Update on recent EFSA Opinions on disease listing and on vectors & reservoirs of listed diseases of aquatic animals

AHAC Meeting

10 November 2023

Drivers for update

Two mandates to EFSA in 2022:

- Assessment concerning species which may act as vectors or reservoirs of diseases listed in accordance with the Animal Health Law

- Assessment concerning the listing and categorisation of certain animal diseases within the framework of the Animal Health Law

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Recently published EFSA Scientific Opinions

- Vectors and reservoirs of listed diseases

  o Species which may act as vectors or reservoirs of diseases covered by the Animal Health Law: Listed pathogens of fish. EFSA Journal 2023; 21(8): 8174

  o Species which may act as vectors or reservoirs of diseases covered by the Animal Health Law: Listed pathogens of molluscs EFSA Journal 2023; 21(8): 8173

  o Species which may act as vectors or reservoirs of diseases covered by the Animal Health Law: Listed pathogens of crustaceans EFSA Journal 2023; 21(8): 8172

- Listing and categorisation of diseases for which certain MS and parts thereof, currently have national measures in accordance with Article 226(3) AHL

  o IPN: https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2023.8028

  o SVC: https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2023.8324

  o *G.salaris*: https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2023.8325

  o BKD: https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2023.8326

  o SAV: https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2023.8327
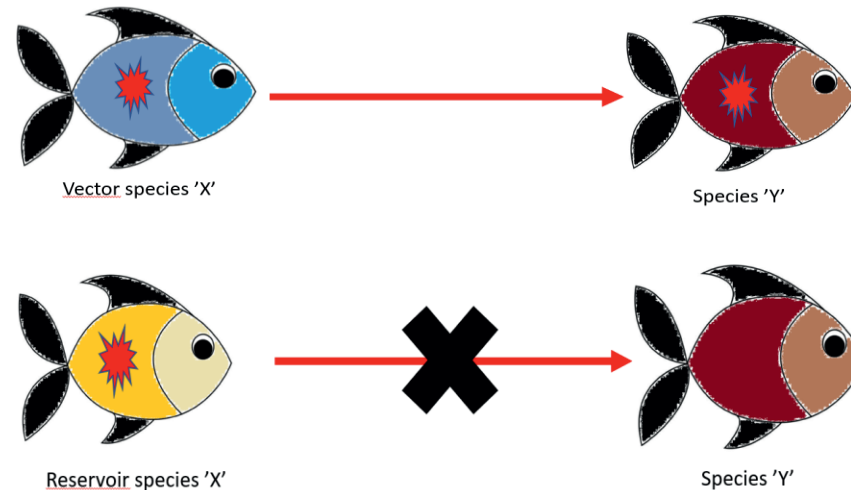
Background: Mandate concerning Vectors/ Reservoirs

- Vector species in the Annex to CIR (EU) 2018/1882 are largely the same as Annex I to Regulation (EC) No 1251/2008

  - some changes were made before adoption in 2018

  - but a complete review was not carried out

- Mandate to EFSA in June 2022 with a view to:

  - Updating the list of vectors/ reservoirs for listed diseases of aquatic animals (covering fish, molluscs & crustaceans) (ToR 1)

  - Reviewing the conditions under which these species should be considered to transmit the relevant disease (ToR 2)

- Reasons:

  - legal basis has changed under the AHL (Article 8)

  - scientific developments since 2008

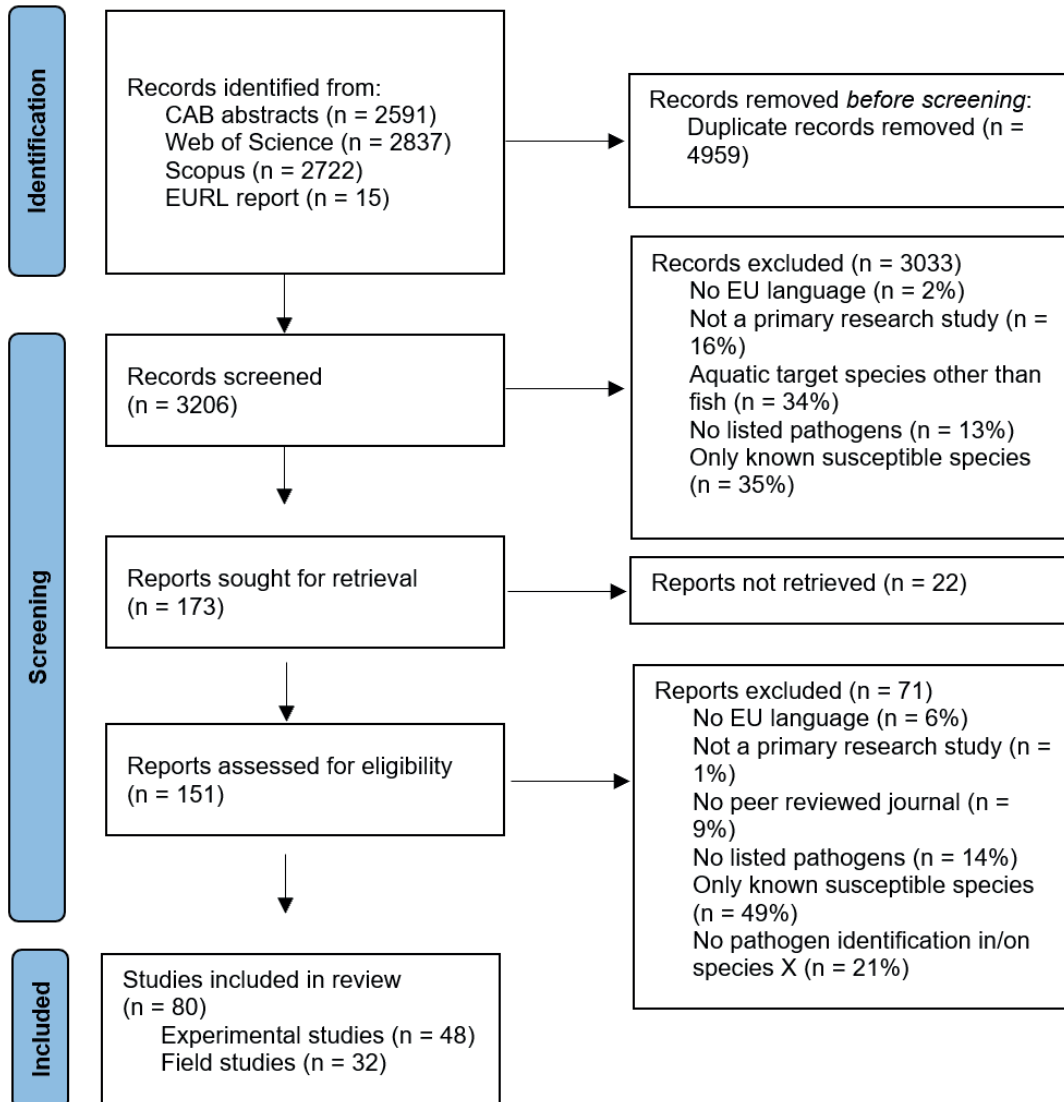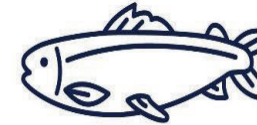# ToR 1: List of Vectors/ Reservoirs

WORKING DEFINITIONS USED IN SCIENTIFIC OPINIONS

A species is considered a **VECTOR** when the pathogen has been **identified in or on the species** and it has been **demonstrated to transmit the pathogen to susceptible species**

A species is considered to be **RESERVOIR** if the pathogen has been **identified in or on the species**, but **evidence of transmission of the pathogen to susceptible species is not available**

Vector species 'X'   Species 'Y'

Reservoir species 'X'   Species 'Y'

EFSA : Extensive Literature Review (ELR)

Methodology

ELR

- EFSA started with 4959 peer reviewed papers, ended up extracting information from 80 of those, after the eligibility screening

STEP 1: Individual assessment of eligible papers by EFSA Panel & Aquatic experts

- How certain are you that species X is a VECTOR OR RESERVOIR species based on the evidence generated through the ELR?

- Yes: >90% certainty / No:<10% certainty

- Inconclusive results fell in between and were elaborated in group discussion

STEP 2: Group discussion

- Objective to reach a consensus judgement

- Small expert WG and then Whole WG

- At Whole WG: cut-off level for classifying species as vectors or reservoirs was set at a minimum certainty of 66%

TOR 1 FINAL DELIVERABLE

- Lists of vector and reservoir species for each of the listed diseases of aquatic animals with certainty levels of 66-90% or >90%

- See details in individual SOs

- Example…….

Example of Conclusions: *B.exitiosa* and *B.ostreae*

Bonamia exitiosa

- Vectors

  - No evidence was found to identify vectors for *Bonamia exitiosa*

- Reservoirs

  - *Ostrea stentina* is considered to be a reservoir species for *Bonamia exitiosa* with >90% certainty

Bonamia ostreae

- Vectors

  - No evidence was found to identify any vectors for *Bonamia ostreae*

- Reservoirs

  - *Ostrea angasi* is considered to be a reservoir species for *Bonamia ostreae* with 66-90% certainty

Discussions with Member States: List of vectors & reservoirs

- PAFF meeting on 20 October

- **According to all 3 Scientific Opinions**: '……….. **risks do exist for the vector species**, since transmission from infected vector species to susceptible species was proven. Where evidence for transmission from infected fish was not found, these were defined as reservoirs. Nonetheless, **the risk of the spread of the pathogens from infected reservoir species cannot be excluded.'**

- **Article 8 of AHL:** 'The list shall comprise those animal species, or groups of animal species which **pose a considerable risk** for the spread of specific listed diseases…'

- Discussed **listing vectors** where the risk they pose can be managed

- Discussed **not listing reservoirs** because the 'considerable risk' requirement not fulfilled

EFSA ToR 2: conditions under which vector/reservoir species should be considered to transmit the relevant disease

APPROACH TAKEN

- Literature review to identify conditions that may prevent transmission of listed diseases by vectors

- Collected ranges of the different durations and temperatures for which transmission has been proven for the different pathogens

- Experts concluded by consensus whether the collected evidence was sufficient to support the need to amend the conditions stipulated in current legislation i.e. Annex I to CDR (EU) 2020/990 and Annex XXX to CDR (EU) 2020/692

CONCLUSIONS

- Taking into account the proposed list of vector species, conclusions reached by EFSA 2 are generally similar to conditions set out in above Regulations

- No proposals concerning the outcomes from ToR 2 at this time

Summary: Mandate concerning Vectors & Reservoirs

- Discussions ongoing with Member States

- Discussing the possibility of listing the species of vectors put forward by EFSA, for which risk management measures can be applied by CAs

- Discussing the possibility of not listing the species of reservoirs put forward by EFSA because they do not pose a 'considerable risk' (according to EFSA working definitions)

- Net result would be to reduce list of vectors from >200 species to 10 species none of which concern Cat B or C diseases => significant simplification of trade

- Depending on outcome of discussions with MS, amend the list of vector species set out in the Annex to CIR (EU) 2018/1882

Second EFSA mandate: Disease listing and categorisation

- In addition to listed diseases of aquatic animals (Annex II to AHL), there are other transmissible diseases for which certain trade measures apply in accordance with Article 226(3) of the AHL

- Details of relevant diseases and Member States/ parts thereof which are disease-free, or which are subject to an eradication programme, are set out in Annexes I and II to Commission Implementing Decision (EU) 2021/260

- Susceptible species 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 => Mandate to EFSA in mid-2022

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

Disease listing & categorisation

TORS concerning SVC, BKD, IPN, GS, SAV

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;

ToR 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

EFSA: Methodology

- The EFSA AHAW Panel used the same methodology for the data collection and assessment concerning this mandate, as had been used for previous listing and categorization exercises (EFSA AHAW Panel et al., 2017).

- Methodology favoured by EFSA as it allows animal diseases to be assessed in a uniform and consistent way

- An EFSA working group (WG) of experts with expertise in aquatic animal diseases was established to support the assessment of the EFSA AHAW panel

EFSA: Probability scale concerning listing

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%

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Outcome expert judgement on eligibility for listing in accordance with Article 5 (Example: SVC)
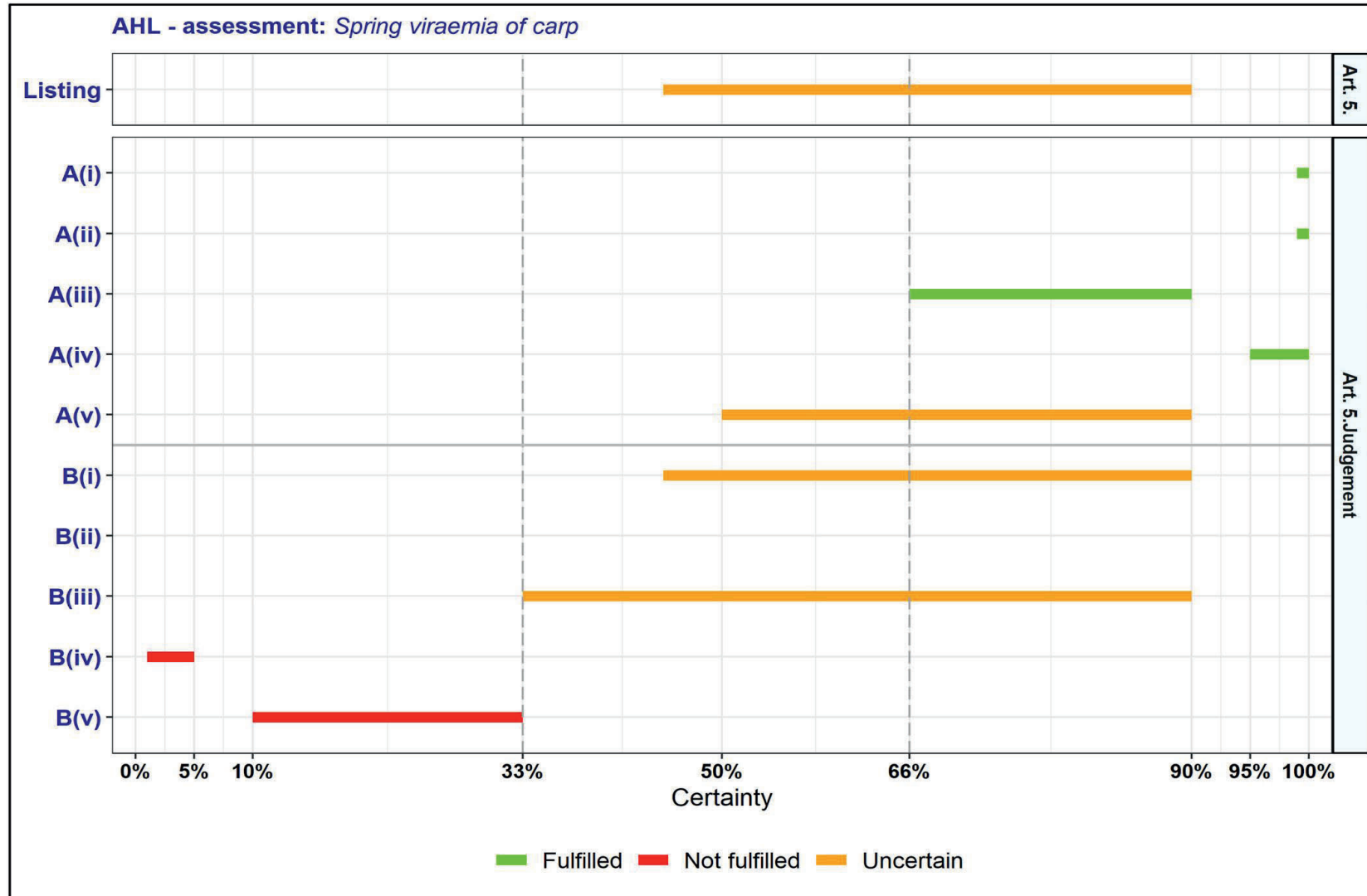
Outcome Expert Judgement on probabilities for categorisation in accordance with Article 9 (Example: SVC)
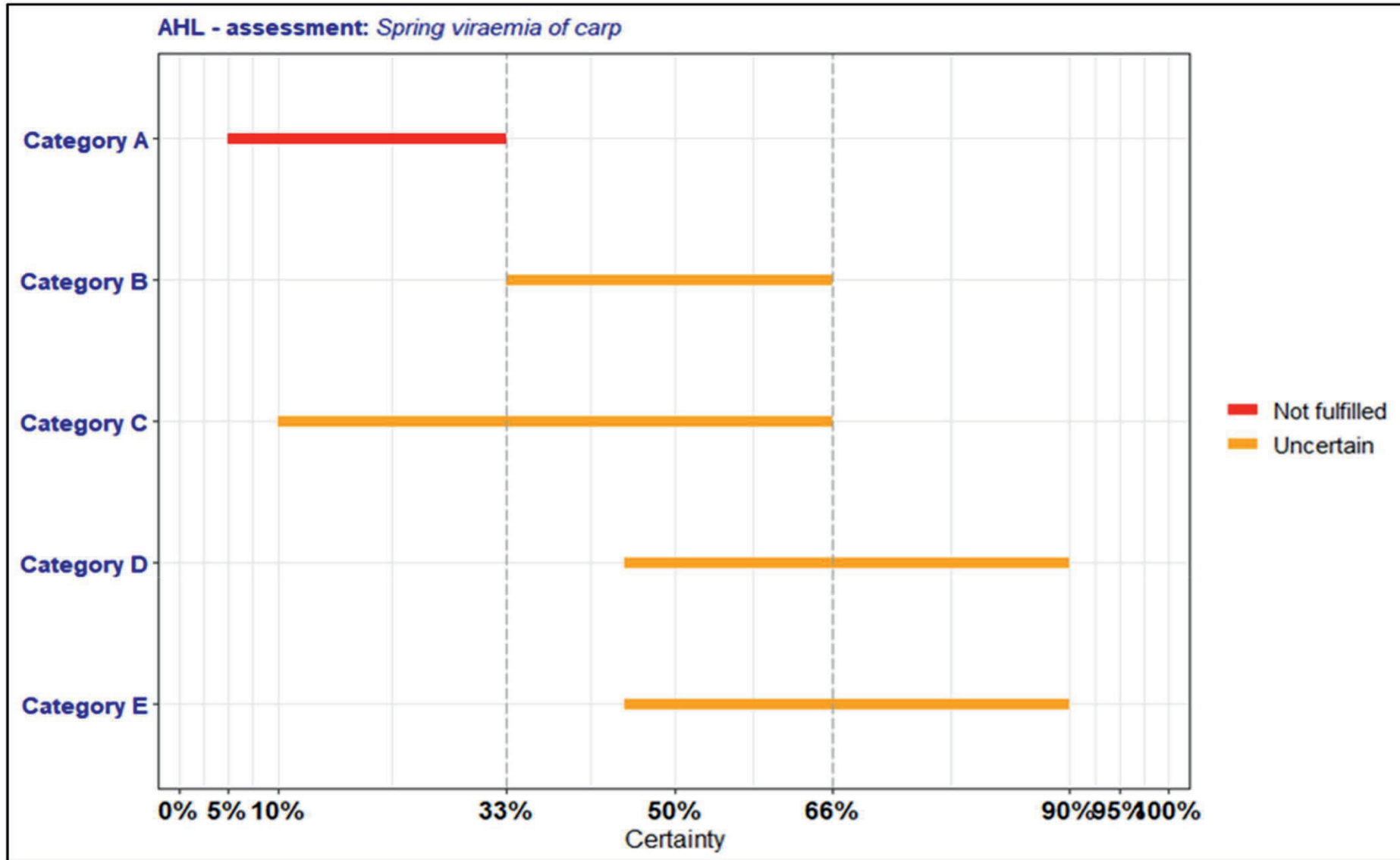
Summary & next steps: Listing & categorisation

- All 5 Scientific Opinions now published

- Only BKD proposed for listing

- GS, IPN, SAV, SVC assessed to be uncertain concerning their eligibility to be listed, with varying probabilities

- Disease categorisation with varying probabilities proposed for each disease

- New lists of species provided

- Discuss shortly with MS, plan next steps

- Future updates on those discussions can be provided

Thank you

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Summary of conclusions: Listing & Categorisation

Disease	Probability whether disease can be considered eligible for listing	Categorisation
BKD	Likely: 66-90%	A: 1-5% B:33-66% C:33-66% D: 66-90% E: 66-90%
IPN	Uncertain: 50-90%	A: 0-1% B:33-66% C:33-66% D: 50-90% E: 50-90%
SAV	Uncertain: 50-80%	A:5-10% B: 50-90% C: 50-90% D: 50-90% E: 50-90%
SVC	Uncertain: 45-90%	A: 5-33% B: 33-66% C:10-66% D: 66-90% E: 45-90%
G. salaris	Uncertain: 33-70%	A: 1-5% B: 33-80% C:10-33% D:33-66% E: 33-70%