) but this predates modern sequencing technologies (WOAH, 2021).

Recently, the effectiveness of a non-lethal hydrogen peroxide bath treatment was investigated as a means of sampling. This bath treatment resulted in gyrodactylid recovery rate for morphological examination of up to 85% of the population (Thrush et al., 2019) and the salmon can be returned to the river unharmed. This method may be successfully applied to the surveillance of gyrodactylid parasites and established as a non-lethal method for sampling farmed and wild fish.

Control tools

Parameter 2 – Existence of control tools

Currently, the control of *G. salaris* infections mainly relies on bath treatment with broad anti-parasitic chemical therapeutants, such as mebendazole, trichlorfon, praziquantel and formaldehyde (Tu et al., 2018) and chemicals such as rotenone. The use of these compounds is often accompanied by serious drawbacks including environmental contamination, risk of residues and toxicity to the host. Novel compounds such as arctigenin are currently under investigation.

G. salaris is sensitive to the most commonly used chemicals for bath treatment of farmed salmon parr and salmon eggs (e.g. high-salinity salt water, formaldehyde and compounds containing chlorine and iodine) (WOAH, 2021).

Rotenone is a naturally occurring substance derived from plants. It is highly toxic to fish and certain invertebrates. It has been used in Norway to eradicate *G. salaris*. Several different protocols have been used over the years, with variable success. The latest one, which entails the use of piscicide, CFT-Legumine®, which contains 3.3% active rotenone was applied at a dose of 1 mg/L using a range of application methods aiming to achieve concentrations of 0.033 mg/L rotenone. For the application of the product, different equipment suited for different purposes and challenges was used. It was adapted to the challenges met by the individual river, for example, it was adapted to accommodate rugged, stony and fast flowing white water. The techniques applied, the rotenone concentrations used and treating two consecutive years had a major role in the Norwegian battle against *G. salaris* (Sandodden, 2018).

Alternatives to *G. salaris* control include the use of metal ions, selective breeding and biological control. *G. salaris* is sensitive to aluminium sulphate which is better tolerated by fish at the concentration used compared to rotenone. It has been used in attempts to eradicate the parasite from river systems, by means of depopulation of the whole river in Norway (Soleng et al., 1999). An essential part of a *G. salaris* eradication programme is the reintroduction of the native fish stocks affected by the rotenone treatment. This strategy involves the use of both living gene bank and milt bank (Sandodden, 2018).

Additional control methods include hyperparasitism, which is one option for biological control and electron microscopy has revealed two hypersymbionts on the tegument of *G. salaris* that could potentially be used for biological control: microcolonies of unidentified rod-shaped bacteria and *Ichthyobodo necator* (Protozoa; Prokinetoplastida) (Bakke et al., 2006). To avoid the spread of infective agents between units in freshwater fish farms general recommended husbandry protocols are required; for example, equipment (e.g. fish nets) used in one unit should not be used in another without adequate disinfection (WOAH, 2021).

3.1.2. Article 7(b) The impact of disease

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

The level of presence of the disease in the Union

Parameter 1 – Number of MSs where the disease is present

In a recent review by Paladini et al. (2021) *G. salaris* was reported in 23 out of 50 states throughout Europe, but only records of 14 of these were confirmed by morphology or molecular tests (Paladini et al., 2021) among them 9 EU MSs: Denmark, Estonia, Finland, Germany, Italy, Latvia, Poland, Romania, Sweden. While for five EU MSs (Czechia, France, Portugal, Slovakia and Spain) further examination is required to confirm *G. salaris* presence or absence.

The loss of production of the disease

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

Mortality in farmed Atlantic salmon fry and parr can be 100% if not treated. Mortality in wild Atlantic salmon fry and parr in Norwegian rivers can be as high as 98%, with an average of about 85%. Mortality in other susceptible host species is usually low or not observed (WOAH, 2021).

In Norway, the yearly socio-economic loss due to the parasite has been estimated to be NOK200-250 million (17.5–22 m€) including both direct losses, such as loss of income from sport fisheries and fisheries in fjords, and secondary effects, such as those related to loss of tourism income (North-East-Atlantic-Commission, 2006).

Fishery losses due to *G. salaris* have been estimated at over 40% of the total reported catch of wild salmon in countries where the disease is endemic (Marine Scotland, 2016).

For Scotland, U.K. potential economic losses from the introduction of *G. salaris* were estimated at £34.5 M (~ 40 M€) to household income and £633 M (~ 736 M€) Net Economic Value per annum as well as the loss of 1,966 Full Time Equivalent jobs (Riddington et al., 2006).

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

Transmissibility between animals and humans

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

There is no evidence in the literature that *G. salaris* infects humans.

Parameter 2 – Incidence of zoonotic cases

There is no evidence in the literature that *G. salaris* infects humans.

Transmissibility between humans

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

There is no evidence in the literature that *G. salaris* infects humans.

Parameter 4 – Sporadic, endemic, epidemic or pandemic potential

There is no evidence in the literature that *G. salaris* infects humans.

Parameter 5 – Disability-adjusted life year (DALY)

There is no evidence in the literature that *G. salaris* infects humans.

The availability of effective prevention or medical treatment in humans

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

There is no evidence in the literature that *G. salaris* infects humans.

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

There is no evidence in the literature that *G. salaris* infects humans.

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

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

High susceptibility following experimental infection and ability to sustain an infection was evidenced in Arctic charr, particularly fry stages (Winger et al., 2008). Baltic strains of Atlantic salmon (*S. salar*) generally do not suffer from clinical disease, although variation is evident (Bakke et al., 2004a) and clinical signs may be observed if a high number of parasites is present. Infection of other strains of Atlantic salmon in Norway has resulted in high levels of juvenile salmon mortality and highly significant reductions in the population (Bakke et al., 1990; Paladini et al., 2014). All stages of the host are susceptible, but mortality has only been observed in fry and parr stages. Evidence for some susceptibility following experimental infection has been shown in brown trout (Jansen and Bakke, 1995), to grayling (*T. thymallus*) (Soleng and Bakke, 2001), but experimental infections have not been sustained for long in these species. If *G. salaris* is introduced into a farm with Atlantic salmon, there is a high probability that all fish in the farm will become infected, depending on the layout of the farm. Infected fish are more susceptible to secondary infections by fungal pathogens, which may contribute to the mortalities observed in the infected population. *G. salaris* can be present in farmed rainbow trout (*O. mykiss*) where it can persist in low numbers and without clinical signs (Paladini et al., 2021; Hansen et al., 2022).

Behavioural changes may also be evident. Flashing is common among moderate to heavily infected farmed fish as they scratch their skin on the bottom or wall of a tank or pond. Heavily infected fish may have reduced activity and stay in low current areas (WOAH, 2021).

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 species listed as being infected by *G. salaris* are listed as endangered or critically endangered in the IUCN red list. None of the species listed appears under any of the CITES appendices.

Parameter 2 – Mortality in wild species

G. salaris results in high mortality in wild fish in rivers, e.g. in Norway, it has caused up to 98% mortality of Atlantic salmon in some rivers (See sections 3.1.1.2 and 3.1.2.1).

Environment

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

Survival of detached parasites depends on temperature; they survive for about 24 h at 19°C, 54 h at 13°C, 96 h at 7°C and 132 h at 3°C (Olstad et al., 2006). Likewise, survival, when attached to a dead host, is temperature dependent: *G. salaris* can survive on dead Atlantic salmon maximum 72, 142 and 365 h at 18, 12 and 3°C, respectively (Olstad et al., 2006). *G. salaris* is known to survive between 0°C to 25°C. Tolerance to temperatures above 25°C is unknown. It is not resistant to freezing. *G. salaris* is sensitive to desiccation. *G. salaris* dies after a few days at $pH \leq 5$. It is more sensitive to low pH ($5.1 < pH < 6.4$) in association with aluminium and zinc than the host Atlantic salmon (Soleng et al., 1999).

G. salaris results in high mortality in wild fish in rivers, e.g. in Norway, it has caused up to 98% mortality of Atlantic salmon in some rivers (See sections 3.1.1.2 and 3.1.2.1).

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

G. salaris is not listed by the Center for Food Security and Public Health (CFSPH).[7]

Infection with *G. salaris* is listed as a notifiable disease by the WOAH.[8]

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

G. salaris is not listed in the Encyclopaedia of Bioterrorism Defence of Australia Group.

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

G. salaris is not listed as a potential bio–agro-terrorism agent. It is also not included in the list[10] of the Centers for Disease Control and Prevention (CDC) as an agent for emergency purposes.

[7] https://www.cfsph.iastate.edu/diseaseinfo/
[8] https://www.woah.org/en/home/
[9] http://www.australiagroup.net/en/human_animal_pathogens.html
[10] https://emergency.cdc.gov/agent/agentlist-category.asp

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

Screening of individual parasites on the host species by real-time PCR targeting the ITS1 region is the recommended test for surveillance to demonstrate freedom of disease in apparently healthy populations. The methods currently available to tentatively identify gyrodactylosis are the following: morphological examination, morphometrics, real-time PCR (using individual parasite samples), ddPCR/RT-PCR (using environmental sample). However, sequencing of the partial CO1 gene target is required to confirm the *G. Salaris* or *G. thymalli* genotype to establish if any parasites tentatively identified as *G. salaris* need to be controlled. (WOAH, 2021).

For confirmatory diagnosis, morphological and molecular techniques should be applied in combination. Although its potential is recognised, WOAH does not currently recognise environment screening as confirmation of infection in a population, as environmental DNA methods will not be an appropriate choice for many aquatic animal disease surveillance purposes (WOAH, 2022).

It should be mentioned that some non-pathogenic *G. salaris* strains to *S. salar* have been described; these strains have a low number of nucleotide differences in their ITS rDNA which can be used to develop specific RFLP-based diagnostic tests (Kania et al., 2007). Morphometrical analysis may be suitable to distinguish between some of the non-pathogenic strains although this has not been fully validated (Shinn et al., 2010).

Effectiveness

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

There are no quantitative data yet available for the diagnostic performance of tests recommended for surveillance or diagnosis, as indicated by WOAH. The diagnostic performance of the tests is specific to the circumstances of each diagnostic accuracy study (including the test purpose, source population, tissue sample types and host species) and diagnostic performance may vary under different conditions (WOAH, 2021).

One study showed that molecular diagnostics, such as RT-PCR offer high-analytical sensitivity (limit of detection: 10^{-4}) and depending on the chemistry used they can offer high-analytical specificity through the use of a probe alongside the amplification primers. However it is not always possible to differentiate between *G. salaris* and the non-pathogenic *G. thymalli* (Collins et al., 2010). CO1 sequence analysis is required to differentiate between these two.

Another study by Shinn et al. (2010) suggests that when a small number of specimens need to be identified, the three methods tested (molecular, morphological identification and statistical approach), when performed by adequately trained personnel, are effective in discriminating '*G. salaris*-like' specimens, but only the combined molecular approach provides a definitive identity. Taking into consideration the causes of potential specimen loss, the highest likelihood of correctly identifying *G. salaris* in a sample was with molecular methodologies (92%), visual characterisation (81%) and morphometric was the lowest (58%). In addition, the probability of a specimen being accurately identified was 92%, 95% and 87% by molecular techniques, visual and morphometric techniques respectively.

Optical equipment must be used to detect *G. salaris*. In the case of a suspected outbreak of infection with *G. salaris* where only light microscopy is available, wet mounts can be used to detect *Gyrodactylus* specimens. However, it is advised not to use this method in a surveillance programme as the presumed specificity and sensitivity are low (values not known) and, therefore, the number of fish examined needs to be high (WOAH, 2009).

The detection of *G. salaris* environmental DNA (water filtering) has been proposed as a complementary method to standard surveillance methods used, as it is less invasive and has high-analytical sensitivity (500 to > 350,000 copies per litre of water). It is still not possible to differentiate between *G. salaris* and the non-pathogenic *G. thymalli* with this later method (Rusch et al., 2018).

Feasibility

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

To detect and isolate worms, fish can be examined under a stereo dissection microscope as whole specimens either live under anaesthesia (for example, with MS222), freshly killed or preserved. In addition, fresh or preserved fins can be examined. Examination of live, anaesthetised fish is very time-consuming and not recommended. Instead of examining the whole fish, the fins can be examined. When Norwegian salmon parr are infected, almost all fish have at least one *G. salaris* on one of the fins. On some fish, *G. salaris* may be present on the body or head, including the nostrils, the gills and the mouth cavity. The distribution of *G. salaris* on fins and other parts of the fish varies among fish species and seems to vary among salmon strains. Fish should be killed immediately and should not be allowed to dry out before preservation. Whole fish should be preserved in 80–100% Ethanol (EtOH) in bottles large enough to provide excess space and preservatives. The concentration of EtOH after preservation should not be below 70% (WOAH, 2021).

Recently, efforts have been diverted towards developing a diagnostic method based on environmental samples with *G. salaris* DNA (water samples). This method is less invasive and has the potential to complement existing diagnostic methods (Rusch et al., 2018; Fossøy et al., 2020).

Article 7(d)(ii) Vaccination

Availability

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

There are currently no authorised vaccines for *G. salaris*.

Parameter 2 – Availability/production capacity (per year)

There are currently no authorised vaccines for *G. salaris*.

Effectiveness

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

There are currently no authorised vaccines for *G. salaris*.

Parameter 4 – Duration of protection

There are currently no authorised vaccines for *G. salaris*.

Feasibility

Parameter 5 – Way of administration

There are currently no authorised vaccines for *G. salaris*.

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

Availability

Parameter 1 – Types of drugs available on the market

As mentioned earlier, *G. salaris* is sensitive to the most commonly used chemicals for bath treatment of farmed salmon parr and salmon eggs (e.g. high-salinity salt water, formaldehyde and compounds containing chlorine and iodine). Furthermore, *G. salaris* is sensitive to acidic solutions (pH 5.0–6.0) of aluminium sulphate (Soleng et al., 1999). As aluminium sulphate is less toxic to fish than to *G. salaris* in moderately acidified waters unlike rotenone, this chemical has been used in attempts to eradicate the parasite from river systems in Norway. Eggs that are transferred from infected farms should be disinfected (iodine-containing compounds have been used) (WOAH, 2021).

As previously mentioned, in Section 3.1.4.1 (*Article 7(a)(viii) The existence of diagnostic and disease control tools*), rotenone treatment has been extensively used in Norway as an essential part of a *G. salaris* eradication programme. *In vitro* data showed that incubation of *G. salaris* in Virkon S results in cessation of movement of *G. salaris* and the Virkon S concentration was found to be associated with this. For a 6log reduction of the *G. salaris*, a load 102 s was required in 1% Virkon solution (Koski et al., 2016). The use of anthelmintics and other parasiticides have been used in water baths for *G. salaris* control. Most of the drugs used were toxic to fish, or not efficient against

G. salaris; bithionol and nitroscanate were the only two tested that showed 100% efficacy at a concentration that was not toxic for the fish (Santamarina et al., 1991).

Parameter 2 – Availability/production capacity (per year)

All the potential drugs and chemicals that can be used for *G. salaris* control should be readily available, although there were no specific quantitative data on this.

Parameter 3 – Therapeutic effect in the field (effectiveness)

It was not possible to find quantitative field data, so this is a knowledge gap. Data from experimental trials showed that exposure to low concentrations of sodium hypochlorite may have a role to play in controlling *G. salaris in* the field. The parasite infection was eliminated by day 6–8 and day 2–4 in the groups on the medium and high concentrations respectively. Importantly, *G. salaris* specimens observed on day 6 in medium and on day 2 in high concentrations were all considered dead by subjective judgement. No mortality in the salmon parr was observed during the first 8 days of the experiment, indicating this may be a useful tool as a parasiticide in large-scale treatments in natural river systems (Hagen et al. 2014).

Rotenone, a naturally occurring complex ketone, has been previously used in the field to remove all potential hosts of *G. salaris* and consequently destroy the parasite by chemical treatment. This strategy was used in Norway to eradicate *G. salaris* from the Norwegian rivers; field data show that even this very aggressive strategy is not 100% efficient. Of 48 rivers to which the parasite had been spread, 34 were treated using rotenone and there was partial success; at the beginning of the year 2022 *G. salaris* was still confirmed present in eight Norwegian river systems (Norwegian Veterinary Institute, 2022).

In contrast to rotenone, aluminium sulphate will kill the parasite but not the fish host. Exposed to water containing 200 μg L^{-1} aluminium sulphate at pH 6.1, the *G. salaris* infection was removed in 4–6 d without aluminium sulphate-related fish mortality (Poléo et al., 2004).

Feasibility

Parameter 4 – Way of administration

In general *G. salaris is* killed by the most commonly used chemicals for bath treatment of farmed salmon parr and eggs (e.g. high-salinity salt water, formaldehyde and compounds containing chlorine or iodine (Thrush et al., 2019).

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

Availability

Parameter 1 – Available biosecurity measures

As previously mentioned, *G. salaris* is sensitive to changes in the chemical composition of the water and killed by the most commonly used chemicals for bath treatment of farmed salmon parr and eggs (e.g. high-salinity salt water, formaldehyde and compounds containing chlorine or iodine) (Thrush et al., 2019). *G. salaris* is sensitive to acidic solutions (pH 5.0–6.0) of aluminium sulphate and zinc (Zn) (Soleng et al., 1999; Poléo et al., 2004). Aluminium sulphate is less toxic to fish than to *G. salaris* in moderately acidified waters and has been used to eradicate the parasite from one river system in Norway (Pettersen et al., 2007). It has also been found that *G. salaris* is sensitive to low doses of chlorine (Hagen et al., 2014).

According to EU Regulation (EU) 2016/429 fish business operators within MSs are obliged to adopt good biosecurity practices (such as quarantine, cleaning and disinfection, establishment and equipment maintenance) and ensure the internal and external traceability of their stock.

Biosecurity measures associated with leisure activities, such as canoeing should also be considered particularly when travelling from infected to *G. salaris*-free countries. For example, thoroughly drying equipment for at least 48 h or drying in sunlight in temperatures above 20°C. Alternatively, disinfecting by immersing equipment in seawater or a salt solution (sodium chloride concentration of 3% or more) for a minimum of 10 minutes can kill the parasite. All equipment should then be thoroughly rinsed in tap water, according to the guidelines provided by the Department for Environment, Food & Rural Affairs (Defra) (British Canoeing, 2023).

Effectiveness

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

Safe sourcing of fish is probably the most effective measure, but this is complicated by the fact that there are asymptomatic hosts that carry a small number of parasites but also other fish that may carry the parasite at low levels and they are difficult to identify. This is particularly relevant for non-target fish, for example rainbow trout, although the risk is small, as the prevalence is often relatively low (Peeler and Thrush, 2004).

Feasibility

Parameter 3 – Feasibility of biosecurity measure

Testing fish on arrival at border inspection posts cannot be considered as feasible, because of the volume; only a small proportion of fish are likely to be tested. Additionally, there are logistical issues with holding fish in biosecure conditions under good welfare standards whilst awaiting test results for the purpose of quarantine. In addition, there is always the complication that *G. salaris* can be transported on non-target fish and also detached if the conditions are appropriate (Peeler and Thrush, 2004).

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

Availability

Parameter 1 – Available movement restriction measures

Regulation (EU) 2016/429) prevents trade in fish species susceptible to listed disease from countries with a lower health status than the country of destination and foresees movement restrictions. To date, only Ireland within the EU, and the UK have been reported as *G. salaris*-free and therefore only they can restrict the import of susceptible species from known *G. salaris* positive countries. In addition, the *G. salaris* status is unknown in more than 10 MSs, as mentioned earlier in Section 3.1.2.1 (Paladini et al., 2021). At the national level, movement restrictions can be applied to *G. salaris* positive sites. Finland for example, although is a *G. salaris* positive state, parts of the country are recognised to be *G. salaris*-free; samples from wild fish and farmed fish from within the *G. salaris*-free and buffer zones are examined yearly (Paladini et al., 2021). These controls all rely on an effective surveillance, testing and reporting system.

Effectiveness

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

Dispersal of infected live fish is considered to be the main cause of inter-river dispersal of *G. salaris* (Peeler and Thrush, 2004) and as a consequence, restricting animal movement should be effective and help towards preventing the between farm spread. The risk of inter-river dispersal by free-living *G. salaris* is relatively low (Høgåsen et al., 2009).

Feasibility

Parameter 3 – Feasibility of restriction of animal movement

The ability to apply movement restrictions at national and international level will vary depending on the resources available within each MS to perform an effective surveillance and detection programme and enforce movement restrictions and measures applied to infected sites. An example was mentioned above, where in Finland movement between *G. salaris* positive and *G. salaris*-free areas is controlled and informed by annual examinations of fish (Paladini et al., 2021). In the UK, mandatory surveillance programmes by the relevant fish inspectorate authorities within each constituent country continue to screen fish samples for *G. salaris* (Paladini et al., 2021). It is unclear whether it is feasible to implement the movement restrictions Europe-wide.

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

Availability

Parameter 1 – Available methods for killing animals

The obligate lifecycle and a distribution restricted to the anadromous zone of freshwater systems make the eradication of *G. salaris* possible. To achieve that, rotenone is most commonly used and kills all fish able to harbour the parasite. The best-known example is the use of rotenone to treat Norwegian rivers as discussed earlier in Section 3.1.1. After a period of monitoring to ensure all fish have been removed, the river can be restocked using eggs from stocks that were removed prior to rotenone treatment (Adolfsen et al., 2021). Depending on the timing of the treatment, re-stocking can also occur through *G. salaris*-free adults returning from the marine environment.

Effectiveness

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

After successful eradication in small and medium-sized rivers during the 1980s with rotenone treatment, there were a series of failed eradication attempts in several more complex river systems from the late 1980s to the early 2000s in Norway (Adolfsen et al., 2021). It was thought that Arctic charr (*S. alpinus*) was potentially a long-term host for the parasite and the infected charr was documented to have survived in small, groundwater-fed tributaries and ponds during the first two eradication attempts. In a third attempt to get Skibotn Region *G. salaris*-free status, treatment for two consecutive years was the main strategy improvement from previous eradication attempts. To the best of our knowledge, this area is now *G. salaris*-free. In this example, it was effective to kill animals to reduce and stop the spread of the disease.

Feasibility

Parameter 3 – Feasibility of killing animals

Biocidal products containing Rotenone can be made available on the market of EU MSs under their transitional regimes in accordance with Article 89 (2) of the Biocidal Product Regulation; Regulation (EU) 528/2012[11]. Such treatments are economically and environmentally costly, but they also eradicate the potential for any host/parasite evolutionary process to occur (Denholm et al., 2017). This lack of host-pathogen co-evolution is considered responsible for the highest susceptibility of Norwegian Atlantic Salmon compared to the Baltic strains.

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

Availability

Parameter 1 – Available disposal option

EU legislation[12,13] on animal by-products not intended for human consumption set out the permissible ways of dealing with various sorts of animal by-products. Carcasses from fish killed or found dead due to infection with *G. salaris* belong to the category II materials and should be disposed and destroyed according to the rules outlined in EC Regulation 1069/2009[9] and EC Regulation 142/2011[10]. The carcases and any relevant by-product must be transported in a sealed container and recorded on both arrival and departure of any site and should be disposed and processed at an approved establishment. A list of approved premises by MSs can be found at European Commission webpage.[14]

Effectiveness

Parameter 2 – Effectiveness of disposal option

Rendering is an effective disposal method for destroying pathogens. Rendering converts waste animal tissue into stable, value-added products. The process simultaneously dries the material and separates the fat from the bone and protein. Tissues are macerated, heated and then subject to centrifugal separation (Vidyarthi et al., 2021).

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[11] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (Text with EEA relevance)Text with EEA relevance: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02012R0528-20220415&qid=1690214954079

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

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

[14] https://food.ec.europa.eu/safety/animal-products/approved-establishments-abp_en

Feasibility

Parameter 3 – Feasibility of disposal option

Rendering is a feasible option if an approved establishment is located within a reasonable distance from the farm and if is willing to accept fish carcasses and other relevant by-products and approved transport is available (EFSA AHAW Panel, 2017b).

3.1.4.7. Article 7(d)(viii) Selective Breeding; Genetic resistance to infection

Availability

Parameter 1 – Available breeds resistant to the pathogen

The Norwegian Atlantic salmon is in general considered more susceptible to *G. salaris* compared to the Baltic salmon (Bakke et al., 1990), although genetic resistance to *G. salaris* is complex, likely under polygenic control (Gilbey et al., 2006); and there have been populations of Baltic salmon equally susceptible to *G. salaris* as Norwegian salmon (Bakke et al., 2004a; Ramírez et al., 2015). There is some evidence for within-breed variation in susceptibility exhibited in European populations of Atlantic salmon (*S. salar*) ranging from resistance to extreme susceptibility; this appears to have a genetic basis (Zueva et al., 2014). Triploid Atlantic salmon of Baltic origin was more susceptible to *G. salaris* infection than their diploid counterparts, possibly due to compromised complement-dependent immune pathways in triploid salmon (Ozerov et al., 2010). In laboratory experiments, selective breeding of Atlantic salmon has resulted in increased survival among the offspring (Salte et al., 2009).

Effectiveness

Parameter 2 – Effectiveness of having resistant breeds

Although there is evidence of genetic resistance to *G. salaris,* stocking rivers with resistant strains is a strategy that has not been attempted because the stock will remain infected and thus the parasite may spread to other rivers and susceptible hosts (WOAH, 2021).

Feasibility

Parameter 3 – Feasibility of having resistant breeds

It has been suggested that stocking with resistant strains of Atlantic salmon (e.g. Baltic strain) in affected rivers is not considered compatible with existing strain management of Atlantic salmon (i.e. preservation of the genetic integrity of wild stocks, which may result in an overall reduction in viability of the wild salmon) (Karlsson et al., 2020; WOAH, 2021).

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)

There is not a lot of data on the cost of *G. salaris* control measures. Data from 2013 show that the Norwegian Government spends about €9 million per year for control measures including surveillance, preventing the spread of the parasite, eradication of the parasite from infected rivers and conservation and restoration of fish populations that are directly affected by the parasite or indirectly, as a result of the actions implemented for the parasite eradication. During the 35-year history of *G. salaris* in Norway, the expenditure has reached €90 million. If we include the loss of income on salmon fishing and loss of local economic ripple effects in the same period, a rough estimate suggests that Norway has a total economic loss of €430–538 million as a consequence of the introduction of *G. salaris* in 1975 (Steinkjer, 2013).

Scotland is currently free of *G. salaris*, but the government looked into a hypothetical scenario of invasion in order to calculate the cost of making the entire freshwater phase biosecure and that was estimated to be £30–40 million, ~ €33–35 million (Riddington et al., 2006).

Parameter 2 – Cost of eradication (culling, compensation)

There is not a lot of data on the cost of eradication, but the costs will be associated with the size and the structure of each site. Enormous efforts have been put into eradicating the parasite in Norway, including treating infected watercourses with rotenone and aluminium sulphate (sometimes requiring the construction of barriers to reduce the area to be treated and the use of gene banks) and surveillance and monitoring programmes. Successful eradication of the parasite has been carried out in several river systems in Norway, however not all succeeded to be *G. salaris*-free. Information provided by Norway in 2007 indicated that the total cost of the eradication programme would be NOK373-630 million. However, the annual socio-economic loss caused by the parasite was estimated to be NOK200-250 million (€175–220 million) (North Atlantic Salmon Conservation Organization, 2015).

Parameter 3 – Cost of surveillance and monitoring

Data from a 2007 report show that annual costs of surveillance and eradication of *G. salaris* in Norway are estimated at USD23 million (~ €20 million) per year although no accurate measurements are available for each component (Bakke et al., 2007).

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

In Norway, since the introduction of the disease, the parasite is estimated to have cost a total of USD450–600 million (~ €400–540 million) (Directorate for Natural Resources, May 2002), without including indirect costs due to restrictions on the export of live salmonids within the EU, or the costs of surveillance and control in other countries within or outside the EU (Bakke et al., 2007).

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

Without control measures, *G. salaris* would have reduced the Norwegian salmon fishery by at least 15% (Bakke et al., 2007).

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

No published studies on the societal acceptance of disease prevention and control measures for *G. salaris* were found. Disease control measures on farms are widely accepted by stakeholders. As the parasite is a major cause of concern for the welfare of the animals it is not expected that control measures will cause any societal concerns. The use of rotenone is controversial as it results in environmental pollution and contamination of fish products caused by drug residues. Structure decision-making (SDM) is a framework for working with diverse groups of people to improve clarity and consensus around decisions. One of the strengths of SDM is that it allows participation from stakeholders with divergent value systems, thereby leading to decision recommendations that reflect the broader society. The use of this framework has been considered to address invasive exotic species eradication or control decisions for natural resource management and may be a useful tool to discover the societal acceptance of control measures for *G. salaris* (Van Poorten and Beck, 2021).

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

For the period that fish are held for quarantine or whilst awaiting test results a suitable biosecurity system is necessary to hold the fish in a sustainable manner. Such systems must have sufficient space to hold the stock, have the ability to feed the fish and maintain the environmental quality of the water they are held in. Where the parasite is detected and the decision is made to cull the stock, care must be taken to employ a suitable humane method that can be applied to a potentially high number of fish (EFSA AHAW Panel, 2017b).

Parameter 2 – Wildlife depopulation as control measure

Wildlife depopulation *per se* is not considered a control measure for *G. salaris* control. As discussed previously rotenone has been used for the eradication of *G. salaris* in Norway; when *G. salaris* was detected on fish, rotenone was used to kill infected wild salmon and the parasite in Norwegian rivers. Depopulation of wild salmon in rivers diagnosed with *G. salaris* has resulted in some success, e.g. Signaldale river has been declared *G. salaris* - free after many years of control measures (Adolfsen et al., 2021). While there may have been some success in reducing the amount of parasite, rotenone does not just target one host or parasite, and its use has an impact on the environment since it can kill various species.

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)

Rotenone, according to the harmonised classification and labelling approved by the European Union, is toxic to aquatic life with long lasting effects (ECHA, 2023). Rotenone's half-life will depend on environmental conditions (e.g. temperature, pH) and varies from a few hours to several weeks. In a recent systematic review, it was demonstrated that in almost 50% of all studies applied rotenone for non-native fish removal (rather than pathogen control) this was applied in autumn rather than any other season (Rytwinski et al., 2018). Decisions on application of rotenone for control of *G. salaris* need to take into consideration migration patterns of the Atlantic salmon.

Biodiversity

Parameter 2 – Mortality in wild species

G. salaris is highly pathogenic to the East-Atlantic salmon in Norway, and it has devastated the populations of salmon fry in 46 Norwegian rivers. In wild rivers in Norway, it has caused up to 98% mortality of Atlantic salmon (Chong, 2022). Other hosts such as Arctic charr and rainbow trout do not show any mortality.

3.2. Assessment of infection with *Gyrodactylus salaris* according to Article 5 criteria of AHL on its eligibility to be listed

3.2.1. Detailed outcome on Article 5 criteria

The results of the collective expert judgement on the criteria of Article 5 of the AHL for infection with *G. salaris* are presented in Table 4 and Figure 2.

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

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

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

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**
B(iii)	The disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union	66–90	Fulfilled	0	14
B(iv)	The disease has the potential to generate a crisis, or the disease agent could be used for the purpose of bioterrorism	1–5	Not fulfilled	0	14
B(v)	The disease has or could have a significant negative impact on the environment, including biodiversity, of the Union	33–66	Uncertain	0	14

NA: not applicable.

In Figure 2, the outcome of the expert judgement is graphically shown together with the estimated overall probability of the infection with *Gyrodactylus salaris* meeting the criteria of Article 5 on the eligibility to be listed (Figure 3).

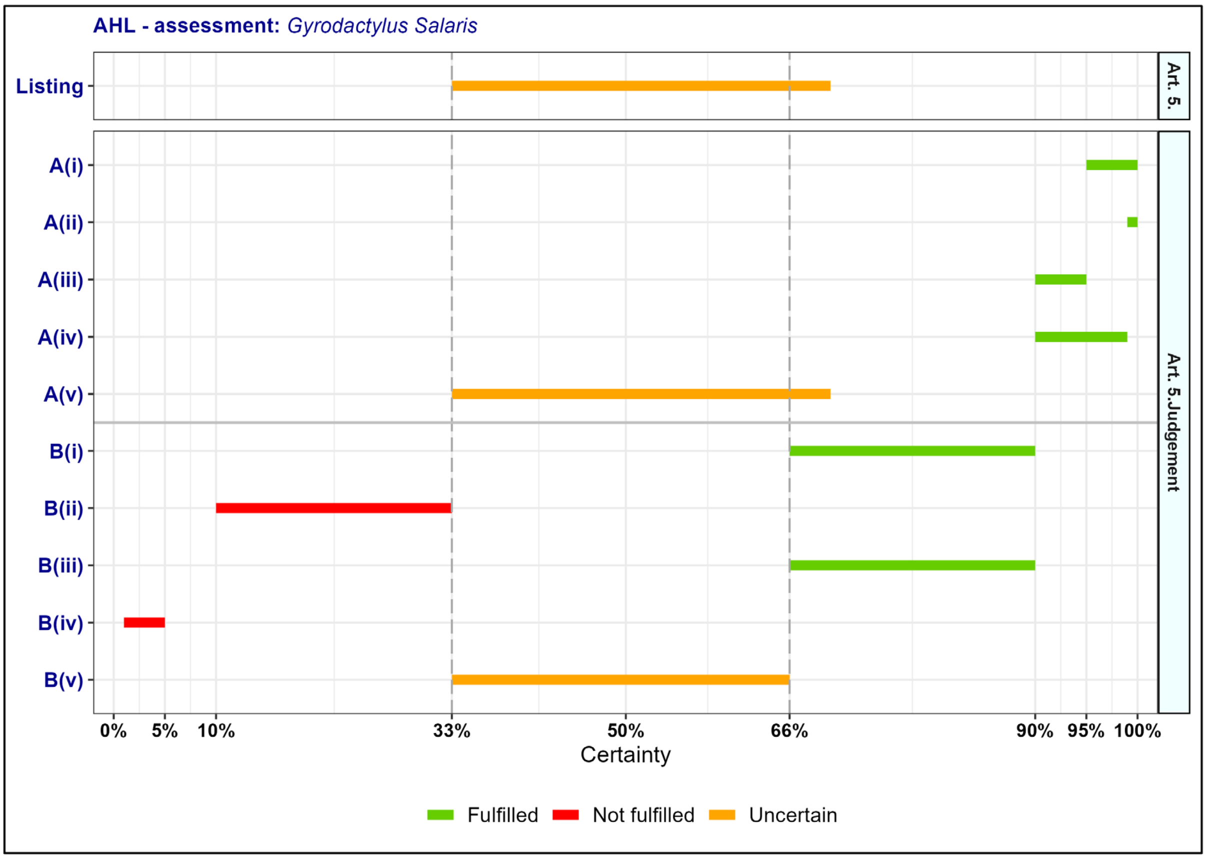


Figure 3: Outcome of the expert judgement on Article 5 criteria of AHL and overall probability of Infection with *Gyrodactylus salaris* on eligibility to be listed

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):*

- Currently, control of *G. salaris* infections relies on bath treatment with broad anti-parasitic chemical therapeutics, such as mebendazole, trichlorfon, praziquantel and formaldehyde and for wild fish species the treatment with chemicals such as rotenone. The use of these

compounds is often accompanied by serious drawbacks including environmental contamination, risk of residues and more critically toxicity to the host and other animals in the environment. Consequently, the impact of the implementation of these treatments, as a control measure, may not be proportionate to the risks posed by the disease.
- Movement controls are very difficult to implement, particularly for aquaculture establishments in contact with wild fish hosts.
- Studies have identified several vector or reservoir species that may carry a small number of parasites, which can be difficult to detect. Moreover, anthropogenic professional and leisure activities, where boats are moving between waters (e.g. canoes) or transported from one area to another, may contribute to a spread that might be difficult to control.
- There are no data on the effectiveness of the control of the *G. salaris* infection and surveillance activities, except from the example of Norway.
- Diagnostic tools are available with good performance in terms of *Se* and *Sp* and they can support the surveillance activities to detect the parasites. The surveillance activities to early detect the disease could be effective and feasible but the situation is not the same for the surveillance activities during the outbreaks. Consequently, the implementation of the surveillance activities in the field will be difficult and costly and thus is considered by the experts as not proportionate.

Criterion B(v) (*the disease has or could have a significant negative impact on the environment, including biodiversity, of the Union):*

- The impact of the treatment on the environment has not been considered in the assessment of this criterion.
- None of the susceptible species to *G. salaris* such as wild salmon and trout are listed as endangered. Nevertheless, some Norwegian strains of wild salmon are endangered but there is no information if these strains are present in EU countries.
- *G. salaris* may affect several wild species and may cause high morbidity and mortality. It is highly pathogenic to the East-Atlantic salmon in Norway, where it devastated the populations of salmon fry in 46 Norwegian rivers. It may result in high mortality in fish in wild rivers: as an example in Norway it has caused up to 98% mortality of Atlantic salmon.
- The infection with *G. salaris* is treated under some conditions but the impact of the treatment on the environment is considerable. The available treatment with substances such as rotenone in wild fish is highly toxic to aquatic life with long lasting effects in the rivers.

3.2.3. Overall outcome on Article 5 criteria

As from the legal text of the AHL, a disease is considered eligible to be listed as laid down in Article 5 of AHL if it fulfils all criteria of the first set from A(i) to A(v) and at least one of the second set of criteria from B(i) to B(v). According to the assessment methodology, a criterion is considered fulfilled when the lower bound of the median range lays above 66%.

According to the results shown in Table 4, Infection with *G. salaris* complies with four criteria of the first set (A(i)–A(iv)), but there is uncertainty (33–70% probability) on the assessment of compliance with criterion A(v). Therefore, it is uncertain whether Infection with *G. salaris* can be considered eligible to be listed for Union intervention as laid down in Article 5 of the AHL. The estimated overall probability range for the Infection with *G. salaris* being eligible to be listed is **33–70%** (see Figure 3).

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

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

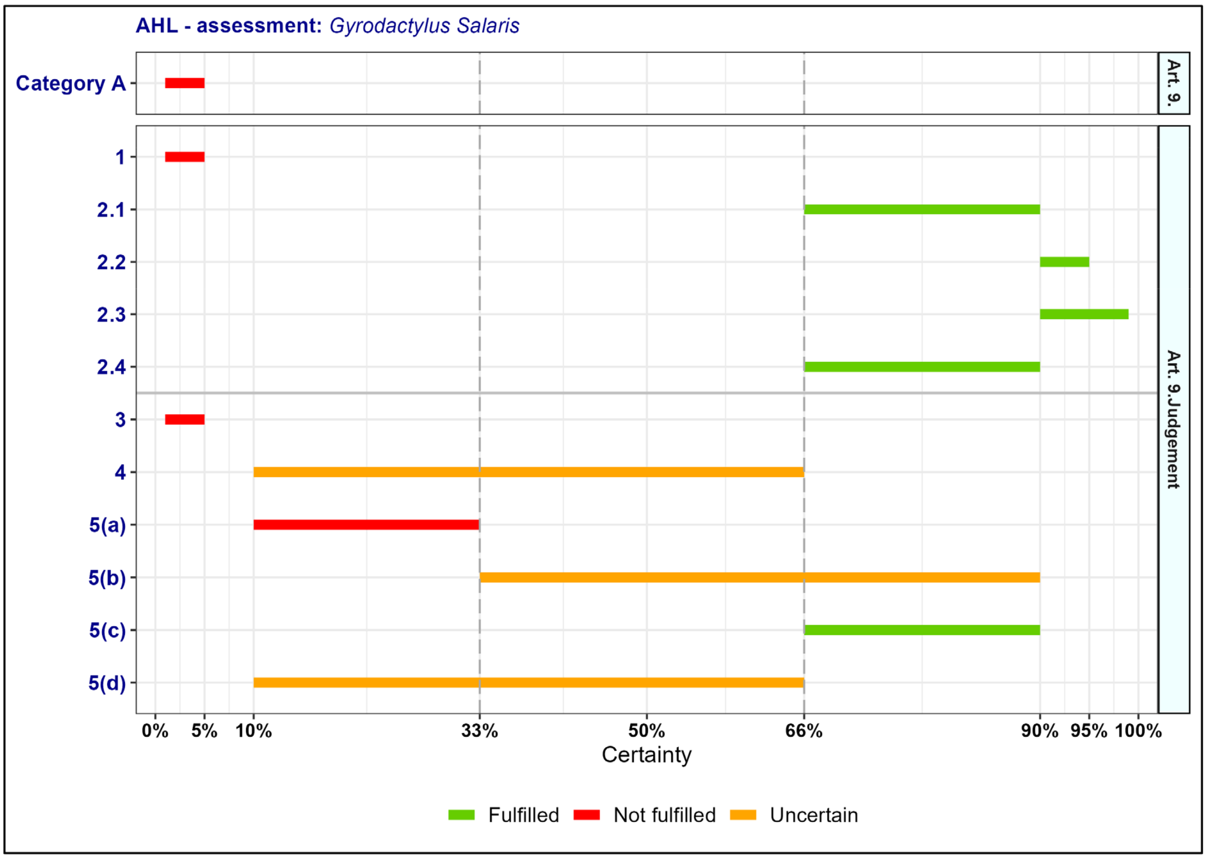
The distribution of the individual answers (probability ranges) provided by each expert for each criterion is reported in Appendix A.

3.3.1. Detailed outcome on Category A criteria

Table 5: Outcome of the expert judgement related to the criteria of Section 1 of Annex IV of AHL (Category A of Article 9 of AHL)

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		**Outcome**			
		Median range (%)	**Criterion fulfilment**	**Number of NA**	**Number of experts**
1	The disease is not present in the territory of the Union or present only in exceptional cases (irregular introductions) or present in only in a very limited part of the territory of the Union	1–5	Not fulfilled	0	14
2.1	The disease is highly transmissible	66–90	Fulfilled	0	14
2.2	There are possibilities of airborne or waterborne or vector-borne spread	90–95	Fulfilled	0	14
2.3	The disease affects multiple species of kept and wild animals or single species of kept animals of economic importance	90–99	Fulfilled	0	14
2.4	The disease may result in high morbidity and significant mortality rates	66–90	Fulfilled	0	14
At least one criterion to be met by the disease: In addition to the criteria set out above at point 1–2.4, the disease needs to fulfil at least one of the following criteria					
3	The disease has a zoonotic potential with significant consequences for public health, including epidemic or pandemic potential or possible significant threats to food safety	1–5	Not fulfilled	0	14
4	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	10–66	Uncertain	0	14
5(a)	The disease has a significant impact on society, with in particular an impact on labour markets	10–33	Not fulfilled	0	14
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	33–90	Uncertain	0	14
5(c)	The disease has a significant impact on the environment, due to the direct impact of the disease or due to the measures taken to control it	66–90	Fulfilled	0	14
5(d)	The disease has a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	10–66	Uncertain	0	14

NA: not applicable.



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

Figure 4: Outcome of the expert judgement on the criteria of Section 1 of Annex IV of AHL and overall probability of Infection with *Gyrodactylus salaris* to be fitting in Category A of Article 9 of AHL

3.3.1.1. Reasoning for uncertain outcome on Category A criteria

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

- Mortality in farmed Atlantic salmon fry and parr can be 100% if not treated. Mortality in wild Atlantic salmon fry and parr in Norwegian rivers can be as high as 98%, with an average of about 85%. Mortality in other susceptible host species is usually low or not observed.
- The cost to control the disease is high according to the experience in Norway where since the introduction of the disease, the parasite is estimated to have cost a total of USD450–600 million (approximately €400–540 million), without including indirect costs due to restrictions on the export of live salmonids within the EU, or the costs of surveillance and control in other countries within or outside the EU.
- When considering the whole Union, the importance of aquaculture (especially Atlantic salmon) seems too limited to consider it a significant impact, although there is more uncertainty if no control measures were in place. There are no data and information and therefore there is uncertainty around the costs and the estimation of the impact on the economy.

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

- Both the current and the potential impact on animal welfare has been assessed under this criterion. The current impact was considered low since the number of outbreaks is limited and concerns few countries.

- Given the high morbidity and mortality rates in affected farms (and in the wildlife), there seems to be potential for animal welfare concerns, particularly if no measures are in place.
- In large fish farms, where there are thousands of fish, *G. salaris* could spread quickly and cause damage to the fish gills and skin, which therefore would be a welfare issue.

Criterion 5d *(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):*

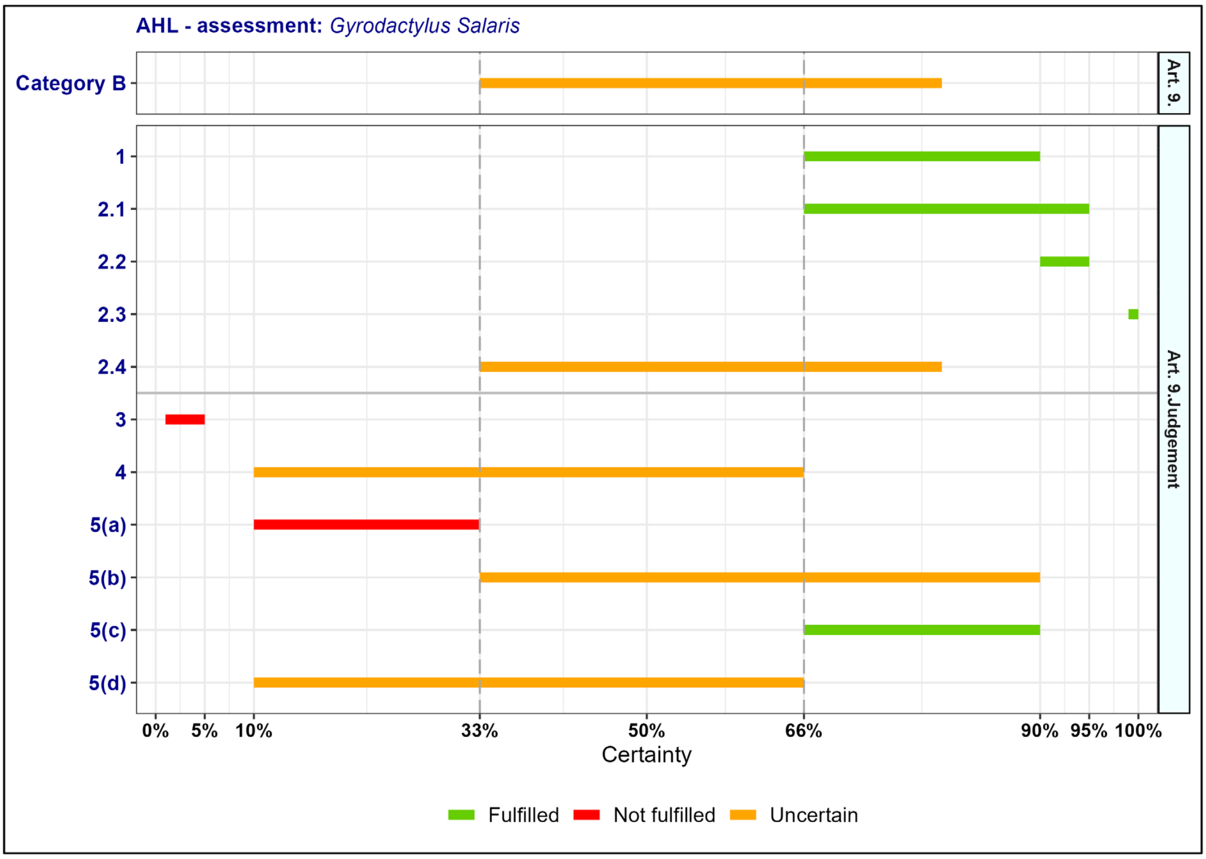
- Both the current and the potential impact have been assessed for this criterion. There is not enough evidence for the current impact.
- The potential impact however might be higher for wild Atlantic salmon.
- None of the susceptible species to *G. salaris* such as wild salmon and trout are listed as endangered. Nevertheless, some Norwegian strains of wild salmon are endangered but there is no information if these strains are present in EU countries. Therefore, the impact could be considered high at local level for genetically unique populations.

3.3.2. Detailed outcome on Category B criteria

Table 6: Outcome of the expert judgement related to the criteria of Section 2 of Annex IV of AHL (Category B of Article 9 of AHL)

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

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



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

Figure 5: Outcome of the expert judgement on criteria of Section 2 of Annex IV of the AHL and overall probability of the Infection with *Gyrodactylus salaris* to be fitting in Category B of Article 9 of AHL

3.3.2.1. Reasoning for uncertain outcome on Category B criteria

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

- It seems that there is a knowledge gap to allow the estimation of morbidity and mortality rates. From the available data, the morbidity and mortality rates may vary depending mainly on the host species and the age/stage of the host.
- Reports from the WOAH mention that morbidity in farmed Atlantic salmon fry and parr can be 100% if not treated. It is possible to have high mortality in fry but adults may not be as susceptible and lower morbidity rates can be expected.
- Mortality in wild Atlantic salmon fry and parr in Norwegian rivers can be as high as 98%, with an average of about 85%. Mortality in other susceptible host species is usually low or not observed less than 50–75%.

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

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

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

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

Criterion 5d: *(the disease has* a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds*):*

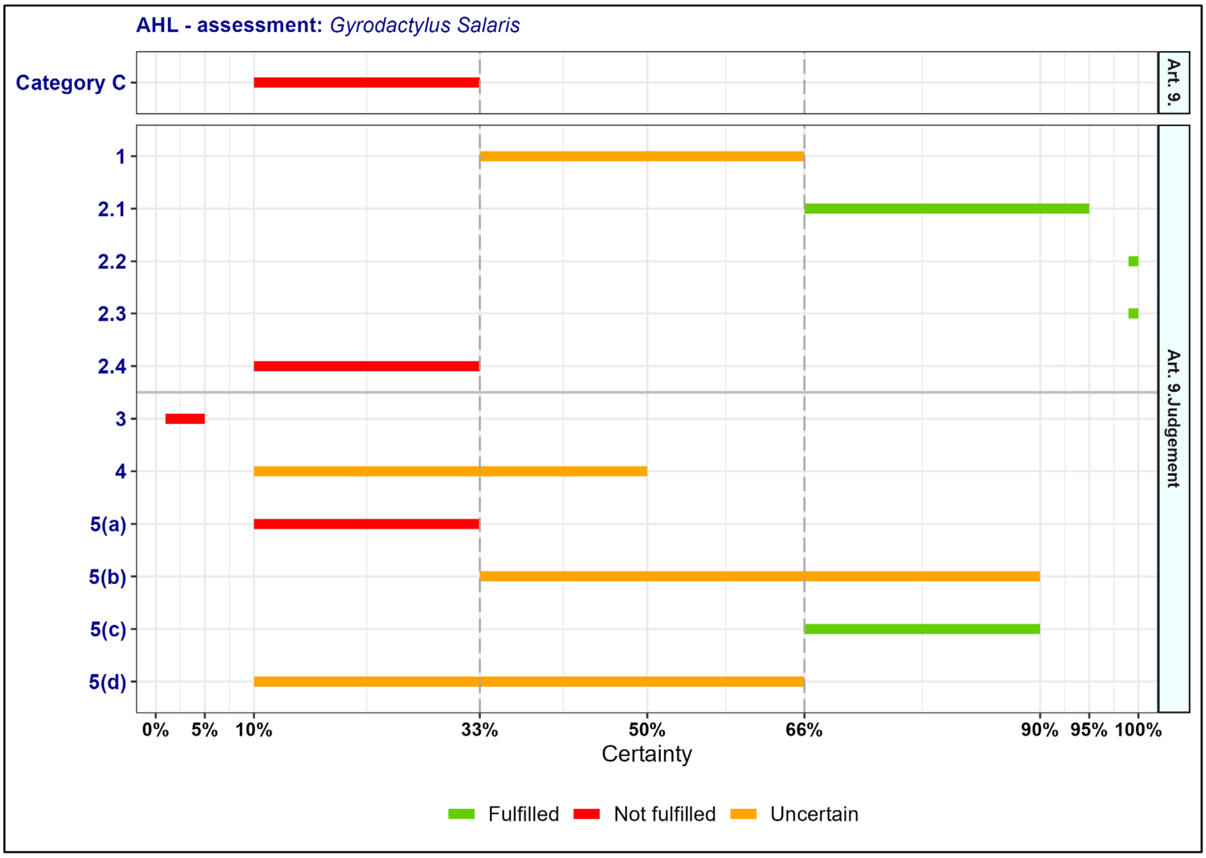
- The reasoning for this criterion has been described in Section 3.3.1.1.

3.3.3. Detailed outcome on Category C criteria

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

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		**Outcome**			
		Median range (%)	**Criterion fulfilment**	**Number of NA**	**Number of experts**
1	The disease is present in the whole OR part of the Union territory with an endemic character OR in **aquatic animals** several Member States or zones of the Union are free of the disease	33–66	Uncertain	0	14
2.1	The disease is moderately to highly transmissible	66–95	Fulfilled	0	14
2.2	The disease is transmitted mainly by direct or indirect transmission[(a)]	–	Fulfilled	0	14
2.3	The disease affects single or multiple species[(b)]	–	Fulfilled	0	14
2.4	The disease may result in high morbidity and usually low mortality and often the most observed effect of the disease is production loss?	10–33	Not fulfilled	0	14
At least one criterion to be met by the disease: In addition to the criteria set out above at point 1–2.4, the disease needs to fulfil at least one of the following criteria					
3	The disease has a zoonotic potential with significant consequences for public health or possible significant threats to food safety	1–5	Not fulfilled	1	14
4	The disease has a significant impact on the economy of the Union, mainly related to its direct impact on certain types of animal production systems	10–50	Uncertain	0	14
5(a)	The disease has a significant impact on society, with in particular an impact on labour markets	10–33	Not fulfilled	0	14
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	33–90	Uncertain	0	14
5(c)	The disease has a significant impact on the environment, due to the direct impact of the disease or due to the measures taken to control it	66–90	Fulfilled	0	14
5(d)	The disease has a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	10–66	Uncertain	0	14

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



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

Figure 6: Outcome of the expert judgement on criteria of Section 3 of Annex IV of the AHL and overall probability of Infection with *Gyrodactylus salaris* to be fitting in Category C of Article 9 of AHL

3.3.3.1. Reasoning for uncertain outcome on Category C criteria

Criterion 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)*:

- *G. salaris* is endemic in Atlantic salmon east of the Baltic Sea but has spread outside these areas via transport and reservoir hosts and stocking of fish. The parasite is endemic in western Sweden, northern Finland and northern Russia. Nevertheless, there is limited information on *G. salaris* infection in the other EU countries.
- *G. salaris* is present in wild populations where it is difficult to estimate the epidemiological situation
- In the literature, it was mentioned that *G. salaris* was identified in many EU countries, but it was not clear whether it has been accurately confirmed in all cases or confused with other parasites in Gyrodactylus family.
- Systematic surveillance is not implemented in all MSs therefore it is difficult to estimate the health status.

Criterion 4: *(the disease has a significant impact on the economy of the Union, mainly related to its direct impact on certain types of animal production systems):*

- Both the current and the potential impact of the disease on the economy of the Union were assessed There is not enough information on the current impact of the disease on the economy of the Union. In addition, the production in wild populations cannot be estimated. Nevertheless, for the local economies of wild fish fishing the impact might be higher.

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

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

Criterion 5d: *(the disease has* a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds*):*

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

3.3.4. Detailed outcome on Category D criteria

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

Diseases in Category D need to fulfil criteria of Section 1, 2, 3 or 5 of Annex IV of the AHL **and the following:**		Outcome			
		Median range (%)	**Criterion fulfilment**	**Number of NA**	**Number of experts**
D	The risk posed by the disease can be effectively and proportionately mitigated by measures concerning movements of animals and products in order to prevent or limit its occurrence and spread	33–66	Uncertain	0	14

NA: not applicable.

3.3.5. Detailed outcome on Category E criteria

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

Diseases in Category E need to fulfil criteria of Section 1, 2 or 3 of Annex IV of the AHL and/or the following:		Outcome	
		Median range (%)	**Fulfilment**
E	surveillance of the disease is necessary for reasons related to animal health, animal welfare, human health, the economy, society or the environment (If a disease fulfils the criteria as in Article 5, thus being eligible to be listed, consequently Category E would apply)	33–80	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 6–10. According to the assessment methodology, a criterion is considered fulfilled when the lower bound of the median range lays above 66%.

The overall outcome of the assessment on criteria in Annex IV of the AHL, for the purpose of categorisation of Infection with *G. salaris* as in Article 9, is presented in Table 10 and Figure 6.

Figure 7

Table 10: Outcome of the assessment on criteria in Annex IV of the AHL for the purpose of categorisation as in Article 9 (fulfilled: green, not fulfilled: red, uncertain: orange)

Category	Article 9 criteria											D	Article 5 criteria
	1° set of criteria					2° set of criteria							
	1	2.1	2.2	2.3	2.4	3	4	5(a)	5(b)	5(c)	5(d)		
	Geographical distribution	Transmissibility	Routes of transmission	Multiple species	Morbidity and mortality	Zoonotic potential	Impact on economy	Impact on society	Impact on animal welfare	Impact on environment	Impact on biodiversity		
A	1–5	66–90	90–95	90–99	66–90	1–5	10–66	10–33	33–90	66–90	10–66		
B	66–90	66–95	90–95	–[(a)]	33–80	1–5	10–66	10–33	33–90	66–90	10–66		
C	33–66	66–95	–[(b)]	–[(b)]	10–33	1–5	10–50	10–33	33–90	66–90	10–66		
D												33–66	
E													33–80

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

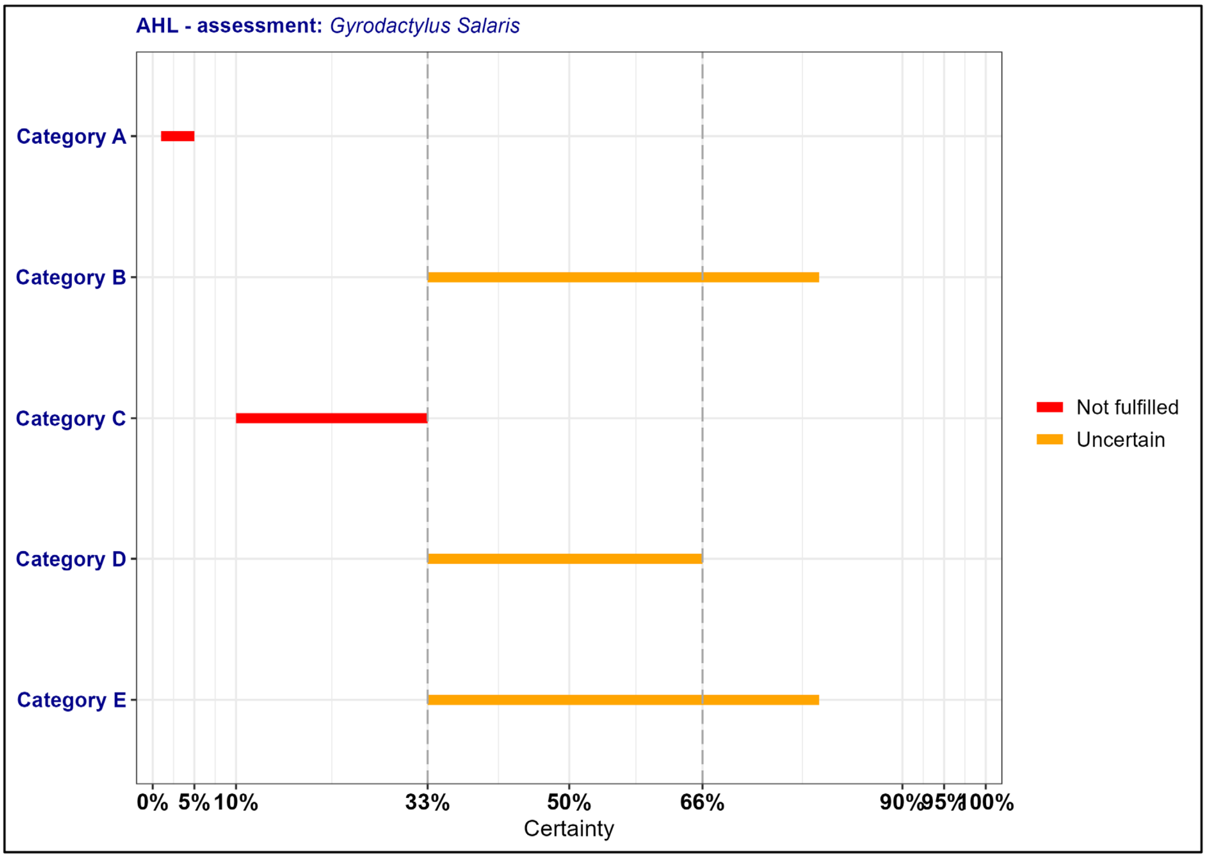


Figure 7: Outcome of the expert judgement on criteria in Annex IV of AHL and overall probabilities for categorisation of Infection with *G. salaris* in accordance with Article 9 of AHL

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

1) To be assigned to **Category A**, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and, according to the assessment, Infection with *G. salaris* complies only with four out of five criteria (2.1, 2.2, 2.3 and 2.4). To be eligible for Category A, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5(a)–(d)) and Infection with *G. salaris* complies with 5 (c) criterion. Overall, it was assessed with **1–5% probability** that Infection with *G. salaris* may be assigned to Category A according to criteria in Section 1 of Annex IV for the purpose of categorisation as in Article 9 of the AHL.
2) To be assigned to **Category B**, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and, according to the assessment, infection with *G. salaris* complies only with four out of five criteria (1, 2.1, 2.2 and 2.3). To be eligible for Category B, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5(a)–(d)) and infection with *G. salaris* complies with 5(c) criterion. Overall, it was assessed with **33–80% probability** that infection with *G. salaris* 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, infection with *G. salaris* complies with three out of five criteria (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 infection with *G. salaris* complies with 5 (c) criterion. Overall, it was assessed with **10–33% probability** that infection with *G. salaris* may be assigned to Category C according to criteria in Section 3 of Annex IV for the purpose of categorisation as in Article 9 of the AHL.
4) To be assigned to **Category D,** a disease needs to comply with criteria of Section 1, 2, 3 or 5 of Annex IV of the AHL and with the specific criterion D of Section 4. Infection with *G. salaris* does not comply with criteria of Section 1, 2, 3 or 5 of Annex IV of the AHL but complies with **33–66% probability** with criterion D.
5) To be assigned to **Category E**, a disease needs to comply with criteria of Section 1, 2 or 3 of Annex IV of the AHL, and/or the surveillance of the disease is necessary for reasons related to animal health, animal welfare, human health, the economy, society or the environment. The latter is applicable if a disease fulfils the criteria as in Article 5, for which the assessment is uncertain with **33–80% probability**.

3.4. Assessment of infection with *Gyrodactylus salaris* according to Article 8 criteria of the AHL

In this section, the results of the assessment on the criteria of Article 8(3) of the AHL for Infection with *G. salaris* 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 of Article 8 criteria of AHL is based on the evidence as extrapolated from the relevant criteria of Article 7, i.e. the ones related to susceptible, vectors and reservoir species or routes of transmission, which cover also the possible role of biological or mechanical vectors.

According to the mapping, as presented in Table 5, Section 3.2, of the Scientific Opinion on the ad hoc methodology (EFSA AHAW Panel, 2017a), the animal species to be listed for infection with *G. salaris* according to the criteria of Article 8(3) of the AHL are as displayed in Table 12 (elaborated from information on animal species concerned reported in Section 3.1.1.1 of the present document).

The table contains all animal species in which infection with *G. salaris* has been described, but also those animal species from which only the infection with *G. salaris* itself has been detected. The latter makes susceptibility to infection with *G. salaris* likely.

Table 12: Animal species to be listed for infection with *G. salaris* according to the criteria of Article 8 of AHL

Type	Class	Order	Family	Genus/Species	References
Susceptible	Actinopterygii	Salmoniformes	Salmonidae	*Oncorhynchus mykiss*	Hansen et al. (2016), Paladini et al. (2009)
				Salmo trutta	Hansen et al. (2016), Jansen and Bakke (1995), Paladini et al. (2009)
				Salmo salar	Paladini et al. (2021)
				Salvelinus alpinus	Paladini et al. (2021), Winger et al. (2008)
				Salvelinus fontinalis	Hansen et al. (2016), Paladini et al. (2021)
				Salvelinus namaycush	Bakke et al. (1992), Peeler et al. (2006)
				Thymallus thymallus	Paladini et al. (2021), Soleng and Bakke (2001), Sterud et al. (2002)
Reservoirs	Actinopterygii	Anguilliformes	Anguillidae	*Anguilla anguilla*	Bakke et al. (1991)
		Cypriniformes	Cyprinidae	*Phoxinus phoxinus*	Peeler et al. (2006)
				Rutilus rutilus	Peeler et al. (2006)
		Gasterosteiformes	Gasterosteidae	*Gasterosteus aculeatus*	Soleng and Bakke (1998)
		Perciformes	Percidae	*Perca fluviatilis*	Peeler et al. (2006)
		Scorpaeniformes	Cottidae	*Cottus poecilopus*	Bakke et al. (2019)
			Gasterosteidae	*Pungitius pungitius*	Soleng and Bakke (1998)
	Cephalaspidomorphi	Petromyzontiformes	Petromyzontidae	*Lampetra planeri*	Peeler et al. (2006)
Vectors	There is no evidence in the literature whether other species can transmit the *G. salaris* to susceptible fish.				

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

4. Conclusions

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

The AHAW Panel concluded that it is uncertain (**33–70% probability)** whether infection with *G. salaris* 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 **1–5% probability** ('extremely unlikely') that Infection with *G. salaris* meets the criteria of Category A, as in Section 1 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in point (a) of Article 9(1) of the AHL.
- The AHAW Panel was uncertain (**33–80% probability**) whether the Infection with *G. salaris* meets the criteria of Category B, as in Section 2 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in point (b) of Article 9(1) of the AHL.

- The AHAW Panel was considered with **10–33% probability** ('unlikely') that the Infection with *G. salaris* meets the criteria of Category C, as in Section 3 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in point (c) of Article 9(1) of the AHL.
- The AHAW Panel was uncertain (**33–66% probability**, 'about as likely as not') whether Infection with *G. salaris* meets the criteria of Category D, as in Section 4 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in point (d) of Article 9(1) of the AHL.
- The AHAW Panel was uncertain (**33–80% probability)** whether Infection with *G. salaris* meets the criteria of Criteria E, as in Section 5 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in point (e) of Article 9(1) of the AHL.

TOR 2(b): *for each of the diseases* a list of animal species that should be considered candidates for listing in accordance with Article 8 of the AHL.

The animal species that can be considered to be listed for Infection with *G. salaris* according to Article 8(3) of the AHL are reported in Table 12 in Section 3.4 of the present document.

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

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

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Abbreviations

AHAW	Animal Health and Welfare
AHL	Animal Health Law
CI	current impact
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	Term Of Reference
WOAH	World Organisation for Animal Health

Appendix A – Expert judgement plotted by question

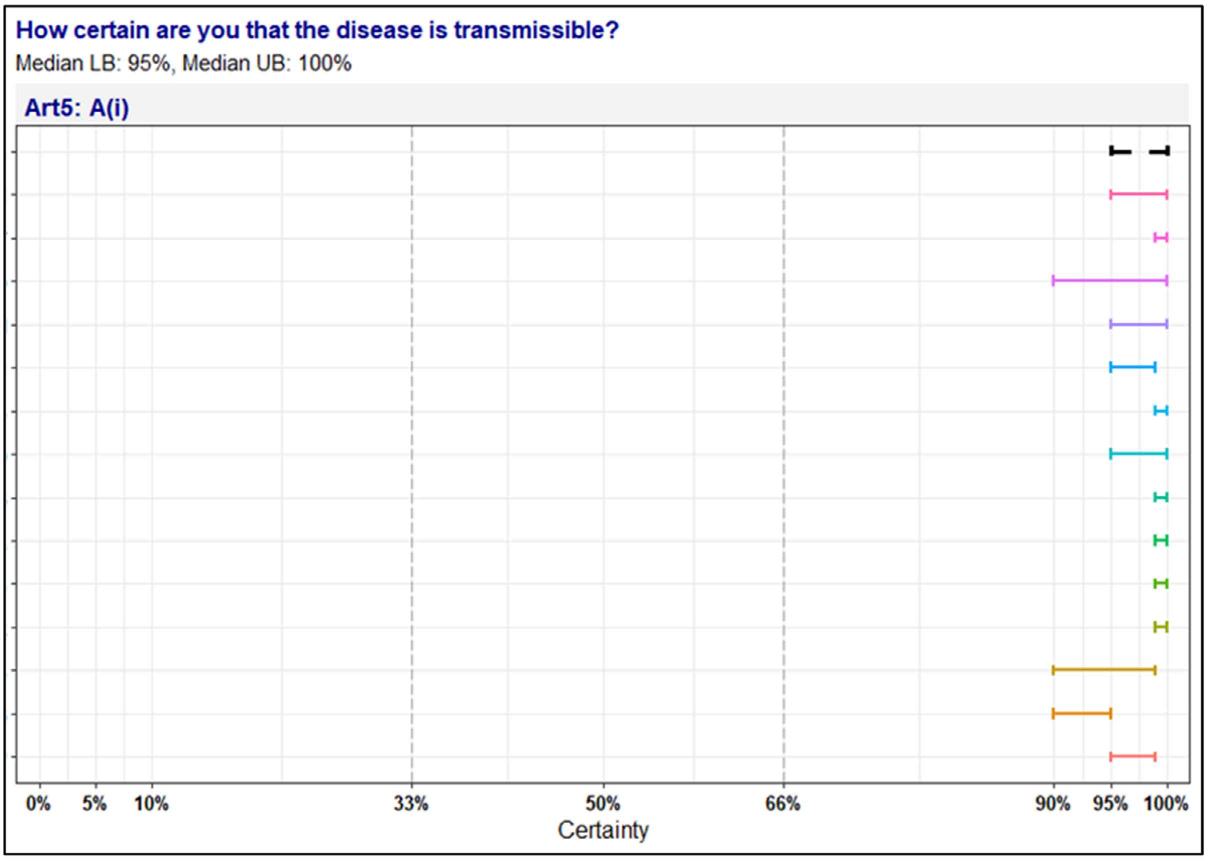

Figure A.1: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion A(i) (the disease is transmissible). The black dotted line on the top indicates the median

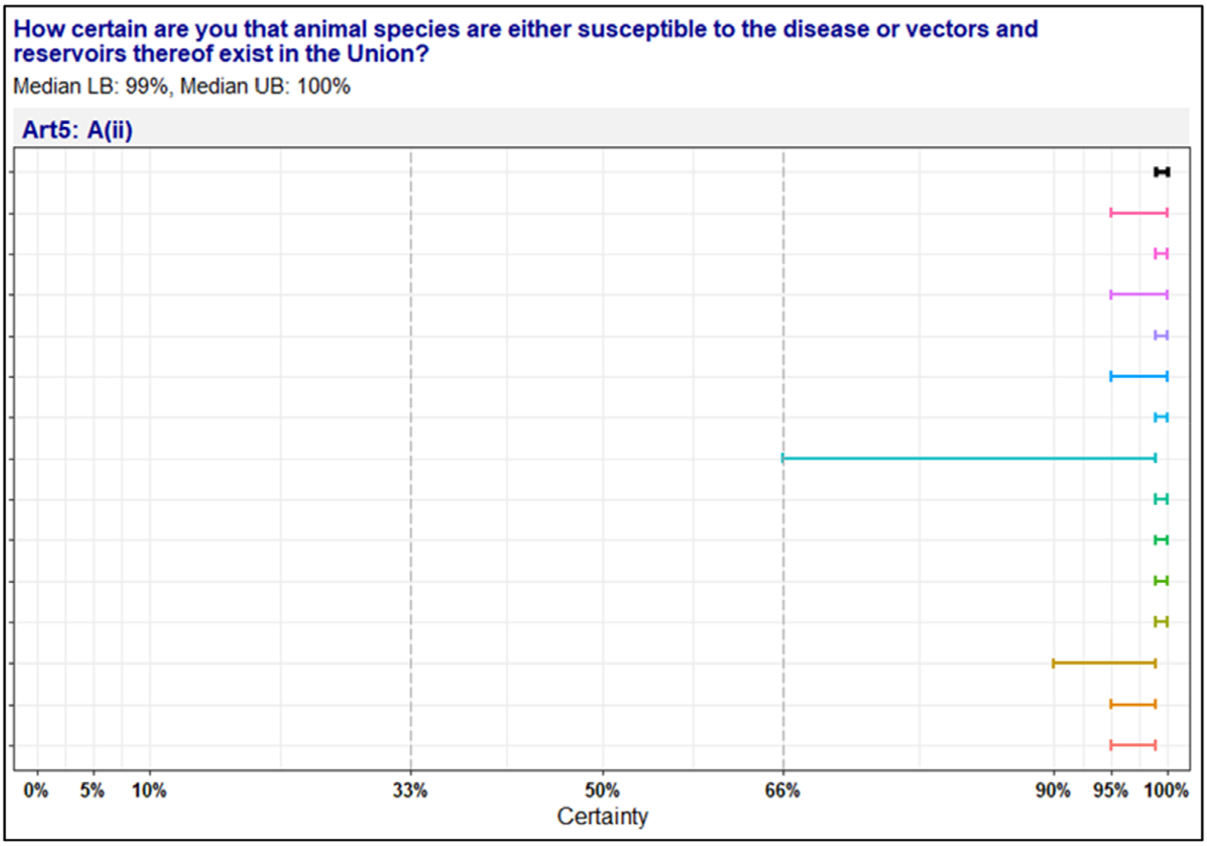

Figure A.2: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion A(ii) (animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union). The black dotted line on the top indicates the median

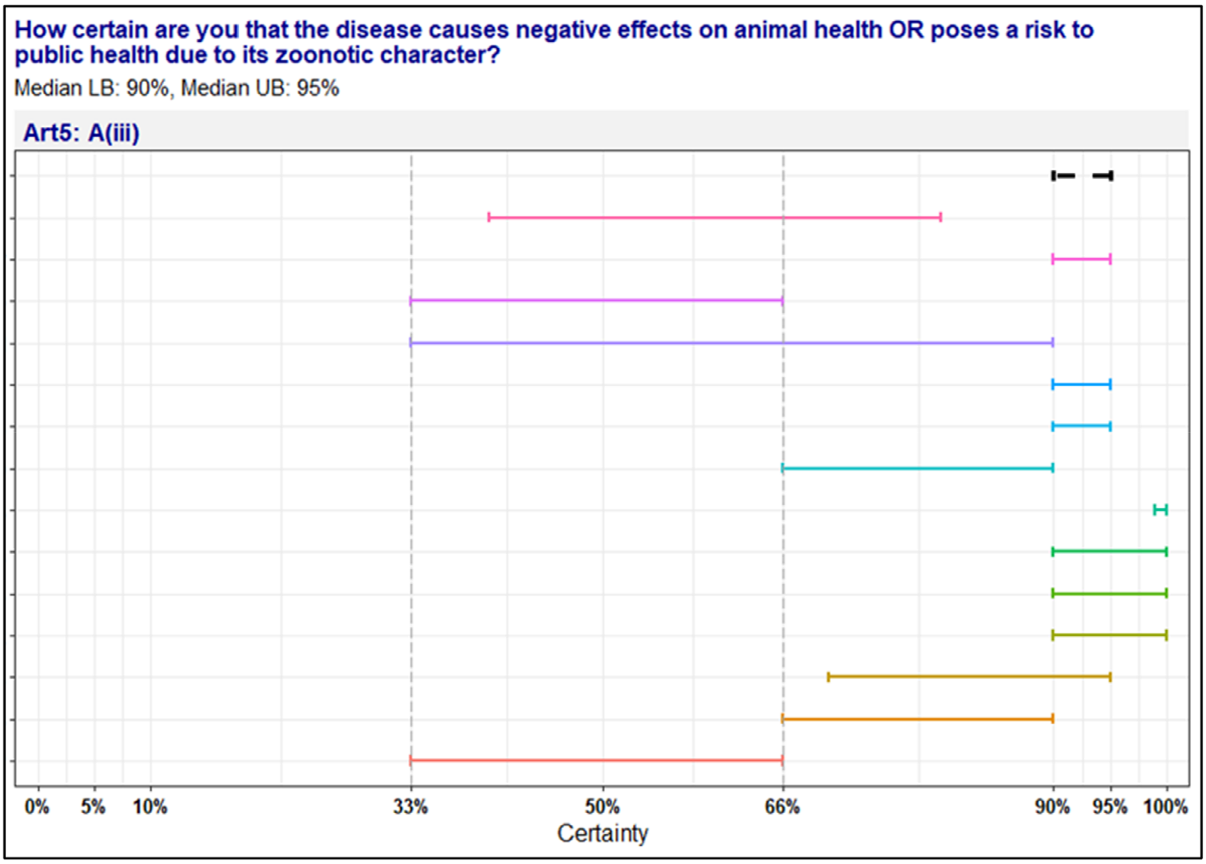

Figure A.3: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion A(iii) (the disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character). The black dotted line on the top indicates the median

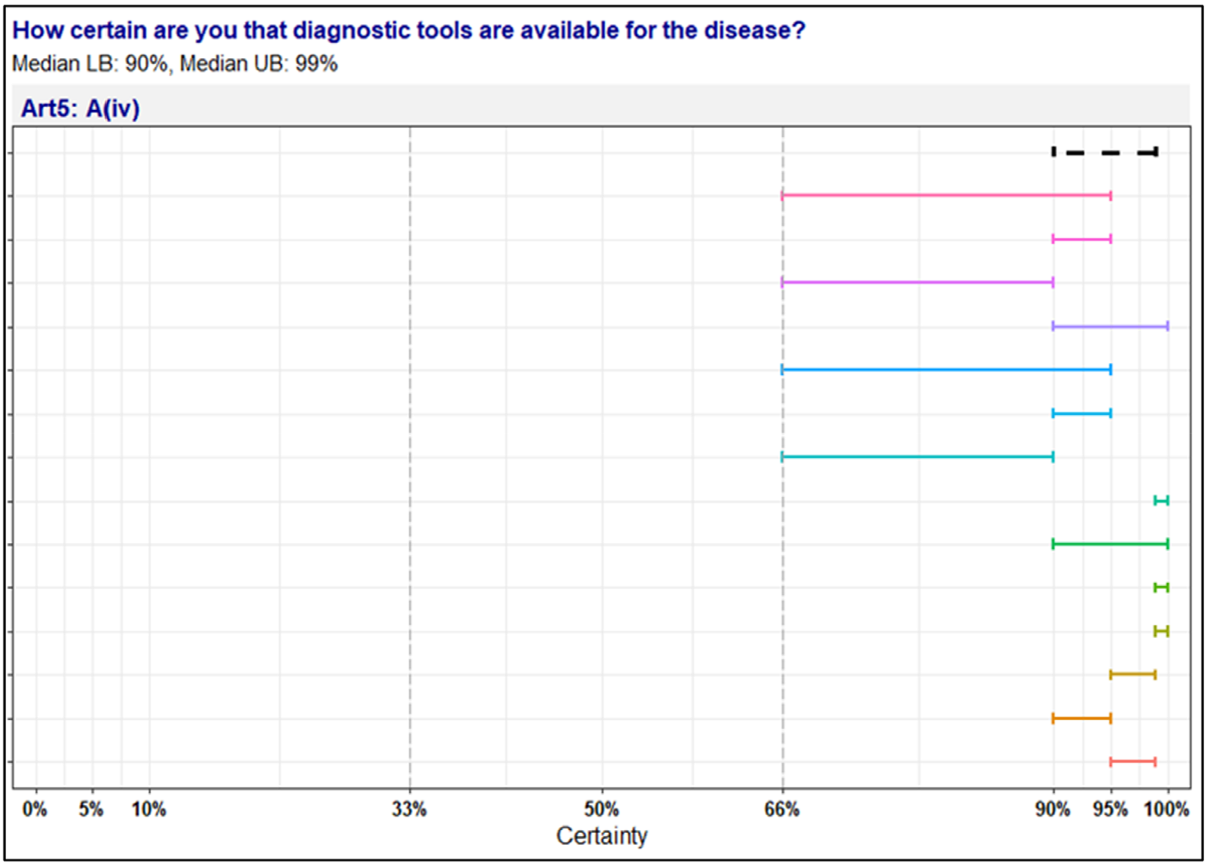

Figure A.4: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion A(iv) (diagnostic tools are available for the disease). The black dotted line on the top indicates the median

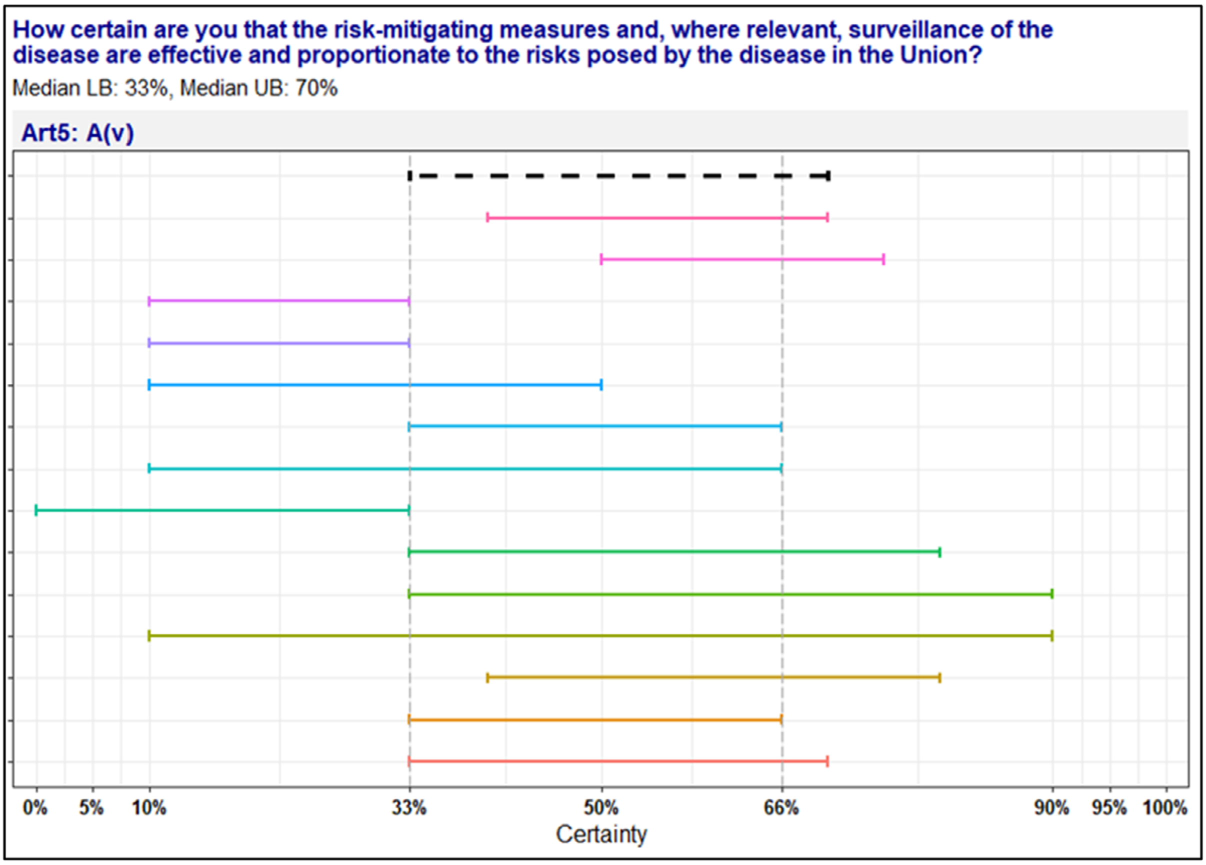

Figure A.5: Individual probability ranges, after the collective judgement, reflecting the uncertain outcome of the criterion A(v) (risk-mitigating measures and, where relevant, surveillance of the disease are effective and proportionate to the risks posed by the disease in the Union). The black dotted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

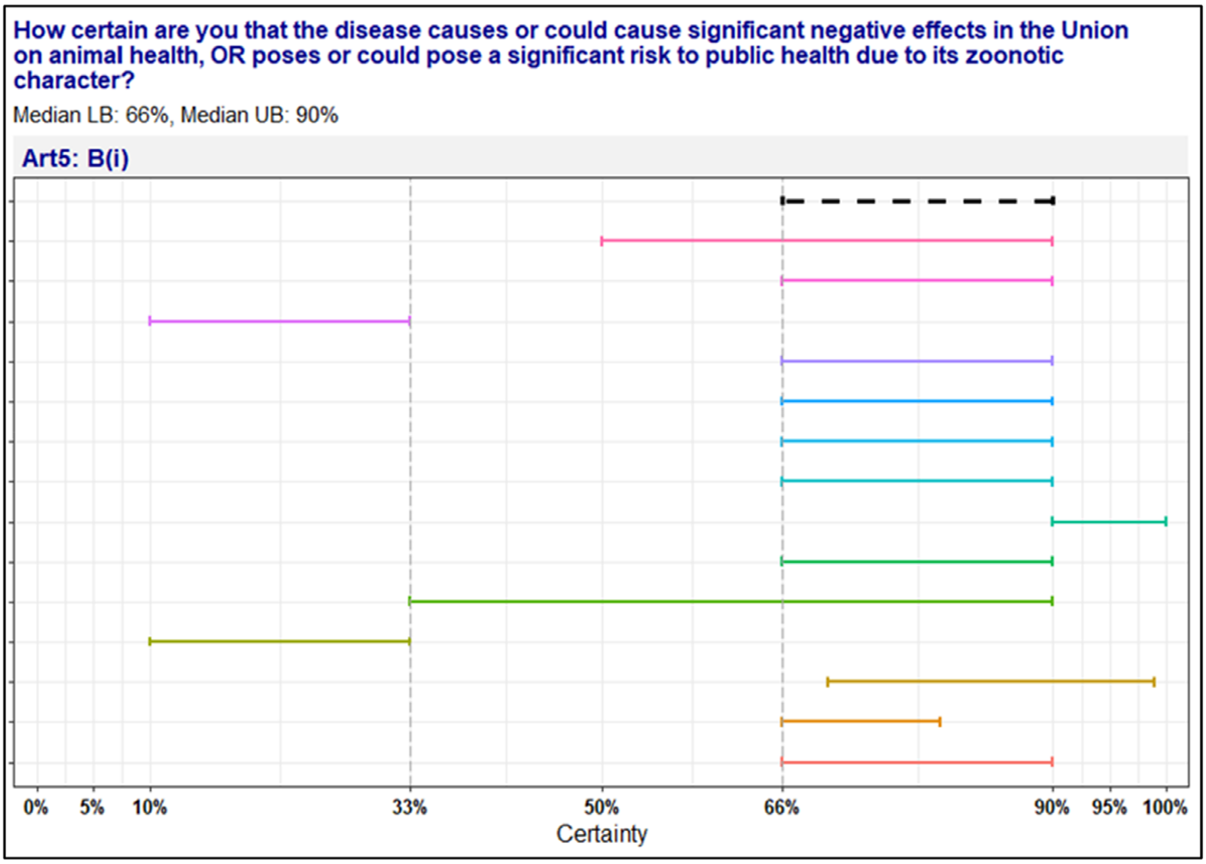

Figure A.6: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion B(i) (the disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic character).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

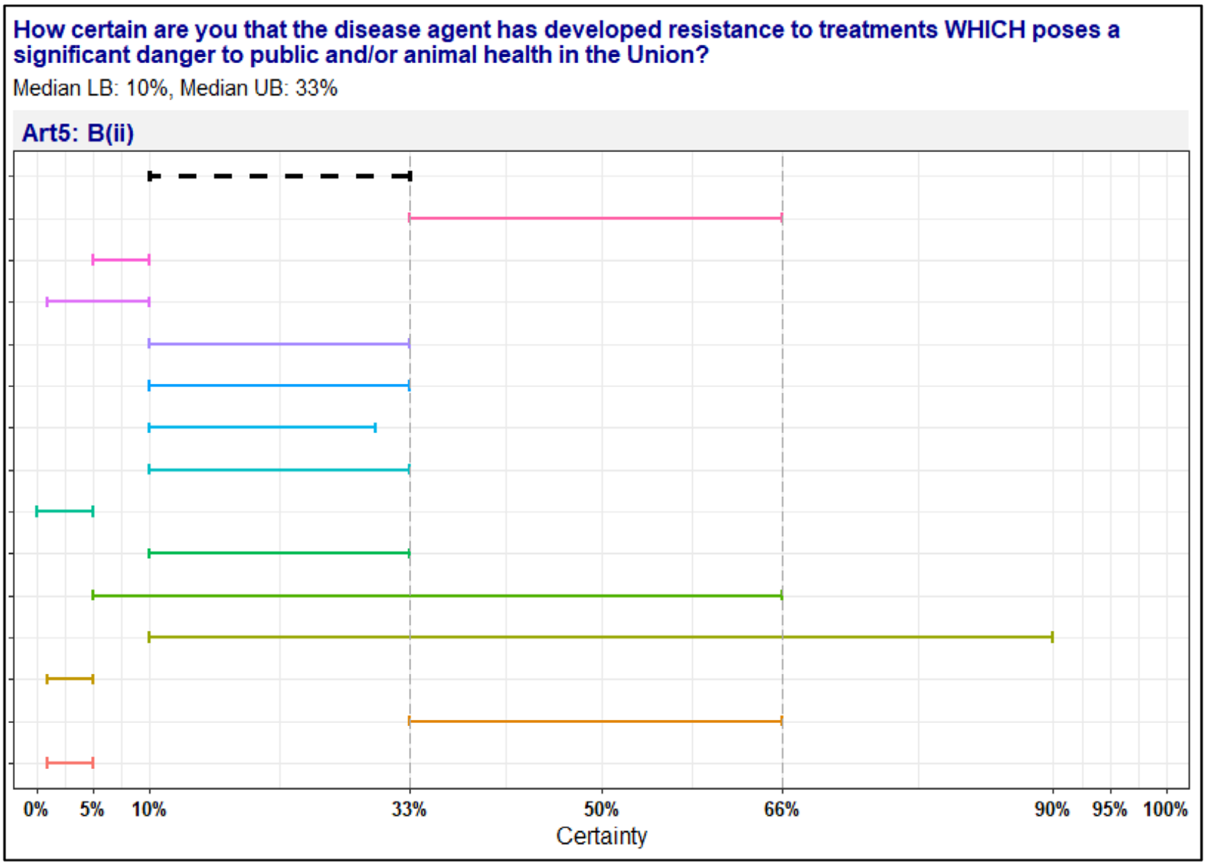

Figure A.7: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion B(ii) (the disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic character).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

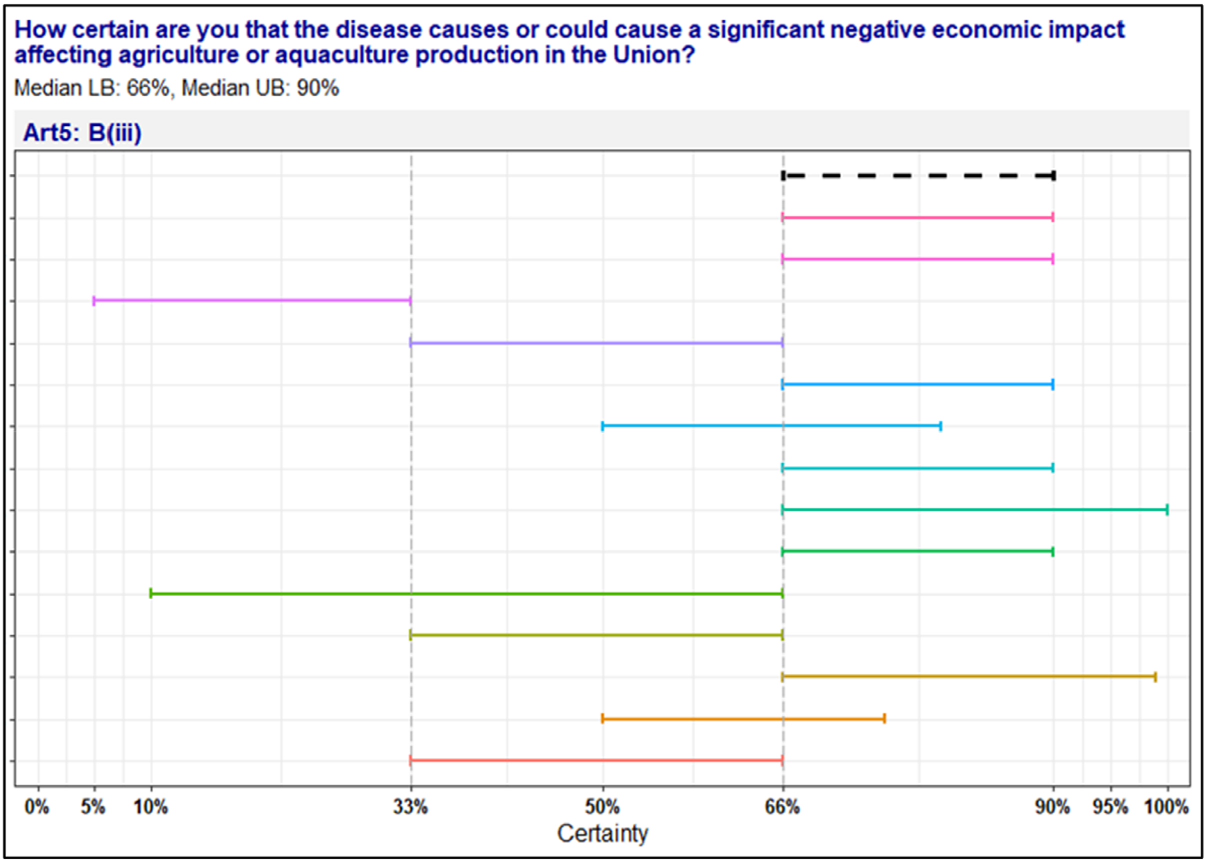

Figure A.8: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion B(iii) (the disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union). The black dotted line on the top indicates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

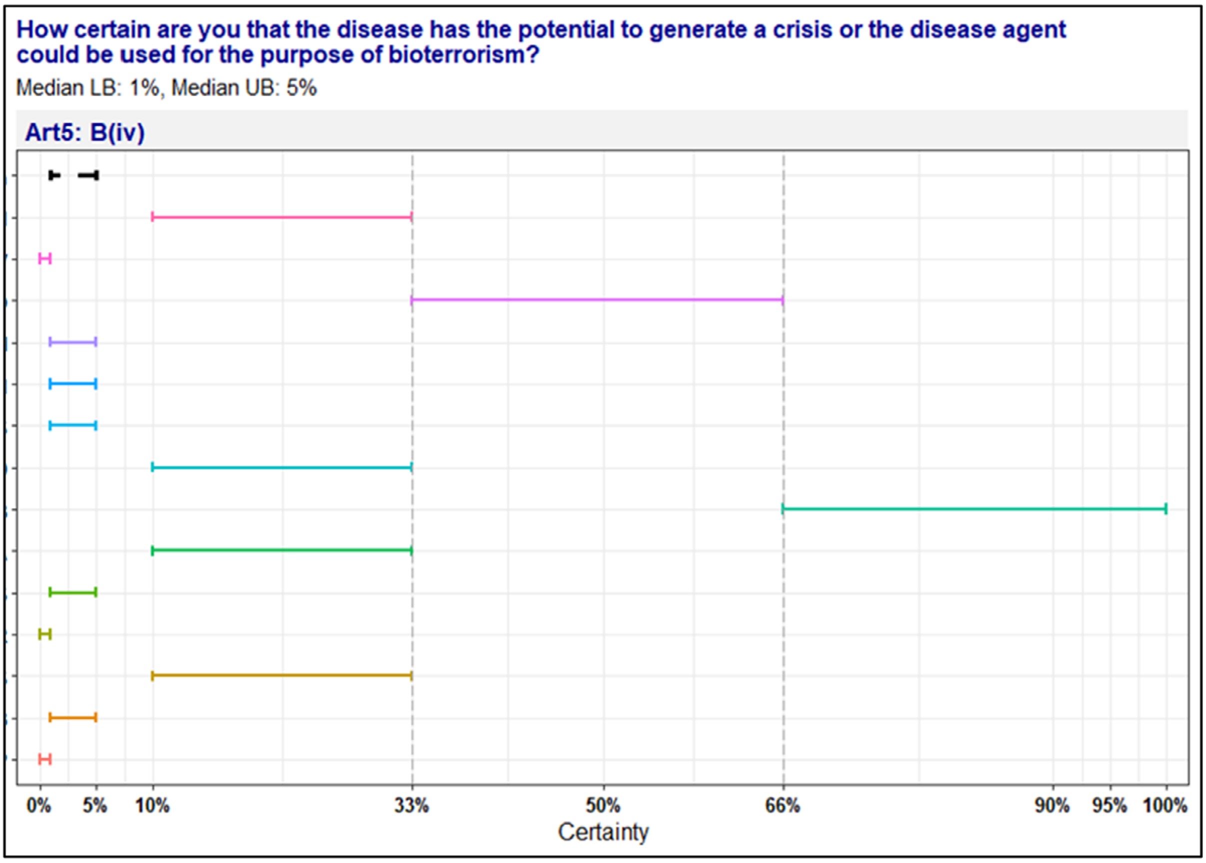

Figure A.9: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion B(iv) (the disease has the potential to generate a crisis, or the disease agent could be used for the purpose of bioterrorism). The black dotted line on the top indicates the median

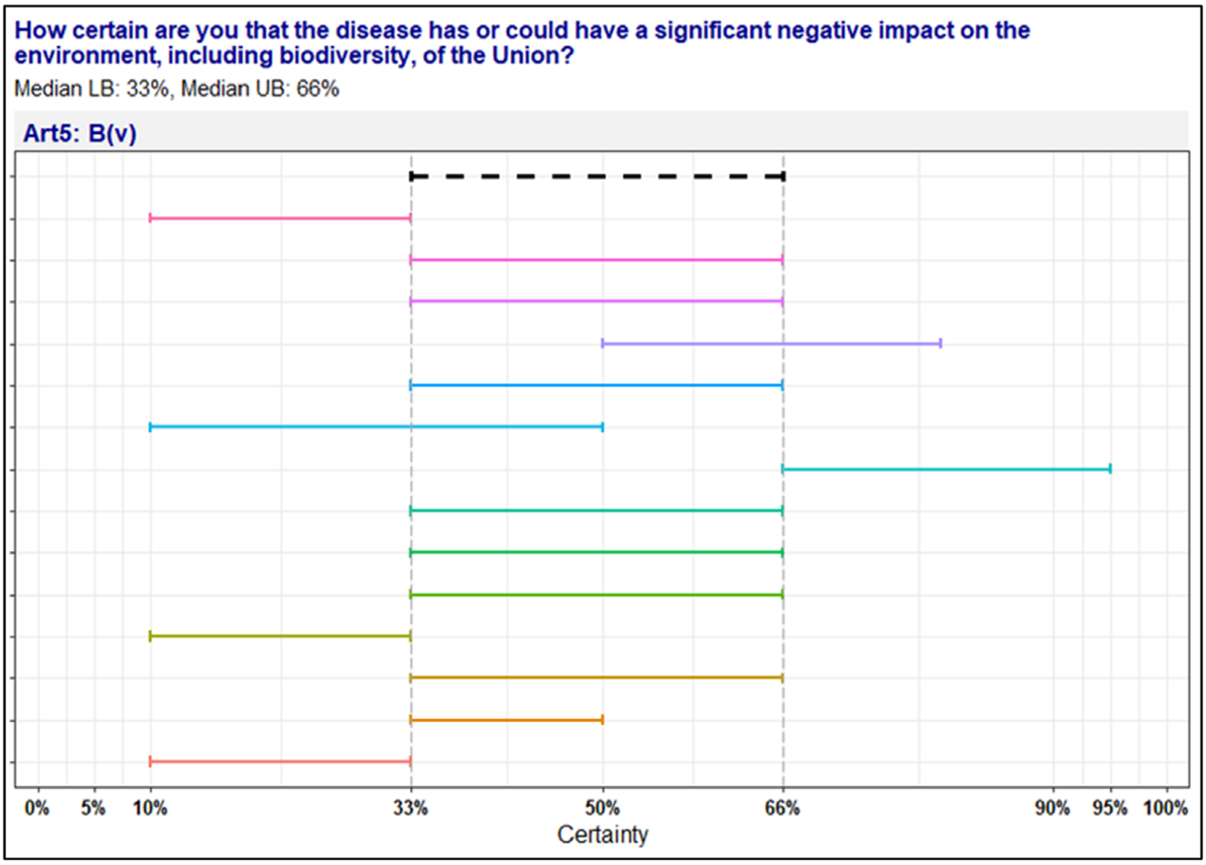

Figure A.10: Individual probability ranges, after the collective judgement, reflecting the uncertain outcome of the criterion B(v) (the disease has or could have a significant negative impact on the environment, including biodiversity, of the Union). The black dotted line on the top indicates the median

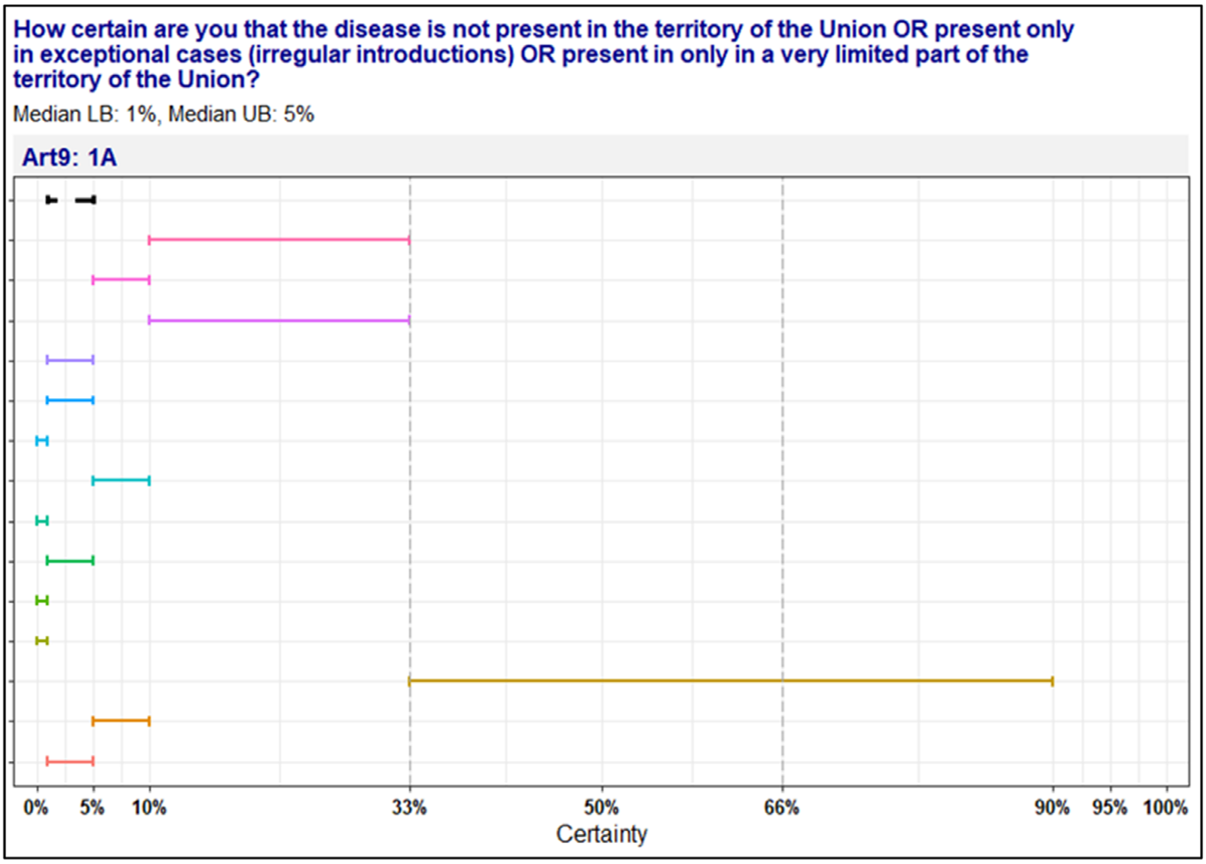

Figure A.11: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 1A (the disease is not present in the territory of the Union or present only in exceptional cases (irregular introductions) or present in only in a very limited part of the territory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

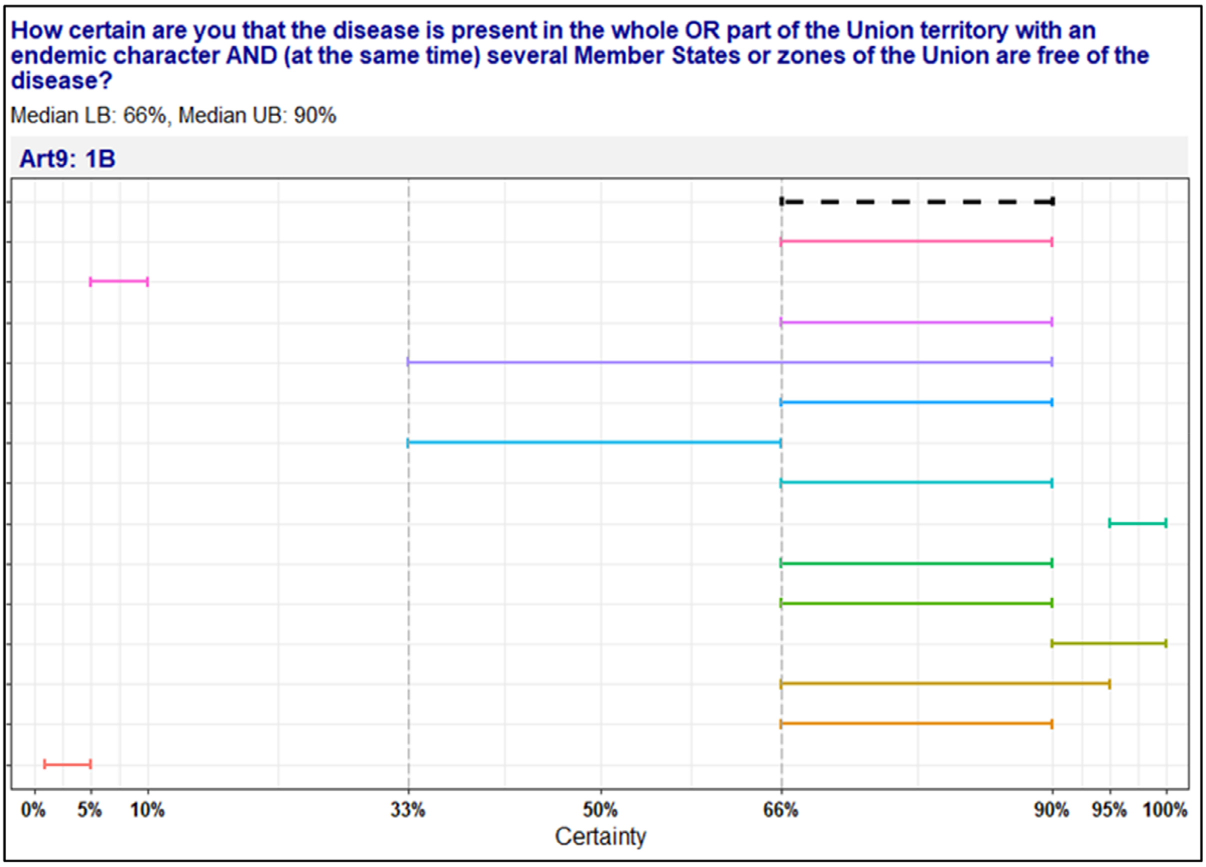

Figure A.12: Individual probability ranges, after the collective judgement, reflecting fulfilment of the criterion 1B (the disease is present in the whole or part of the Union territory with an endemic character and (at the same time) several Member States or zones of the Union are free of the disease).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

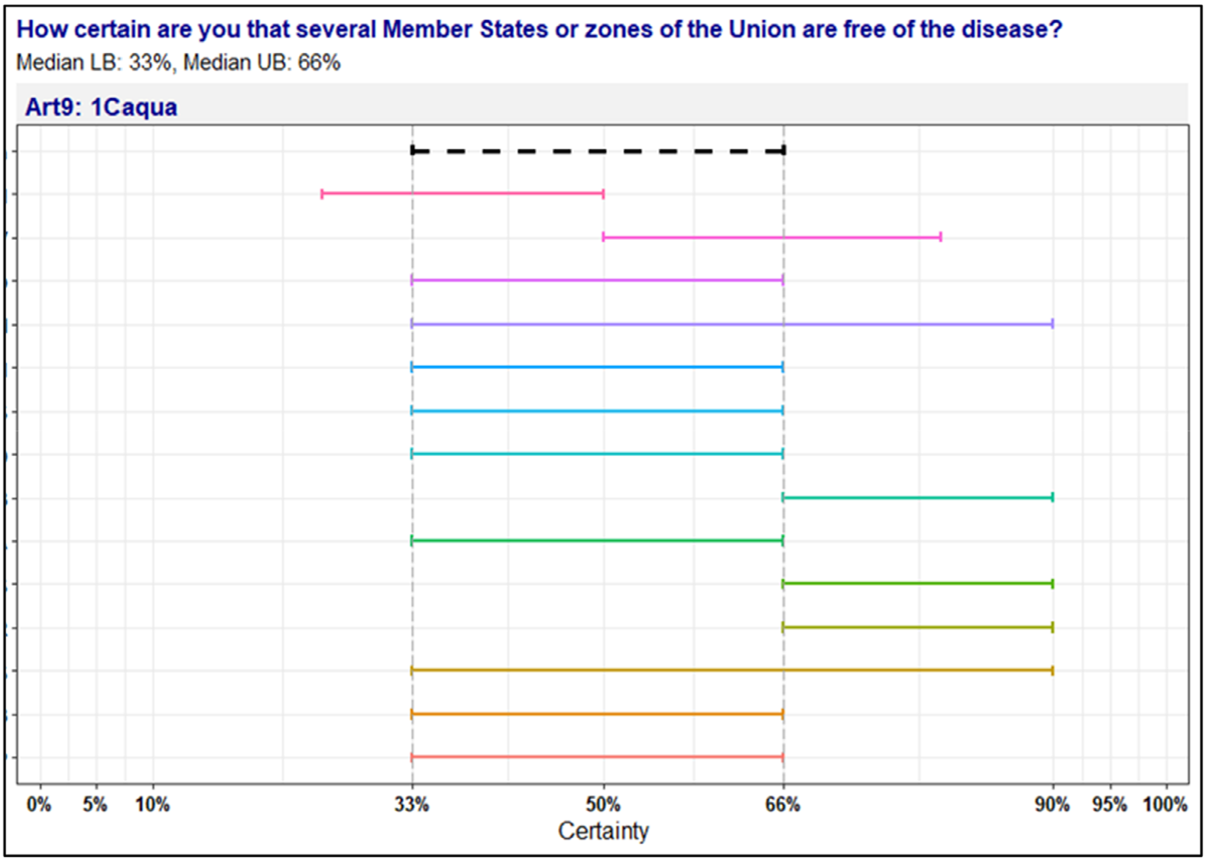

Figure A.13: Individual probability ranges, after the collective judgement, reflecting the uncertain outcome of the criterion 1Caqua (the disease is present in the whole or part of the Union territory with an endemic character). The black dotted line on the top indicates the median

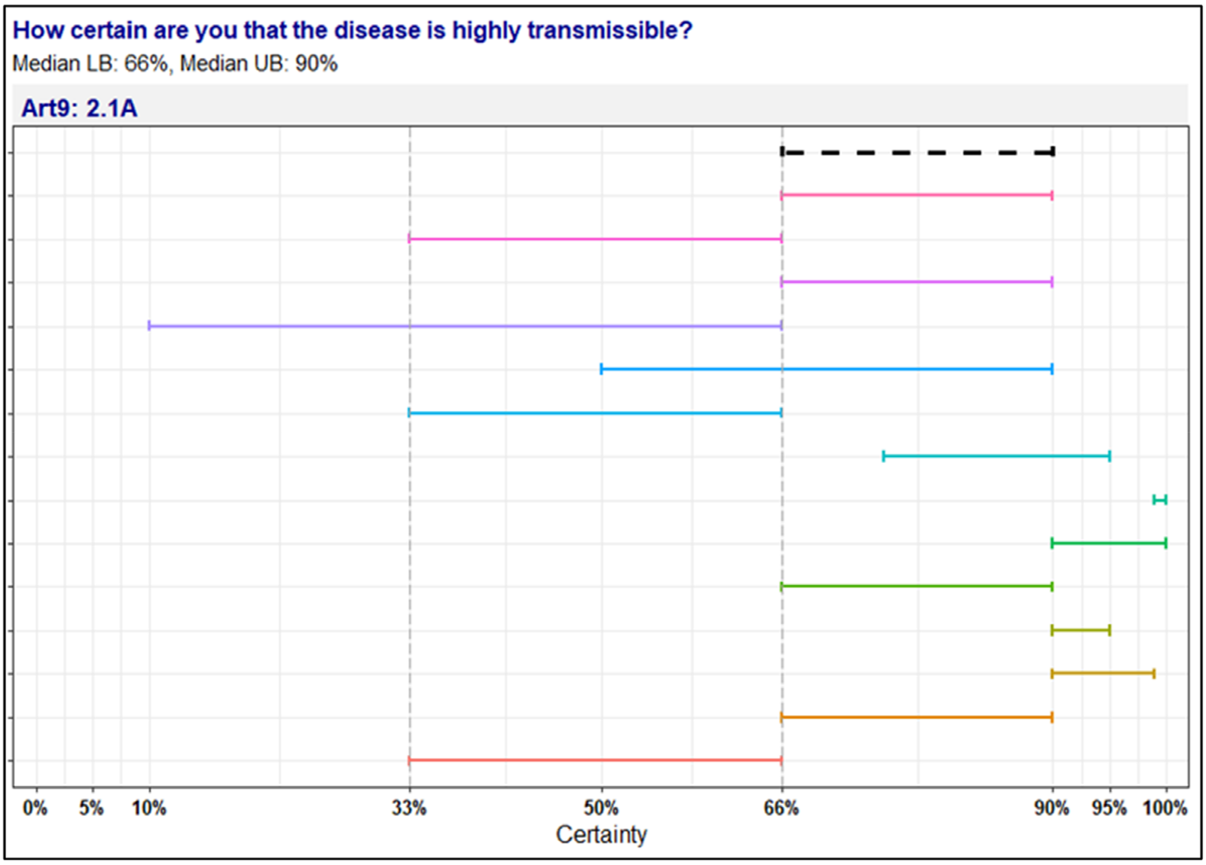

Figure A.14: Individual probability ranges, after the collective judgement, reflecting fulfilment of the criterion 2.1A (the disease is highly transmissible). The black dotted line on the top indicates the median

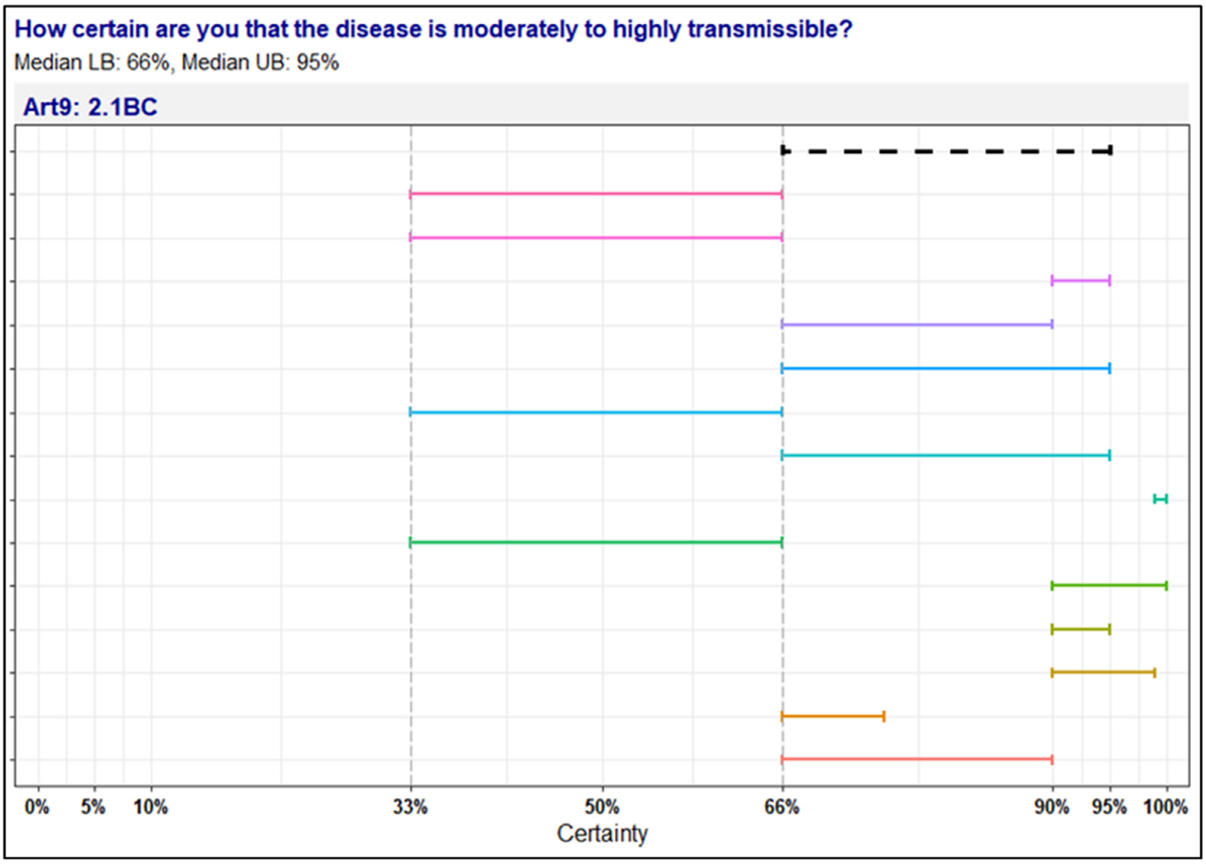

Figure A.15: Individual probability ranges, after the collective judgement, reflecting fulfilment of the criterion 2.1 BC (the disease is moderately to highly transmissible).The black dotted line on the top indicates the median

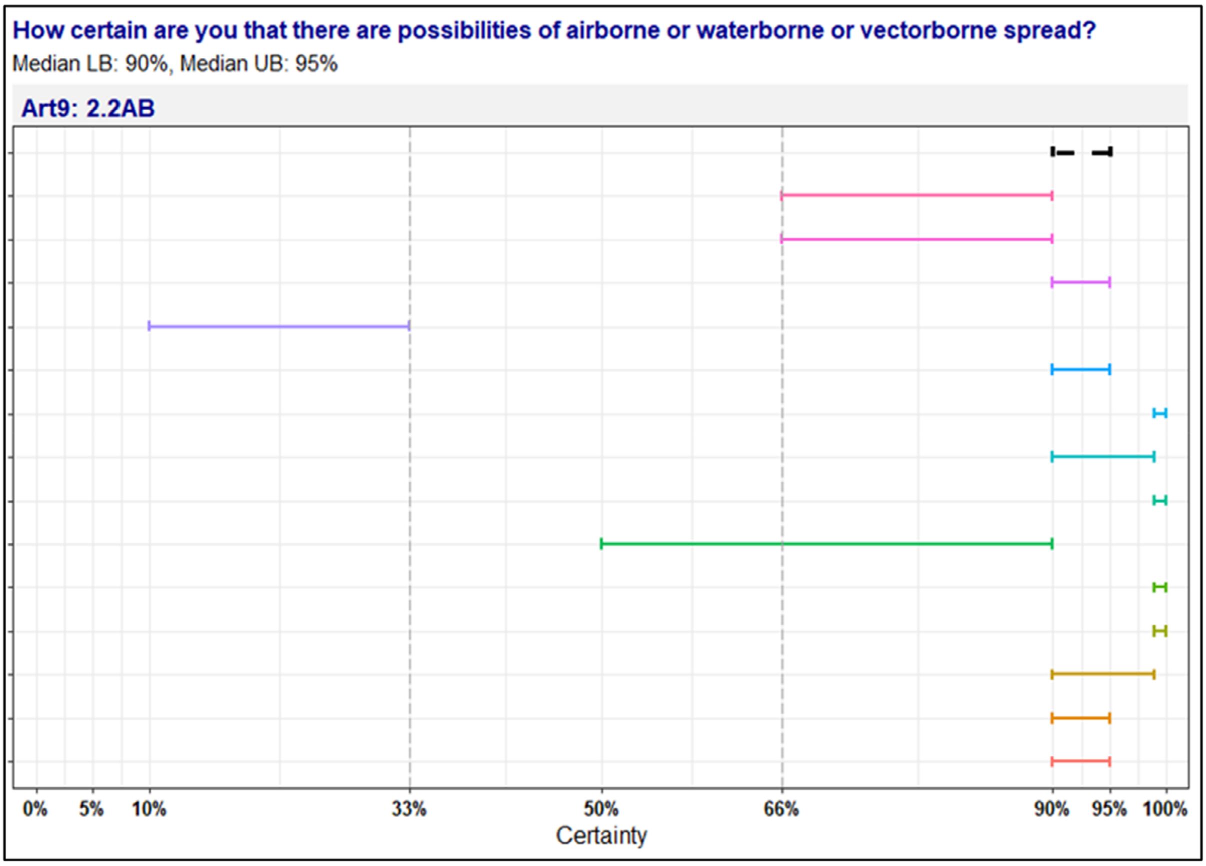

Figure A.16: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion 2.2AB (there are possibilities of airborne or waterborne or vector-borne spread). The black dotted line on the top indicates the median

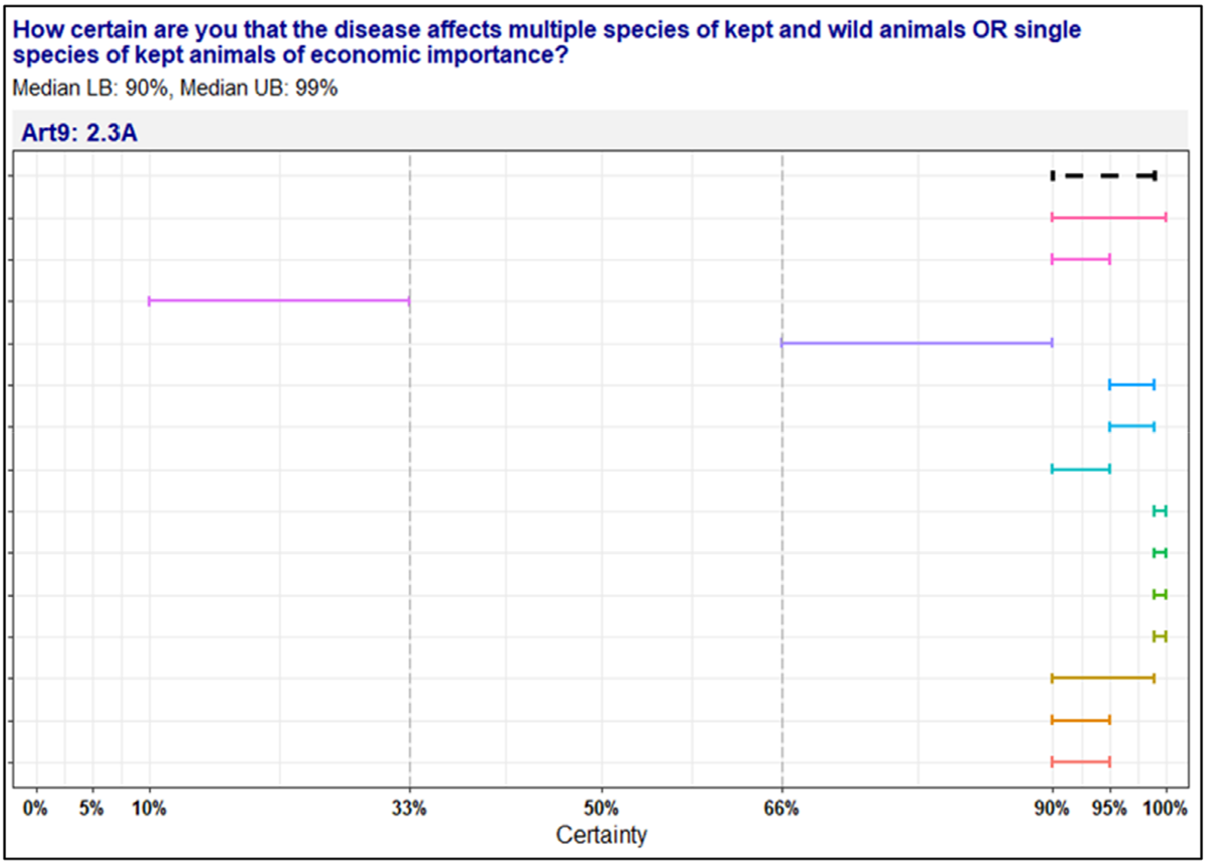

Figure A.17: Individual probability ranges, after the collective judgement, reflecting fulfilment of the criterion 2.3A (the disease affects multiple species of kept and wild animals or single species of kept animals of economic importance). The black dotted line on the top indicates the median

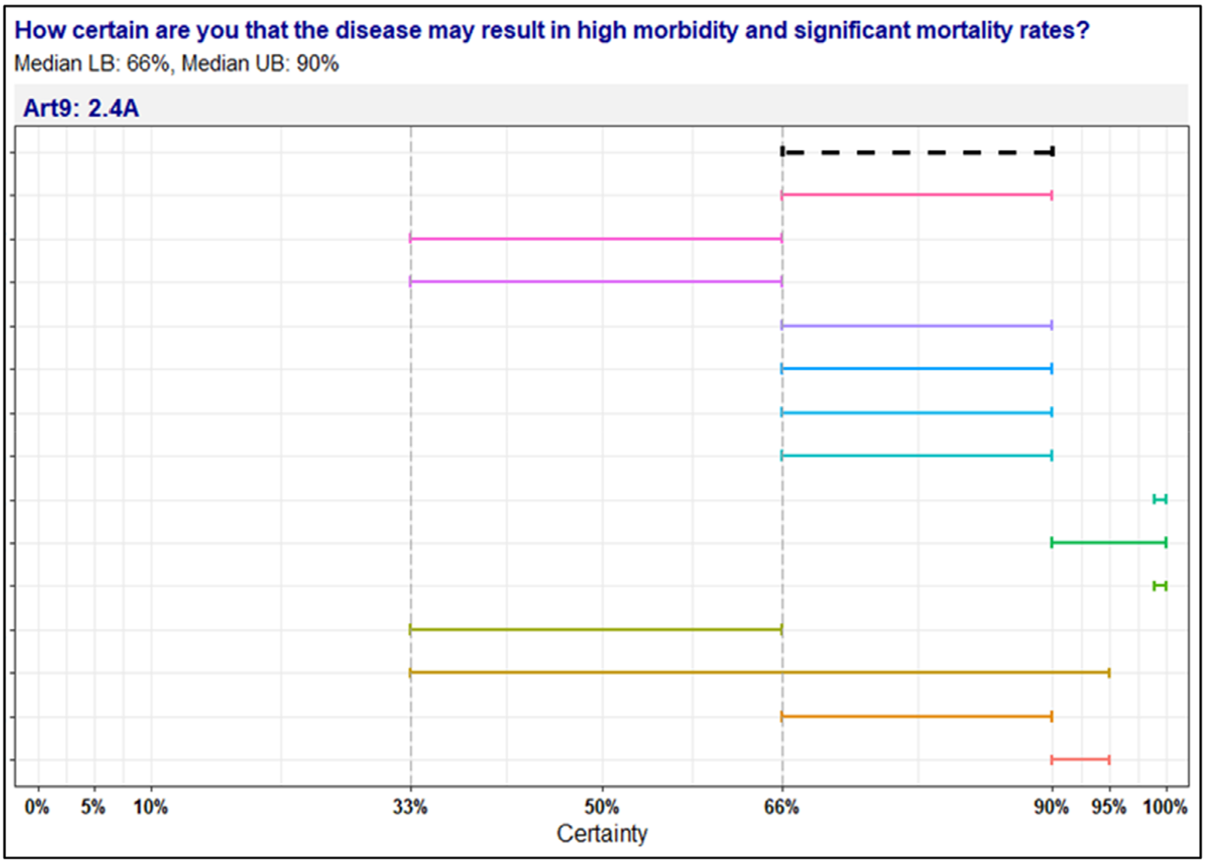

Figure A.18: Individual probability ranges, after the collective judgement, reflecting fulfilment of the criterion 2.4A (the disease may result in high morbidity and significant mortality rates). The black dotted line on the top indicates the median

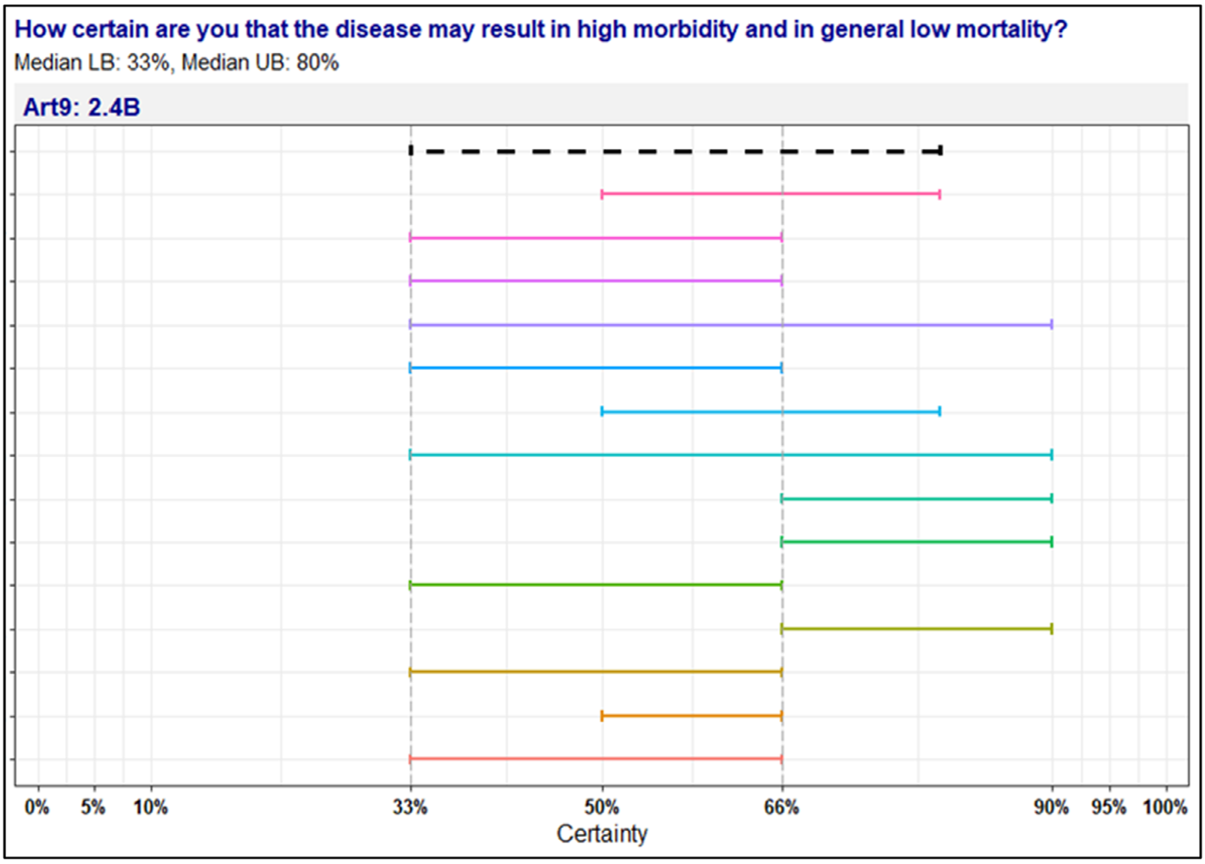

Figure A.19: Individual probability ranges, after the collective judgement, reflecting the uncertain outcome of the criterion 2.4B (the disease may result in high morbidity with in general low mortality). The black dotted line on the top indicates the median

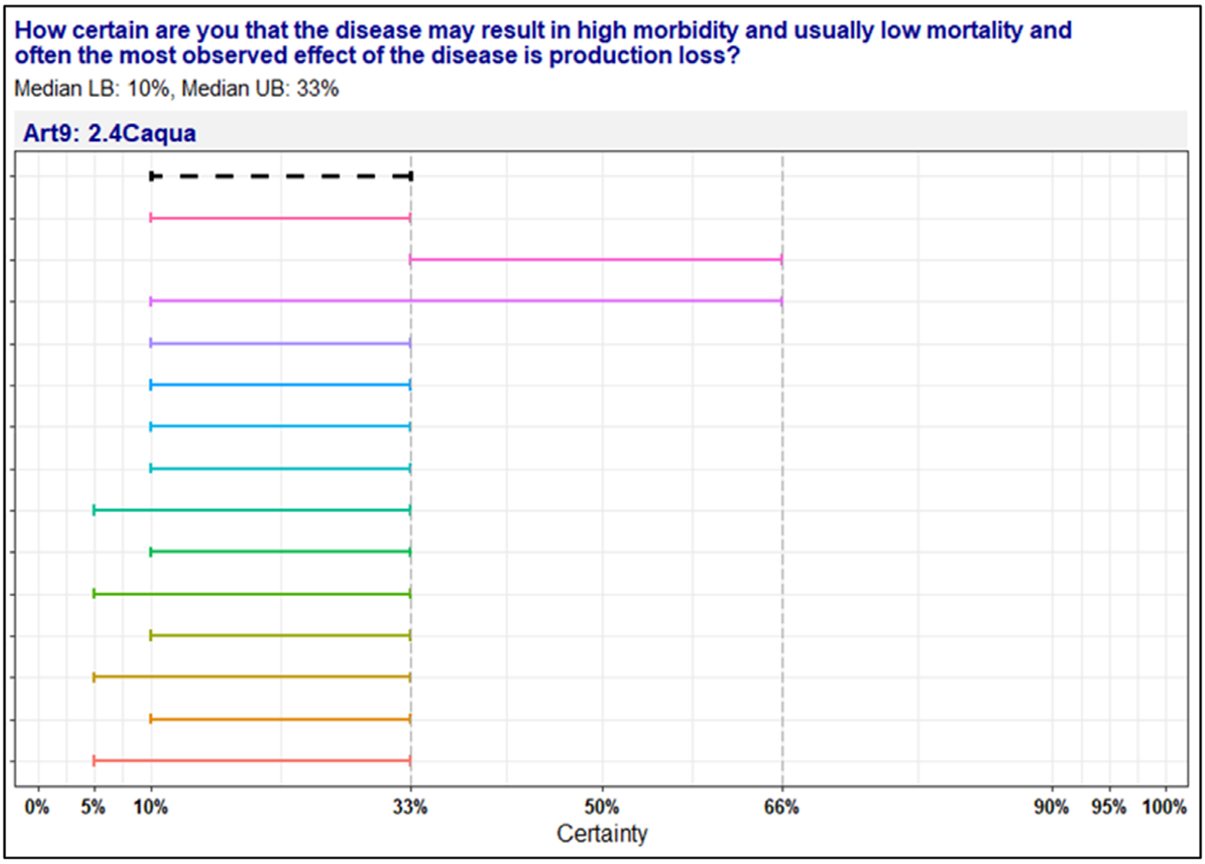

Figure A.20: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 2.4Caqua (the disease usually does not result in high morbidity and has negligible or no mortality and often the most observed effect of the disease is production loss). The black dotted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

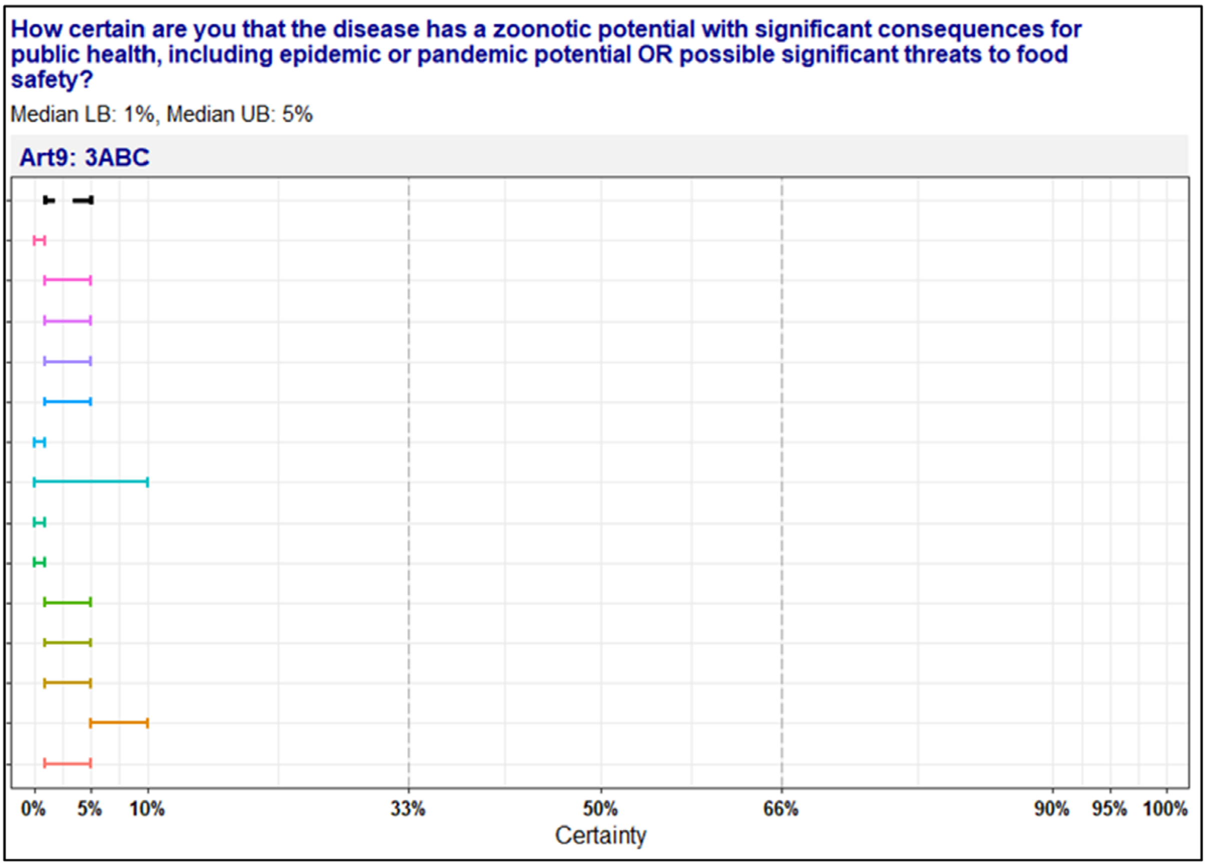

Figure A.21: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 3ABC (the disease has a zoonotic potential with significant consequences for public health or possible significant threats to food safety). The black dotted line on the top indicates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

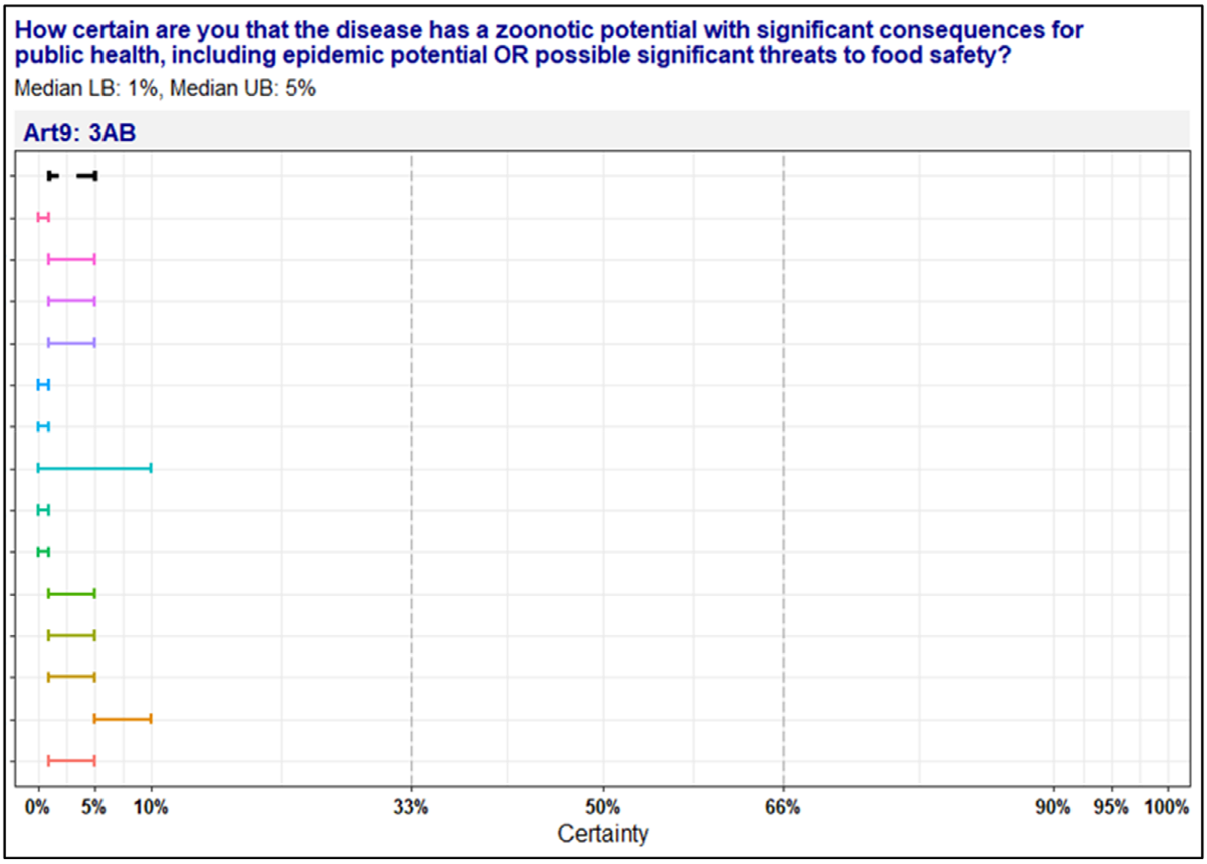

Figure A.22: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 3AB (the disease has a zoonotic potential with significant consequences for public health, including epidemic potential or possible significant threats to food safety). The black dotted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

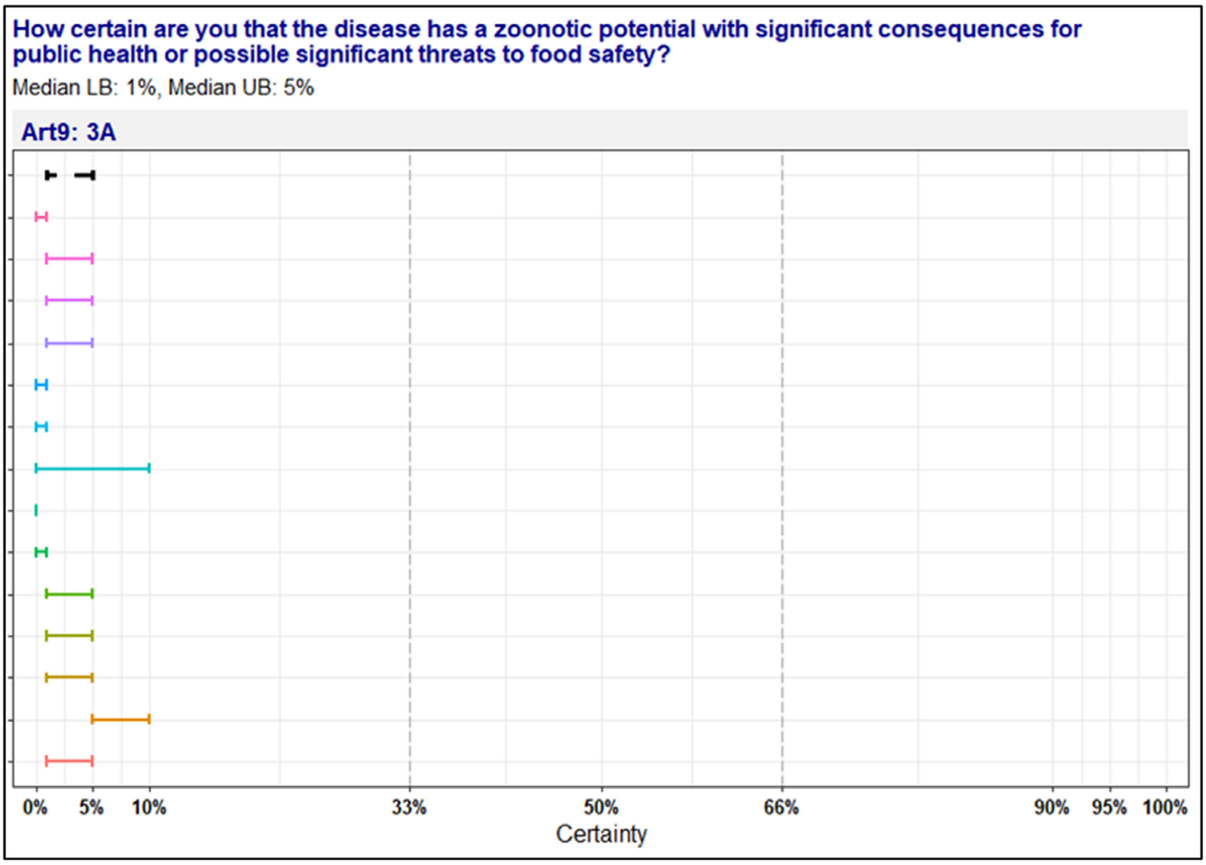

Figure A.23: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 3A (the disease has a zoonotic potential with significant consequences for public health, including epidemic or pandemic potential or possible significant threats to food safety). The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

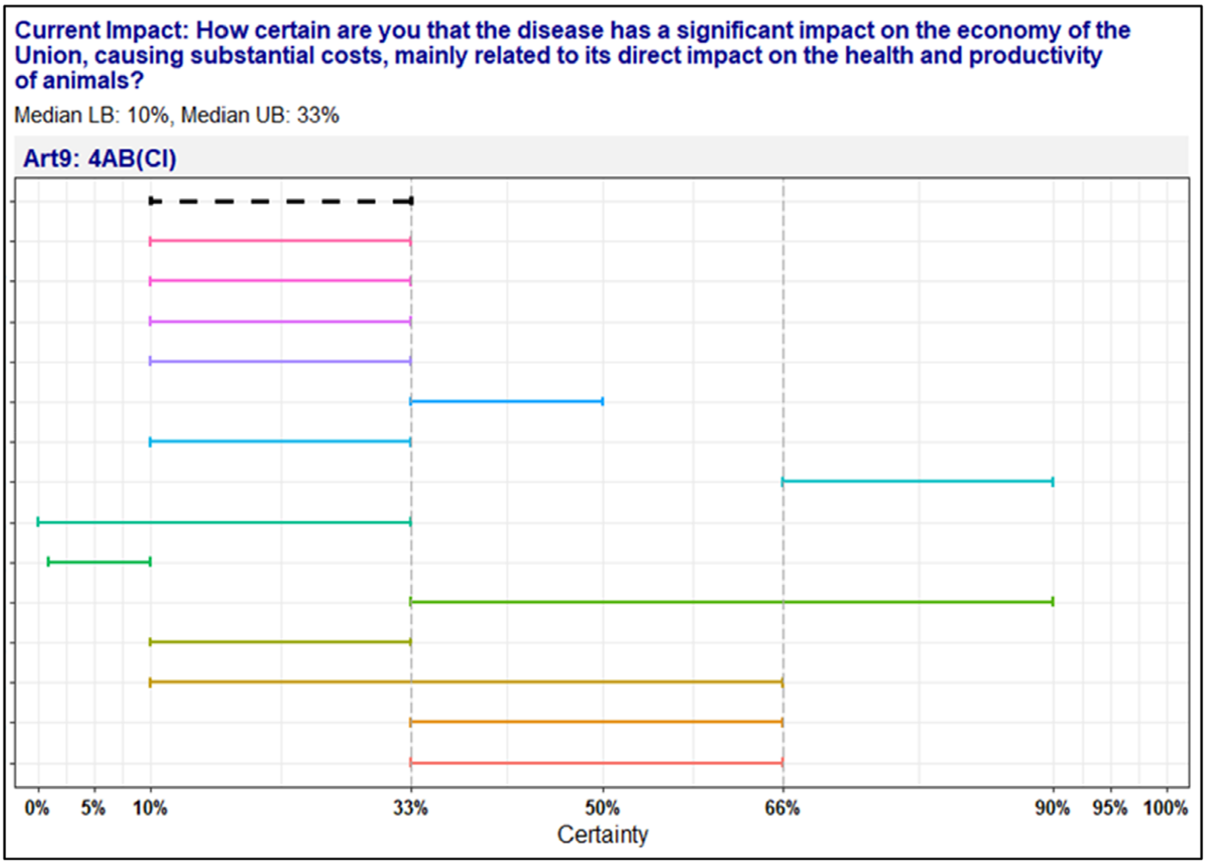

Figure A.24: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 4AB (current impact) (the disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity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

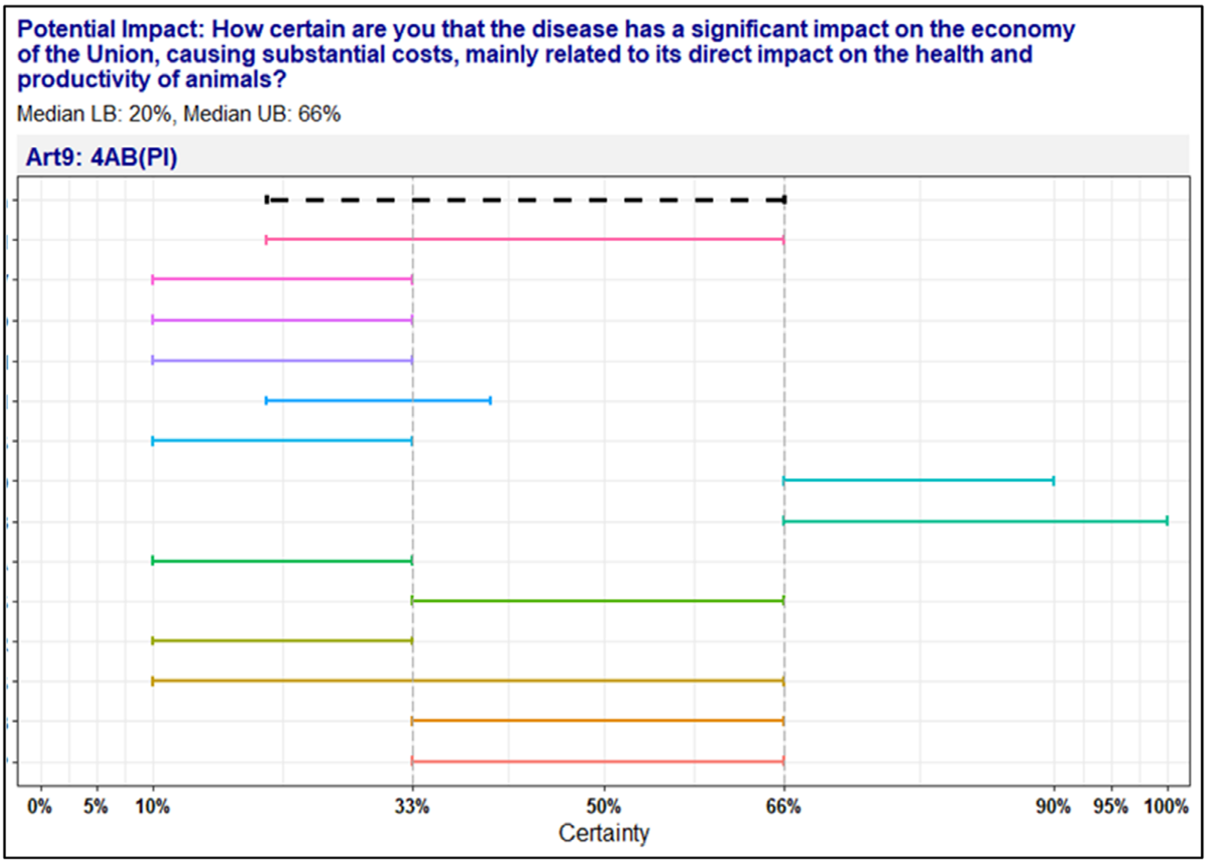

Figure A.25: Individual probability ranges, after the collective judgement, reflecting the uncertain outcome of the criterion 4AB (potential impact) (the disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity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

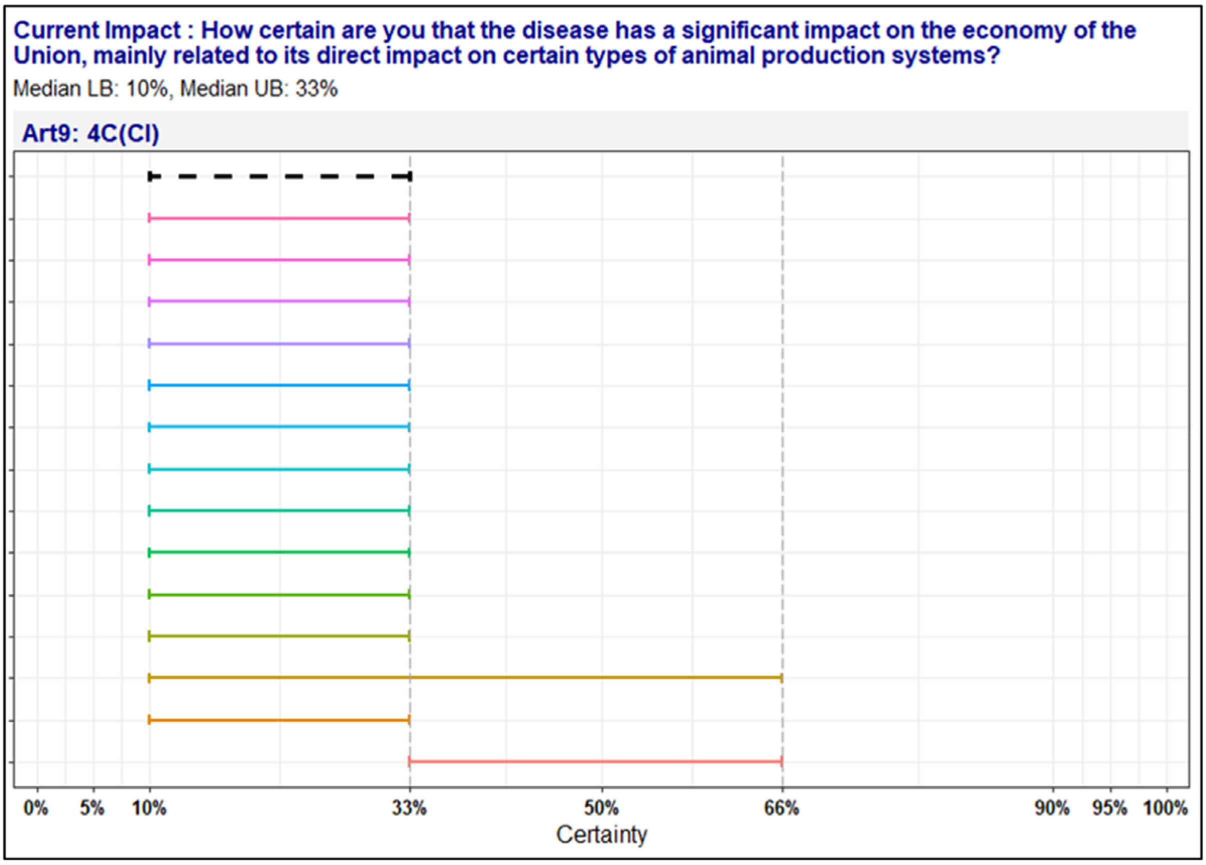

Figure A.26: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 4C (current impact) (the disease has a significant impact on the economy of the Union, mainly related to its direct impact on certain types of animal production systems). The black dotted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

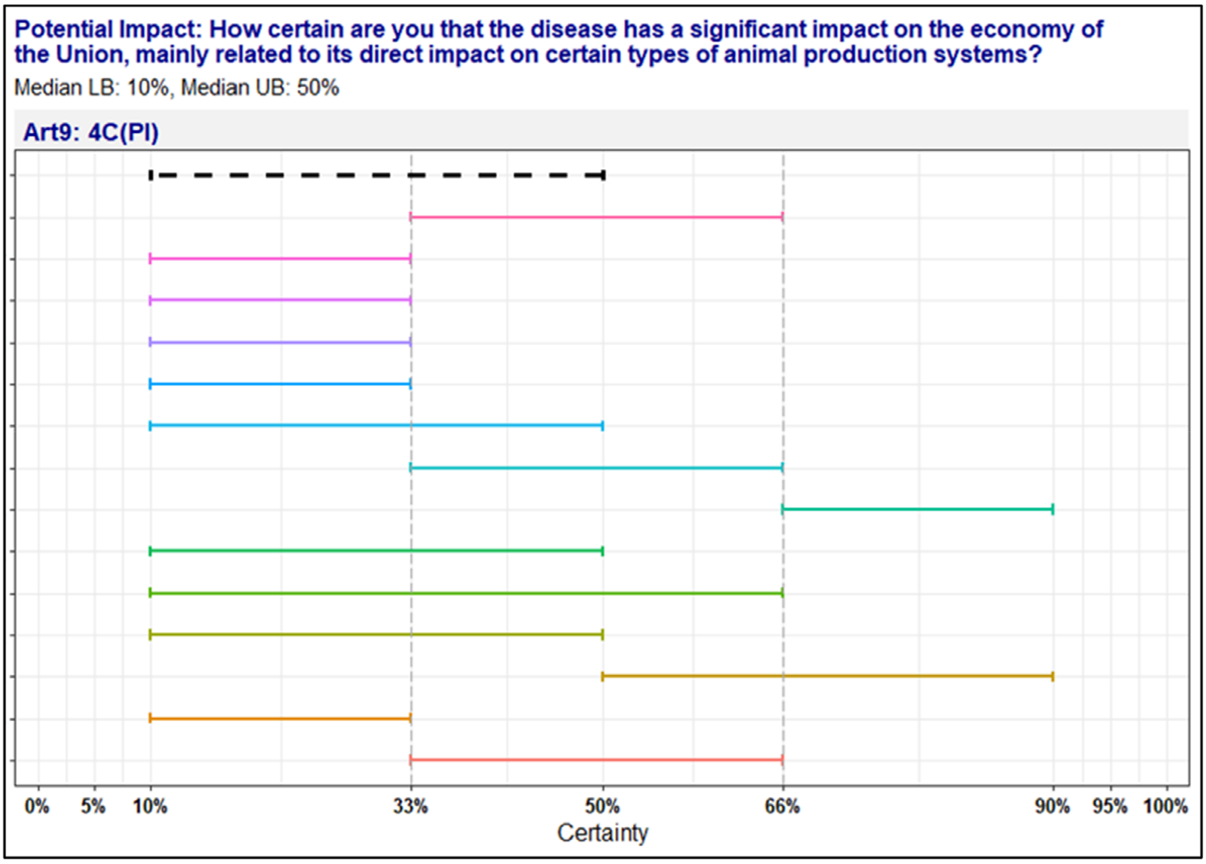

Figure A.27: Individual probability ranges, after the collective judgement, reflecting the uncertain outcome of the criterion 4C (potential impact) (the disease has a significant impact on the economy of the Union, mainly related to its direct impact on certain types of animal production systems). The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

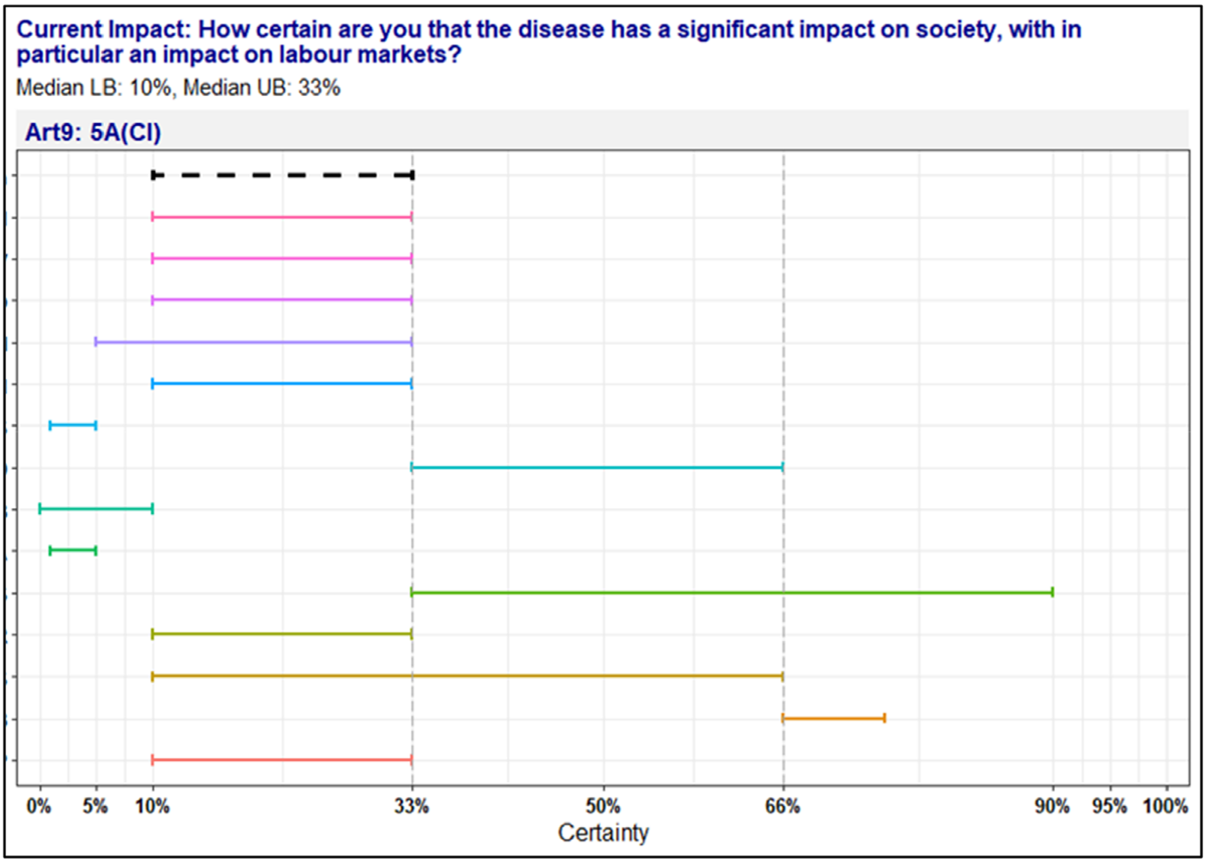

Figure A.28: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 5(a) (current impact) (the disease has a significant impact on society, with in particular an impact on labour markets). The black dotted line on the top indicates the median

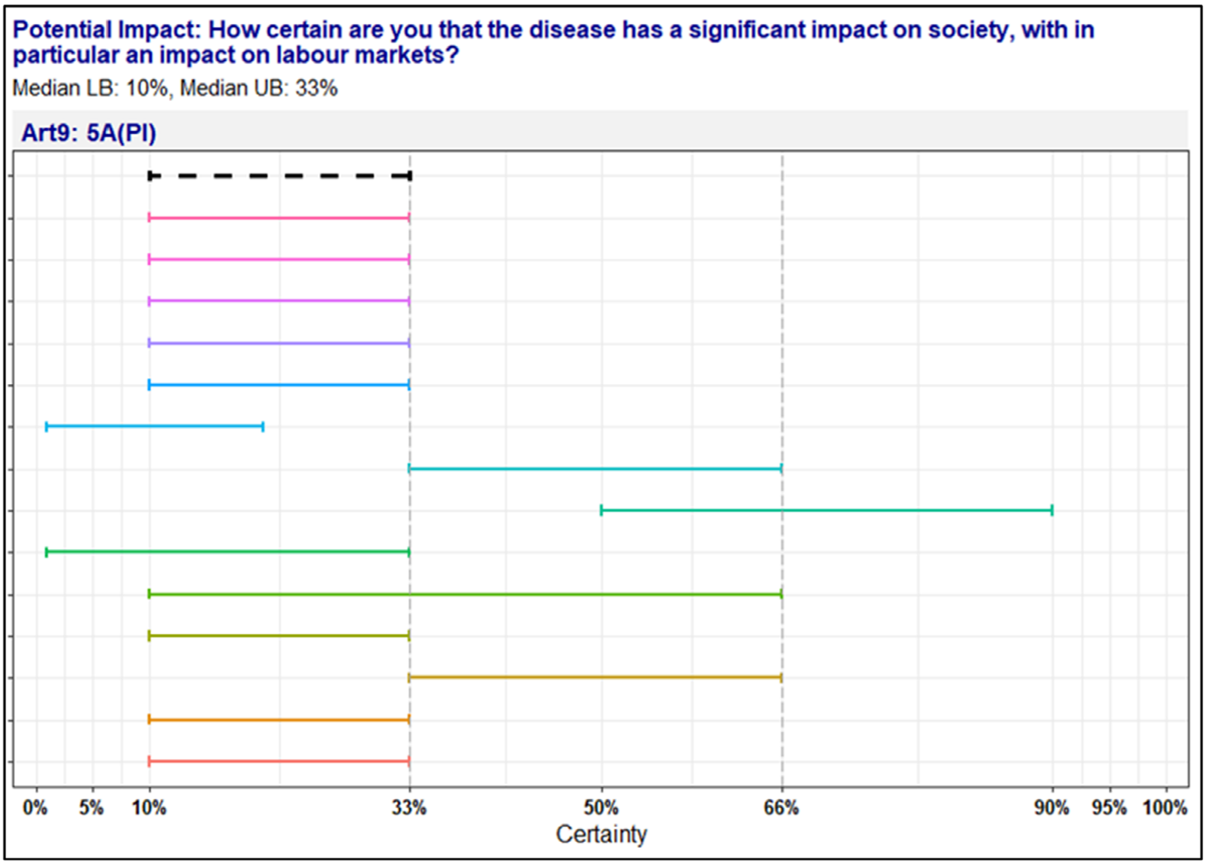

Figure A.29: Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 5(a) (potential impact) (the disease has a significant impact on society, with in particular an impact on labour markets). The black dotted line on the top indicates the median

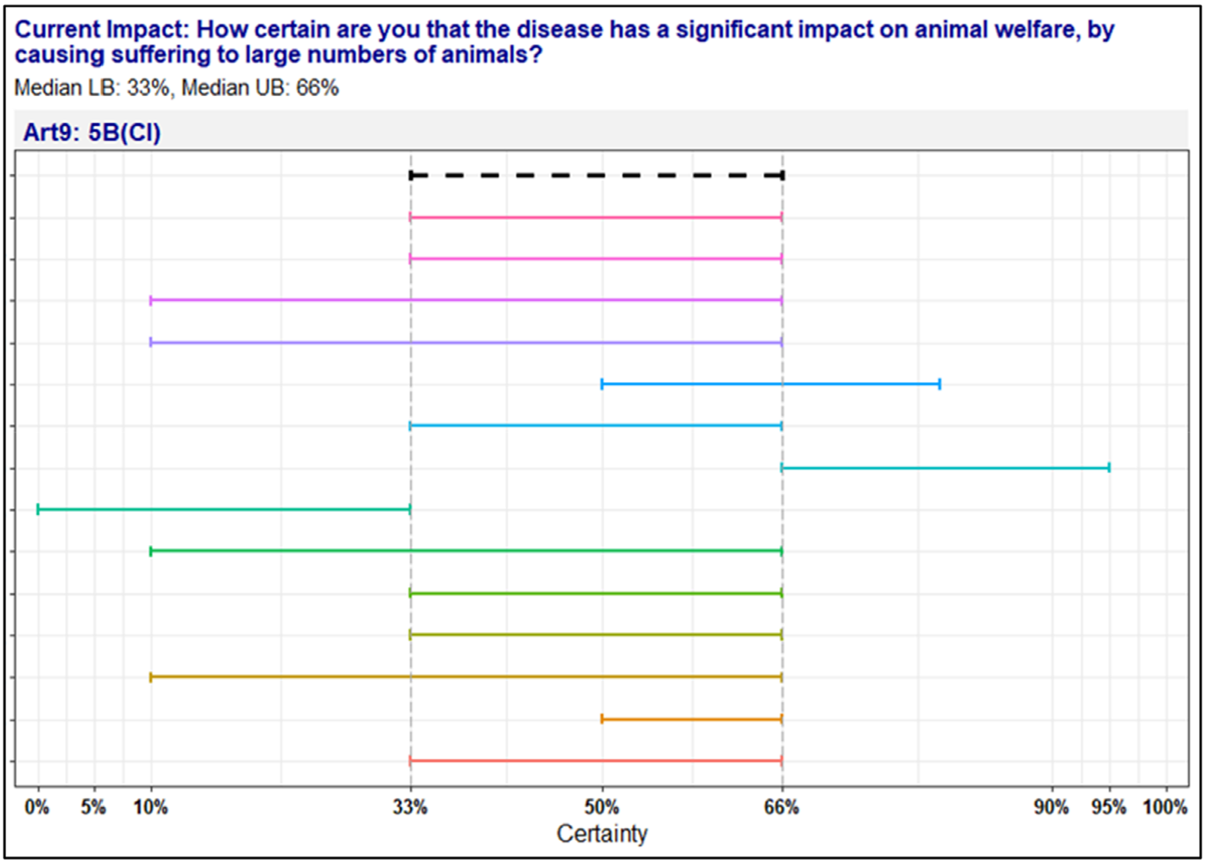

Figure A.30: Individual probability ranges, after the collective judgement, reflecting the uncertain outcome of the criterion 5(b) (current impact) (the disease has a significant impact on animal welfare, by causing suffering of large numbers of animals). The black dotted line on the top indicates the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

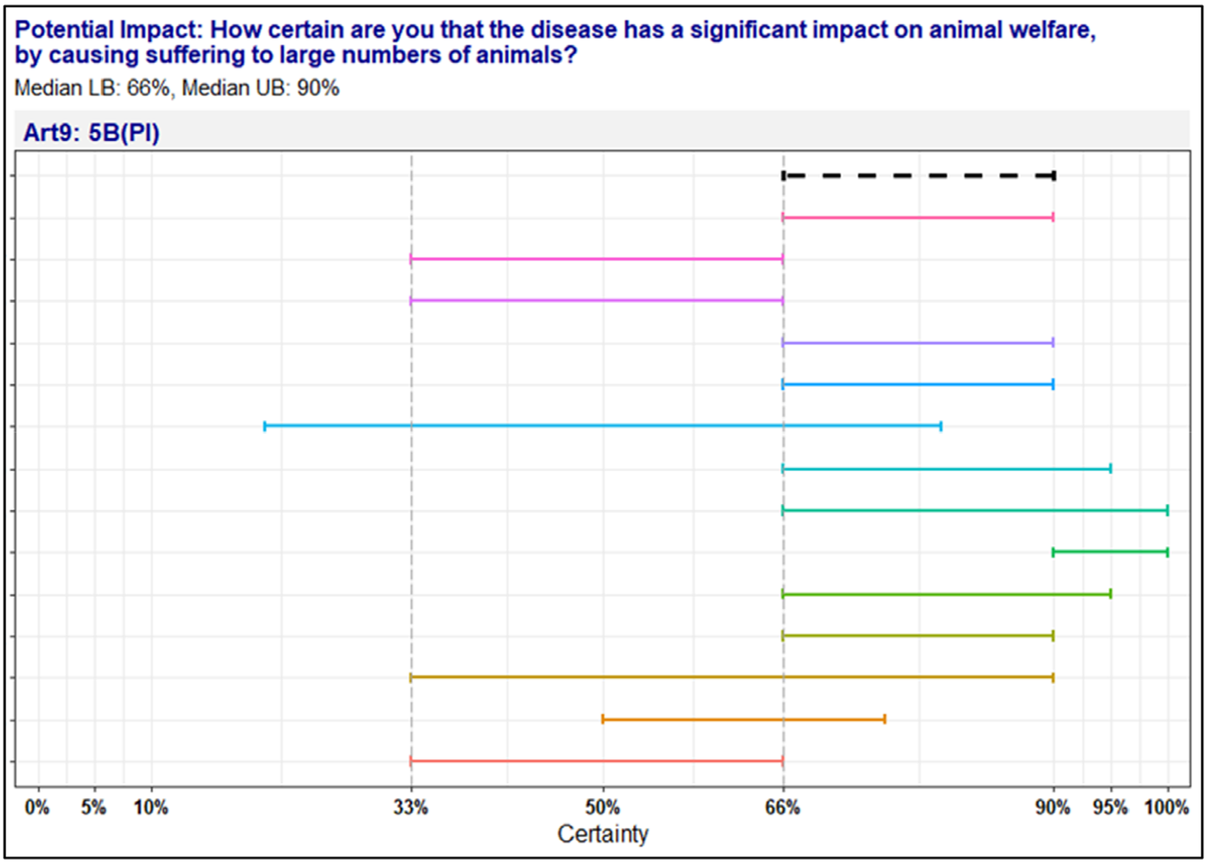

Figure A.31: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion 5(b) (potential impact) (the disease has a significant impact on animal welfare, by causing suffering of large numbers of animals). The black dotted line on the top indicates the median

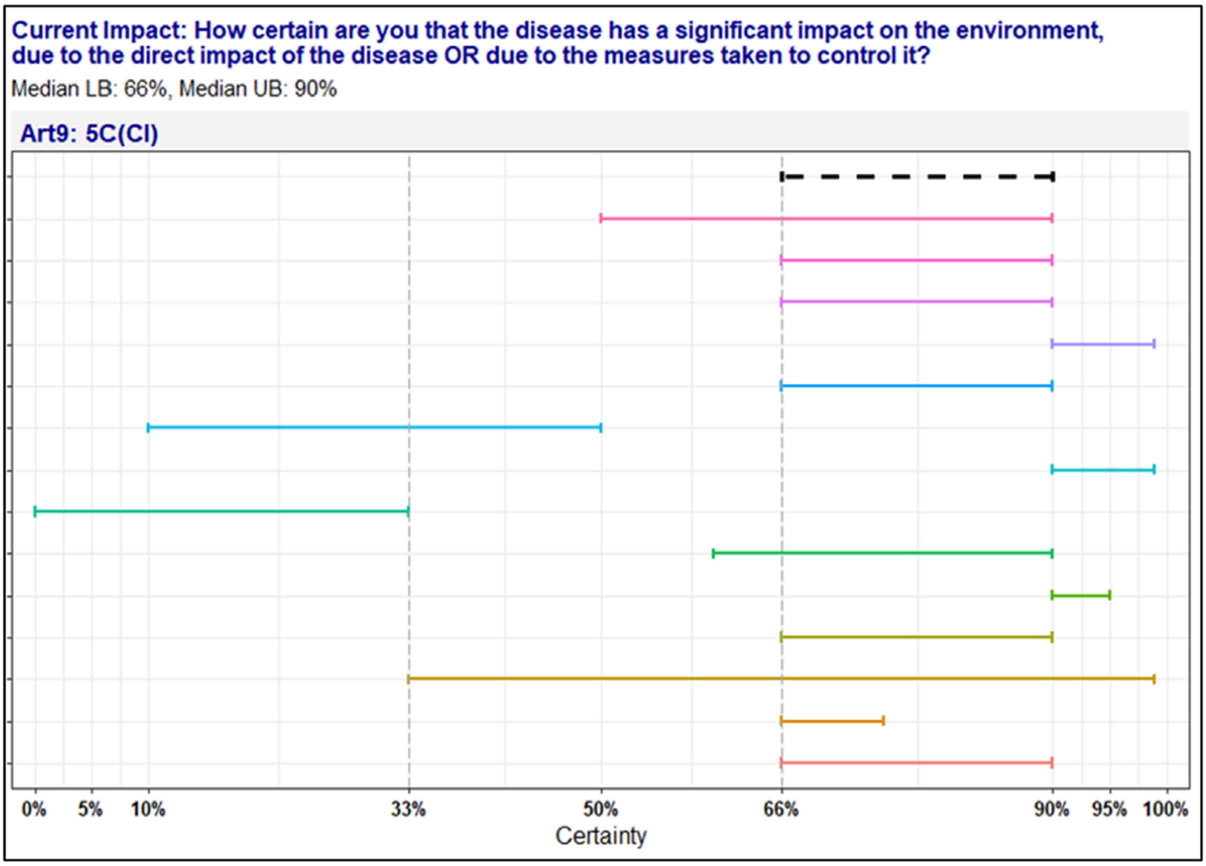

Figure A.32: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion 5(c) (current impact) (the disease has a significant impact on the environment, due to the direct impact of the disease or due to the measures taken to control it)**.** The black dotted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

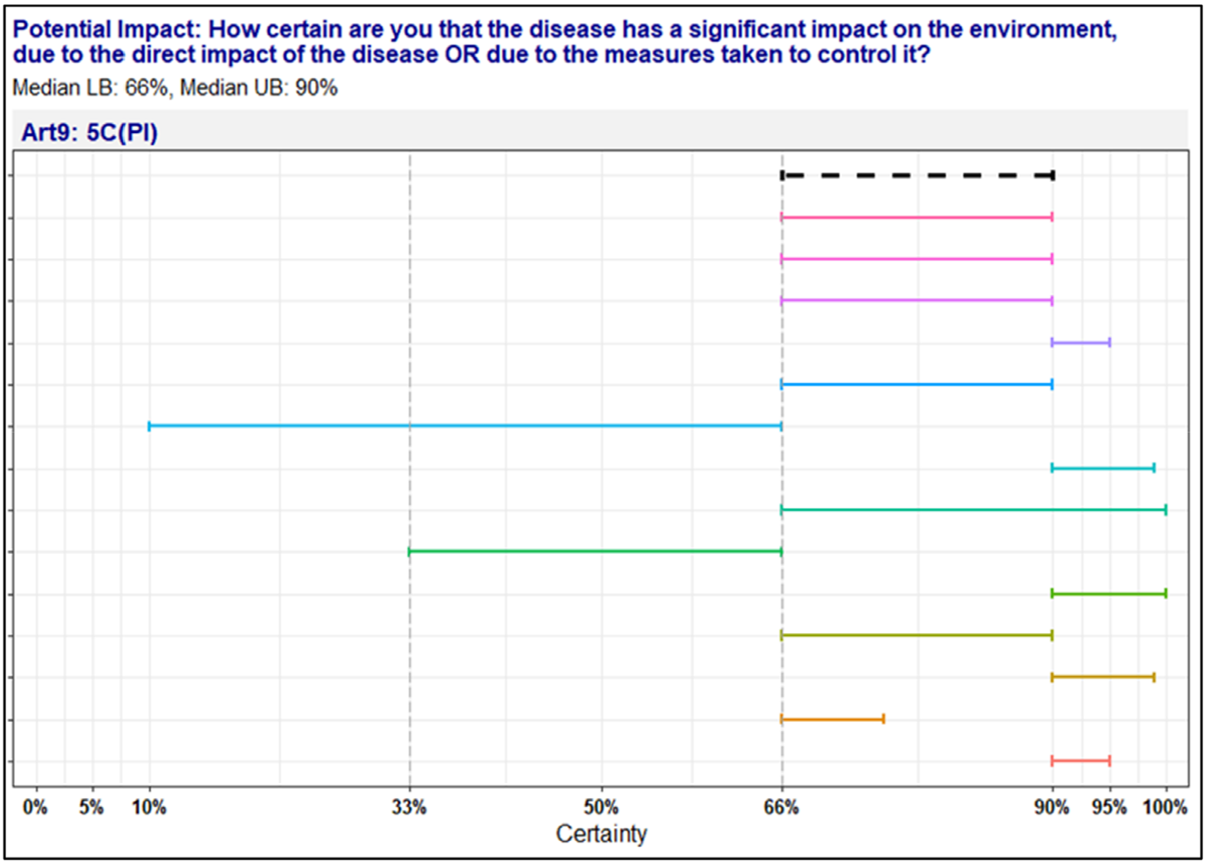

Figure A.33: Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion 5(c) (potential impact) (the disease has a significant impact on the environment, due to the direct impact of the disease or due to the measures taken to control it). The black dotted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

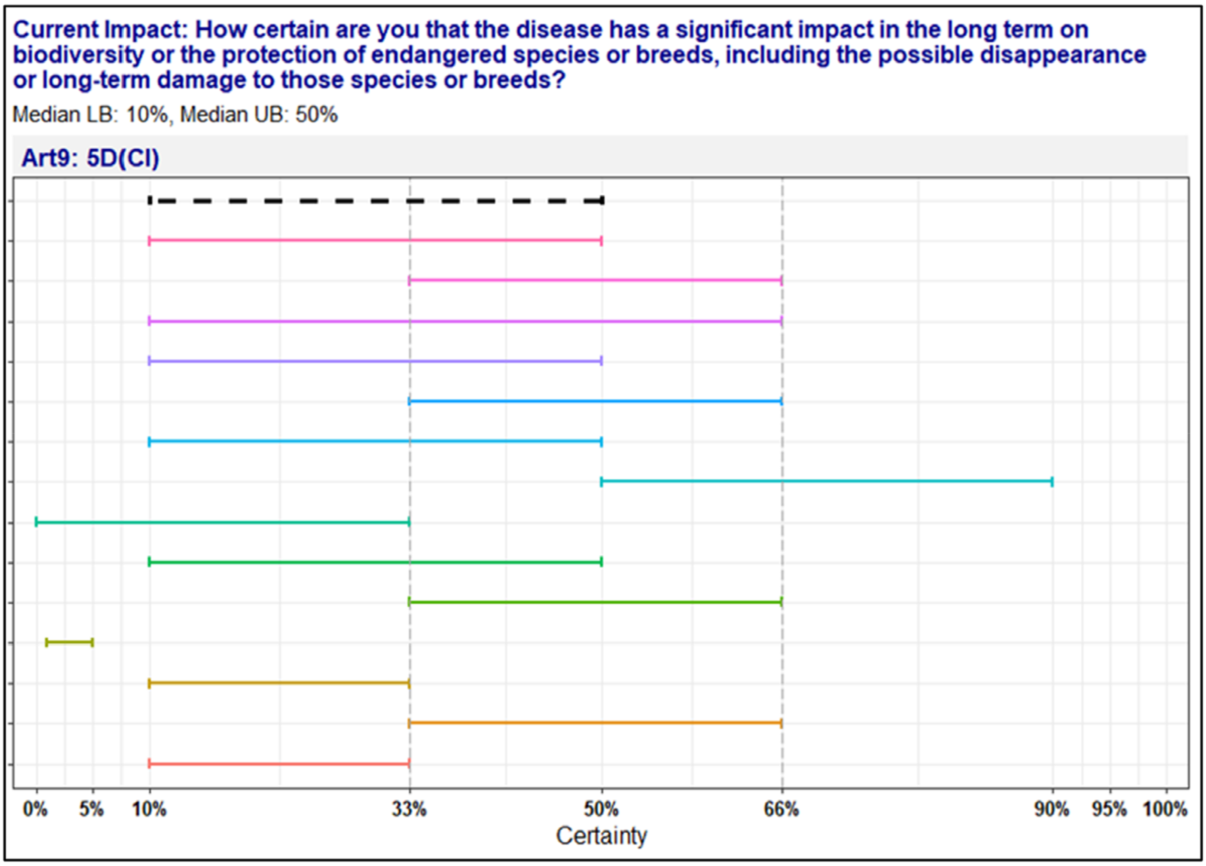

Figure A.34: Individual probability ranges, after the collective judgement, reflecting the uncertain outcome of the criterion 5(d) (current impact) (the disease has a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance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

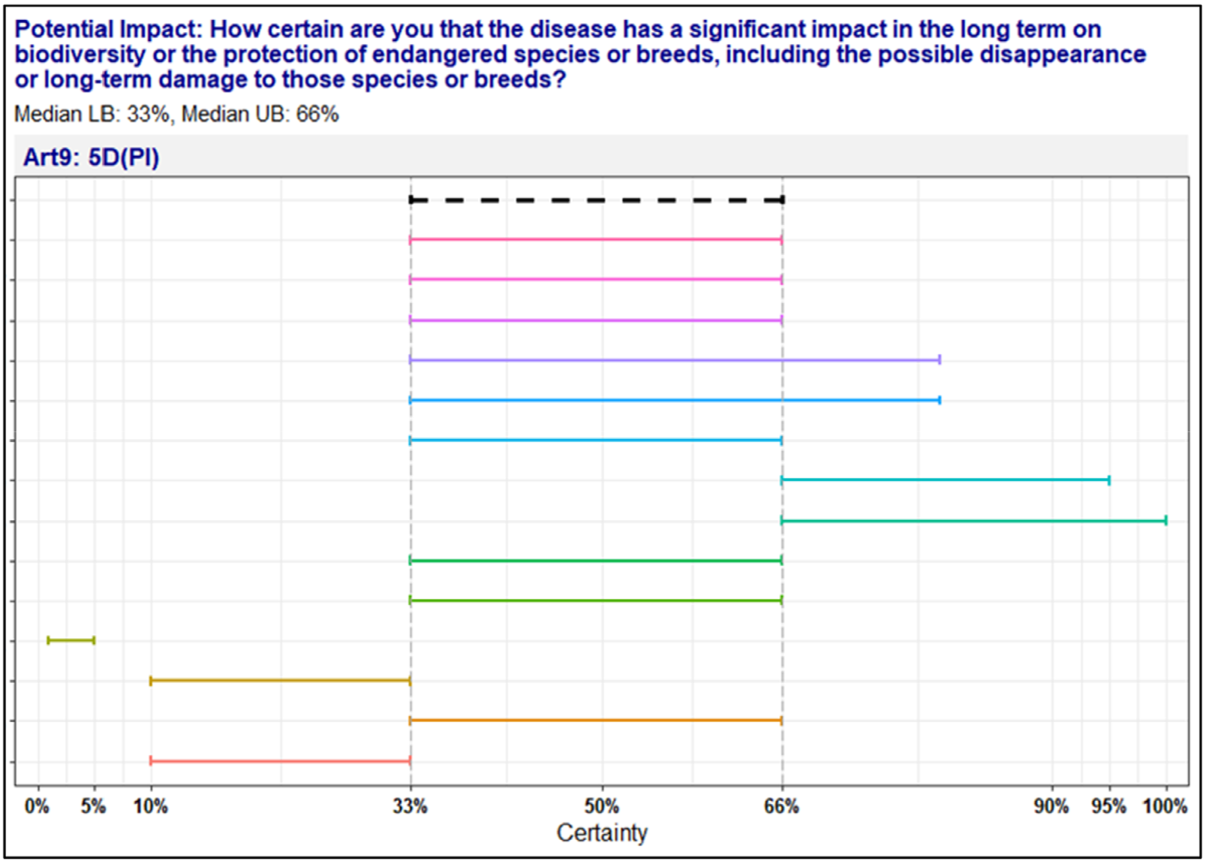

Figure A.35: Individual probability ranges, after the collective judgement, reflecting the uncertain outcome of the criterion 5(d) (potential impact) (the disease has a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance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

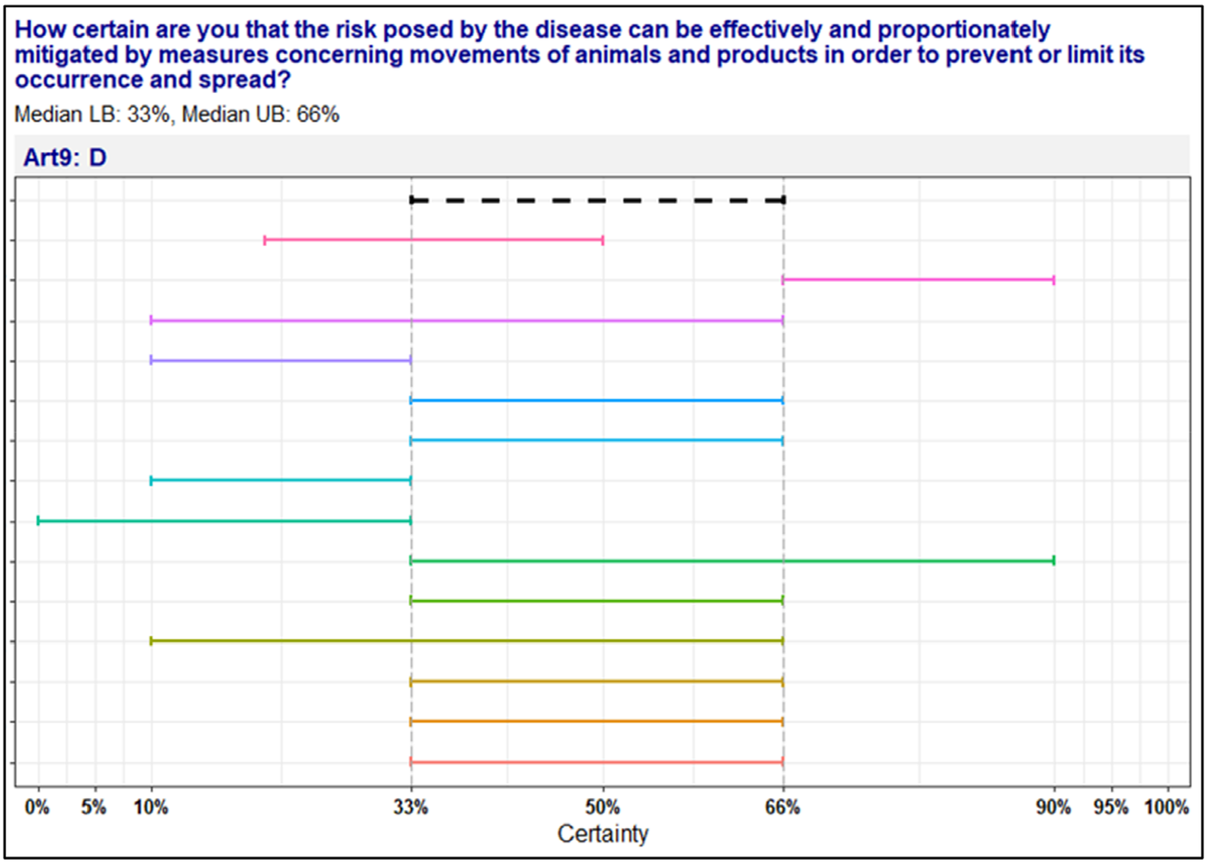

Figure A.36: Individual probability ranges, after the collective judgement, reflecting the uncertain outcome of the criterion D (the risk posed by the disease can be effectively and proportionately mitigated by measures concerning movements of animals and products in order to prevent or limit its occurrence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

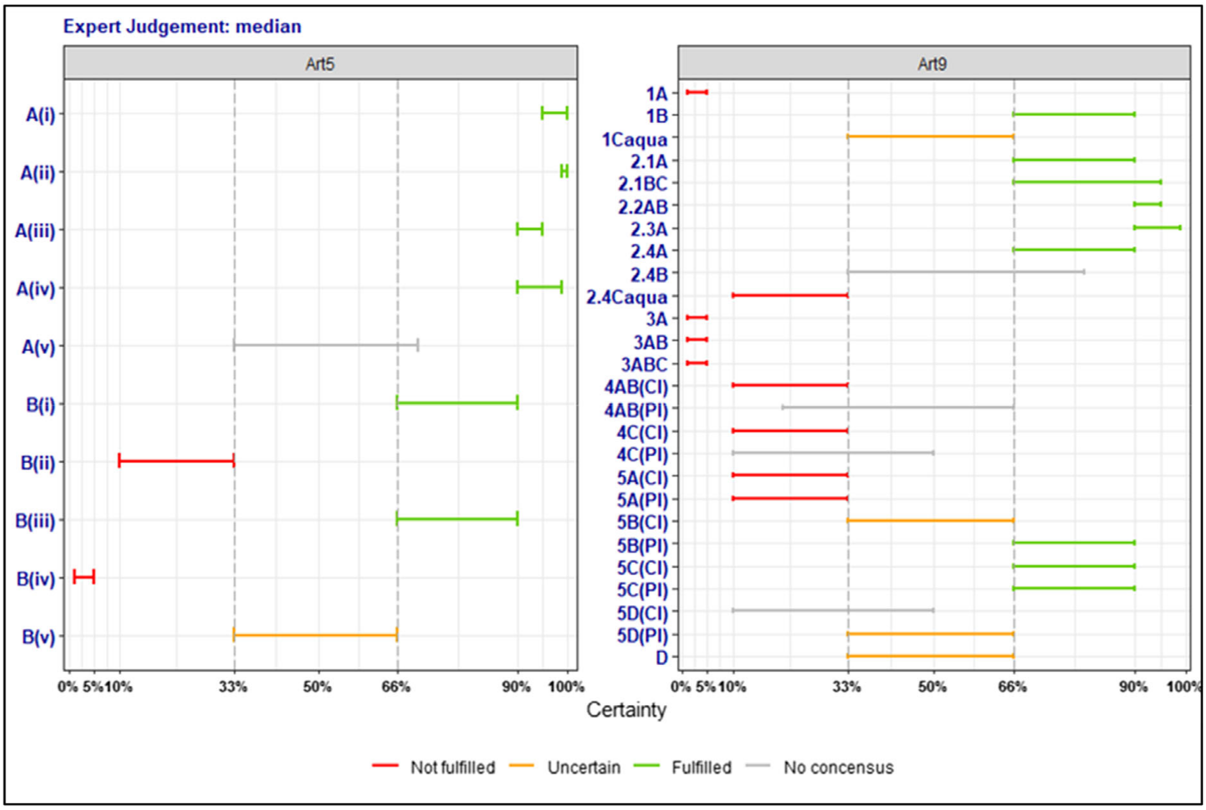

Figure A.37: Medians of the judgement replies in questions related to Article 5 (left side) and Article 9 (right side) of the AHL