# **SCIENTIFIC OPINION**

ADOPTED: 27 September 2023 doi: 10.2903/j.efsa.2023.8324



# Assessment of listing and categorisation of animal diseases within the framework of the Animal Health Law (Regulation (EU) 2016/429): Spring Viraemia of Carp (SVC)

EFSA Panel on Animal Health and Welfare (AHAW),

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

# Abstract

Spring Viraemia of Carp (SVC) was assessed according to the criteria of the Animal Health Law (AHL), in particular the criteria of Article 7 on disease profile and impacts, Article 5 on its eligibility to be listed, Annex IV for its categorisation according to disease prevention and control rules as in Article 9 and Article 8 for listing animal species related to SVC. The assessment was performed following the ad hoc method for data collection and assessment previously developed by the AHAW panel and already published. The outcome reported is the median of the probability ranges provided by the experts, which indicates whether each criterion is fulfilled (lower bound  $\geq$  66%) or not (upper bound  $\leq$  33%), or whether there is uncertainty about fulfilment. Reasoning points are reported for criteria with an uncertain outcome. According to the assessment performed here, it is uncertain whether SVC can be considered eligible to be listed for Union intervention according to Article 5 of the AHL (45-90% probability). According to the criteria in Annex IV, for the purpose of categorisation related to the level of prevention and control as in Article 9 of the AHL, the AHAW Panel concluded that SVC does not meet the criteria in Section 1 (Category A; 5-33% probability of meeting the criteria) and it is uncertain whether it meets the criteria in Sections 2, 3, 4 and 5 (Categories B, C, D and E; 33-66%, 10-66%, 45-90% and 45-90% probability of meeting the criteria, respectively). The animal species to be listed for SVC according to Article 8 criteria are provided.

© 2023 European Food Safety Authority. *EFSA Journal* published by Wiley-VCH GmbH on behalf of European Food Safety Authority.

**Keywords:** aquatic animals, Animal Health Law, Spring Viraemia of carp, listing, categorisation, impact

Requestor: European Commission Question number: EFSA-Q-2023-00062 Correspondence: biohaw@efsa.europa.eu **Panel members:** Søren Saxmose Nielsen, Julio Alvarez, Dominique Joseph Bicout, Paolo Calistri, Elisabetta Canali, Julian Ashley Drewe, Bruno Garin-Bastuji, José Luis Gonzales Rojas, Christian Gortázar, Mette S Herskin, Virginie Michel, Miguel Ángel Miranda Chueca, Barbara Padalino, Helen Clare Roberts, Hans Spoolder, Karl Ståhl, Antonio Velarde, Arvo Viltrop and Christoph Winckler.

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

**Acknowledgements:** The AHAW Panel wishes to acknowledge the expert Dr Robert Potts selected through the Individual Scientific Advisor schema (ISA expert; EOI/EFSA/SCIENCE/2022/01 – CT 01 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.

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

**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): Spring Viraemia of Carp (SVC). *EFSA Journal*, *21*(10), 1–76. https://doi.org/10.2903/j.efsa.2023.8324

#### **ISSN:** 1831-4732

© 2023 European Food Safety Authority. *EFSA Journal* published by Wiley-VCH GmbH on behalf of European Food Safety Authority.

This is an open access article under the terms of the Creative Commons Attribution-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.

EFSA may include images or other content for which it does not hold copyright. In such cases, EFSA indicates the copyright holder and users should seek permission to reproduce the content from the original source.



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



18314732, 2023, 10, Downloaded from https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochranettalia, Wiley Online Library on [04/02/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.con/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

#### **Table of contents**

Abstract		1
1	Introduction	5
11	Packaround and Tarms of Deference as provided by the requester	5
1.1.	Background and remis of Reference as provided by the requestor	5
1.1.1.	Disease specific information	5
1.1.2.	Disease specific information	2
1.1.3.	Terms of Reference	0
1.2.	Interpretation of the terms of Reference	0
2.	Data and methodologies	/
3.	Assessment.	8
3.1.	Assessment according to Article / criteria.	8
3.1.1.	Article /(a) Disease Profile	8
3.1.1.1.	Article /(a)(i) Animal species concerned by the disease	8
3.1.1.2.	Article /(a)(ii) The morbidity and mortality rates of the disease in animal populations	11
3.1.1.3.	Article 7(a)(iii) The zoonotic character of the disease	11
3.1.1.4.	Article 7(a)(iv) The resistance to treatments, including antimicrobial resistance	11
3.1.1.5.	Article $7(a)(v)$ The persistence of the disease in an animal population or the environment	11
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	12
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	13
3.1.1.8.	Article 7(a)(viii) The existence of diagnostic and disease control tools	15
3.1.2.	Article 7(b) The impact of disease	16
3.1.2.1.	Article 7(b)(i) The impact of the disease on agricultural and aquaculture production and other parts	
	of the economy	16
3.1.2.2.	Article 7(b)(ii) The impact of the disease on human health	16
3.1.2.3.	Article 7(b)(iii) The impact of the disease on animal welfare	17
3.1.2.4.	Article 7(b)(iv) The impact of the disease on biodiversity and the environment	17
3.1.3.	Article 7(c) Its potential to generate a crisis situation and its potential use in bioterrorism	17
3.1.4.	Article 7(d) The feasibility, availability and effectiveness of the following disease prevention and	
	control measures	18
3.1.4.1.	Article 7(d)(i) Diagnostic tools and capacities	18
3.1.4.2.	Article 7(d)(ii) Vaccination	18
3.1.4.3.	Article 7(d)(iii) Medical treatments.	19
3.1.4.4.	Article 7(d)(iv) Biosecurity measures	19
3.1.4.5.	Article 7(d)(v) Restrictions on the movement of animals and products	20
3.1.4.6.	Article 7(d)(vi) Killing of animals	21
3.1.4.7.	Article 7(d)(vii) Disposal of carcasses and other relevant animal by-products	21
3.1.4.8.	Article 7(d)(viii) Selective Breeding; Genetic resistance to infection	22
3.1.5.	Article 7(e) The impact of disease prevention and control measures	22
3.1.5.1.	Article 7(e)(i) The direct and indirect costs for the affected sectors and the economy as a whole	22
3.1.5.2.	Article 7(e)(ii) the societal acceptance of disease prevention and control measures	23
3.1.5.3.	Article 7(e)(iii) The welfare of affected subpopulations of kept and wild animals	23
3.1.5.4.	Article 7(e)(iv) The environment and biodiversity	23
3.2.	Assessment of spring viraemia of carp according to article 5 criteria of AHL on its eligibility to be	
	listed	24
3.2.1.	Detailed outcome on Article 5 criteria	24
3.2.2.	Reasoning for uncertain outcome on Article 5 criteria	25
3.2.3.	Overall outcome on Article 5 criteria	26
3.3.	Assessment Spring Viraemia of Carp according to criteria in Annex IV for the purpose of	_
	categorisation as in Article 9 of the AHL	26
3.3.1.	Detailed outcome on Category A criteria	27
3.3.1.1.	Reasoning for uncertain outcome on Category A criteria	28
3.3.2.	Detailed outcome on Category B criteria	29
3.3.2.1.	Reasoning for uncertain outcome on category B criteria	30
3.3.3.	Detailed outcome on Category C criteria	31
3.3.3.1.	Reasoning for uncertain outcome on Category C criteria	32
3.3.4.	Detailed outcome on Category D criteria	33
3.3.5.	Detailed outcome on Category E criteria	33
3.3.6.	Overall outcome on criteria in Annex IV for the purpose of categorisation as in Article 9	33
3.4.	Assessment of Spring Viraemia of Carp according to Article 8 criteria of the AHL	35
4.	Conclusions	37

18314732, 2023, 10, Downloaded from https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by CochraneItalia, Wiley Online Library on [04/02/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

# 

References	38
Abbreviations	40
Appendix A – Expert judgement plotted by question	41

# 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),<sup>1</sup> provides 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 Tests 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

18314732, 2023, 10, Downloaded from https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochranettalia, Wiley Online Library on [04/02/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.con/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

<sup>&</sup>lt;sup>1</sup> 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.

<sup>&</sup>lt;sup>2</sup> 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 Spring viraemia of carp (SVC) according to the criteria of the AHL articles as follows:

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

1022021; See the Terms and Conditions (https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia

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 SVC.

# 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 Scientific Opinion on 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 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.

Committee, 2018)	
Probability term	Subjective probability range
Almost certain	99_100%

Table 1: Approximate probability scale recommended for harmonised use in EFSA (EFSA Scientific

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%

1022021; See the Terms and Conditions (https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2024]. See the Terms and Conditions (https://online.library on [04/02/2024]. See the Terms and Conditions (https://

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 01 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 SVC disease according to the criteria of Article 7 of the AHL and the related parameters in Table 2 of the Scientific Opinion on the 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

Spring viraemia of carp virus (SVCV) is a rhabdovirus first detected in the former Yugoslavia in the 1970s and SVC has since become a notifiable disease within the European Union (WOAH, 2021) that causes significant impact on aquaculture. SVCV is defined by the partial G gene sequence that clusters with the viruses in the fish vesiculo-like genogroup I (Ia–Id) and not viruses from genogroups II–IV. This distinction is crucial to separate SVCV from closely related viruses including *Sprivivirus esox* (PFRV), tench rhabdovirus (TenRV) and grass carp rhabdovirus (GCRV). These viruses are widespread within the EU and only genogroup I is included in this assessment (Stone et al., 2003).

The SVCV genome is a negative sense single stranded RNA. The genome is non-segmented and contains 11.019 nucleotides encoding five proteins. The virus primarily infects cyprinid fishes, such as the common carp (*Cyprinus carpio*). Infection with SVCV can cause a range of clinical signs in fish, including swelling and haemorrhage, and it can compromise the immunity of affected fish (Ahne et al., 2002). Effective treatments for SVCV are currently not available, therefore biosecurity is the main protection against disease outbreaks.

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

# Susceptible animal species

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

The virus primarily infects cyprinid fishes, including the common carp (*C. carpio*), including all varieties and subspecies. Many other species can also be infected according to WOAH (WOAH, 2021). Fish naturally susceptible to SVCV are listed in Table 2.

Fish Species (common name (scientific name)	Wild/farmed	Reference
Bream (Abramis brama)	Wild and farmed	Basic et al. (2009)
Bighead carp (Aristichthys nobilis)	Wild	Stone et al. (2003)
Common carp (Cyprinus carpio)	Wild and farmed	Fijan et al. (1971)
Fathead minnow (Pimephales promelas)	Wild	Boonthai et al. (2017)
Goldfish (Carassius auratus)	Farmed	Kanellos et al. (2006)
Golden Shiner ( <i>Notemingonus</i> crysoleucas)	Wild	Boonthai et al. (2017)
Grass carp (Ctenopharyngodon idella)	Wild	Haenen and Davidse (1993)
Jingsha barbel carp (Percocypris pingi)	Farmed	Zheng et al. (2018)
Koi carp (Cyprinus carpio koi)	Farmed	Ashraf et al. (2016)
Wels catfish or Sheatfish (Silurus glanis)	Wild	Fijan (1984), Jorgensen et al. (1989), Sheppard et al. (2007)

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

The susceptible farmed species through natural infection are described in Table 2.

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

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

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

The experimentally susceptible domestic (farmed) species are described in Table 3.

#### Table 3: Wild and farmed aquatic animals experimentally susceptible to SVCV

Fish species	Wild/farmed	Experiment setting	Reference
Amur Carp ( <i>Cyprinus rubrofuscus</i> )	Wild and farmed	Bath challenge	Adamek et al. (2019)
Caspian white fish ( <i>Rutilus kutum</i> )	Farmed	Bath challenge and Injection	Ghasemi et al. (2014)
Roach (Rutilus rutilus)	Wild	Bath challenge	Haenen and Davidse (1993)
Zebrafish (Danio rerio)	Wild and farmed	Bath challenge	Sanders et al. (2003)

Reservoir animal species

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

Species listed as having incomplete evidence for susceptibility to SVCV by WOAH include: spotfin shiner (*Cyprinella spiloptera*) (Boonthai et al., 2017) and creek chub (*Semotilus atromaculatus*) (Boonthai et al., 2017). SVCV has also been isolated from rainbow trout (*Oncorhynchus mykiss*) (Johnson et al., 1999; Jeremić et al., 2006), crucian carp (*Carassius carassius*), pike (*Esox lucius*), fire belly newt (*Cynops orientalis*), silver carp (*Hypophthalmichthys molitrix*), yellow perch (*Perca flavescens*), white sucker (*Catostomus commersonii*), Nile tilapia (*Oreochromis niloticus*), emerald shiner (*Notropis atherinoides*), mrigal carp (*Cirrhinus mrigala*), tench (*Tinca tinca*), Chinook salmon (*Oncorhynchus tshawytscha*), sockeye salmon (*Oncorhynchus nerka*) and Pacific white shrimp (*Litopenaeus vannamei*) (Johnson et al., 1999).

Other sources report infection by SVCV in northern pike (*Esox lucius*) (Ahne et al., 1998), silver carp (*Hypophthalmichthys molitrix*) (Ashraf et al., 2016), bluegill (*Lepomis macrochirus*) and largemouth bass (*Micropterus salmoides*) (Phelps et al., 2012).

Species where there is currently insufficient evidence that they are susceptible to SVCV but there is evidence that they may carry the virus, can be considered as potential reservoirs for the disease. These are given in Table 4.

Genus Species(common name [scientific name])	Experimental trial or natural infection	Pathogen identification	References
Bluegill ( <i>Lepomis</i> macrochirus)	Natural infection (outbreak)	Virus isolation, RT-PCR and sequencing	Phelps et al. (2012)
Chinook salmon ( <i>Oncorhynchus tshawytscha</i> )	Injection and bath challenge	Virus isolation and sequencing	Emmenegger et al. (2016)
Creek chub ( <i>Semotilus</i> atromaculatus)	Injection	Cell culture	Boonthai et al. (2017)
Crucian carp <i>(Carassius carassius)</i>	Natural infection	Sequencing	Miller et al. (2007)
Emerald shiner ( <i>Notropis atherinoides</i> )	Injection	RT-PCR and sequencing	Misk et al. (2016), Su and Su (2018)
Fire belly newt ( <i>Cynops</i> orientalis)	Natural infection	Cell culture and sequencing	Ip et al. (2016)
Guppy (Lebistes reticulatus)	Bath challenge	Not mentioned	Pyecroft et al. (2022), Su and Su (2018)
Largemouth bass ( <i>Micropterus salmoides</i> )	Injection	Virus isolation	Boonthai et al. (2017), Phelps et al. (2012)

**Table 4:** Wild aquatic species, which can serve as reservoirs for SVCV

18314732, 2023

Genus Species(common name [scientific name])	Experimental trial or natural infection	Pathogen identification	References
Mrigal carp ( <i>Cirrhinus</i> <i>merigala</i> )	Natural infection	RT-PCR and sequencing	Haghighi Khiabanian asl et al. (2008)
Nile tilapia ( <i>Sarotherodon</i> niloticus)	Natural infection	RT-PCR, histopathological examination and electron microscopy examination	Soliman et al. (2008)
Northern Pike (Esox lucius)	Bath challenge	Sequencing	Ahne (1985), Su and Su (2018)
Pacific white shrimp ( <i>Litopenaeus vannamei</i> )	Natural infection (outbreak)	Sequencing	Johnson et al. (1999)
Pumpkinseed ( <i>Lepomis gibbosus</i> )	Bath challenge	Not mentioned	Su and Su (2018)
Rainbow trout (Oncorhynchus mykiss)	Natural infection and experimental (intraperitoneal injection)	Serum neutralisation	Jeremić et al. (2006)
	Injection and bath challenge	Virus isolation and sequencing	Emmenegger et al. (2016), Stone et al. (2003)
	Experimental (bath challenge)	Cell cultivation	Haenen and Davidse (1993)
Silver carp ( <i>Hypophthalmichthys</i> <i>molitrix</i> )	Natural infection	Sequencing	Stone et al. (2003)
Sockeye salmon (Oncorhynchus nerka)	Injection and bath challenge	Virus isolation and sequencing	Emmenegger et al. (2016)
Spotfin shiner ( <i>Cyprinella spiloptera</i> )	Injection	Cell culture	Boonthai et al. (2017)
Steelhead trout ( <i>Oncorhynchus mykiss</i> irideus)	Injection and bath challenge	Virus isolation and sequencing	Emmenegger et al. (2016)
Tench (Tinca tinca)	Natural infection	Sequencing	Miller et al. (2007)
White sucker ( <i>Catostomus</i> commersonii)	Injection	RT-PCR and sequencing	Misk et al. (2016)
Yellow perch (Perca flavescens)	Injection and bath challenge	Virus isolation and sequencing	Emmenegger et al. (2016)

PCR: polymerase chain reaction; RT-PCR: reverse transcription polymerase chain reaction; SVCV: Spring Viraemia of Carp Virus.

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

There is evidence that SVCV may remain undetected in common carp populations and in that case, they can be potential reservoirs for SVCV (WOAH, 2021) and it is unclear whether this is also the case for other species that can become infected with SVCV (see Section 3.1.1).

# Vector animal species

# Parameter 7 - Wild vector species (or family/orders)

SVCV RNA has been extracted from live fish louse *Argulus foliaceus* (Crustacea, Branchiura) (Ahne, 1985) and the leech *Piscicola geometra* (Annelida, Hirudinea) (Ahne, 1985). The heron *Ardea cinerea* has also been implicated as a potential vector of SVCV (Peters and Neukirch, 1986). Aquatic arthropods have been suggested as possible vectors, but there is no experimental evidence to support this claim (Ahne et al., 2002). Evidence for transmission of SVCV by these vectors is limited. The parasitic invertebrates *A. foliaceus* and *P. geometra* transferred SVCV from diseased to healthy fish under experimental conditions and the virus has been isolated from *A. foliaceus* removed from infected carp (Ahne et al., 2002; Dixon, 2019).

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

No domestic/farmed species have been identified as vectors of SVCV, as many are susceptible to the virus. Subclinically infected animals from domestic species may act as vectors (WOAH, 2021).

# **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 is evidence to suggest that infection with SVCV can occur without clinical implications (WOAH, 2021). There is a knowledge gap for prevalence and incidence in individual countries within populations. Monitoring of prevalence in geographically similar EU populations of Koi carp suggests that can vary from low (3%) to high (96%) prevalence (Clouthier et al., 2021a). Studies in common carp have shown that few adult fish are infected when the water temperature is above  $17^{\circ}$ C, but juveniles can be infected even at  $22-23^{\circ}$ C (Ahne et al., 2002; Ashraf et al., 2016).

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

Clinical signs are not consistently observed in infected fish, and death can occur rapidly following the initial onset of clinical signs of the disease. This makes it difficult to assess morbidity, but generally not all fish in an infected population display signs of infection (WOAH, 2021). Younger fish are more susceptible to infection and mortality by SVCV. Adult fish can be affected in an outbreak but usually at lower morbidity and mortality rates (figures were not mentioned) (Pyecroft et al., 2022).

#### Parameter 3 – Case-fatality rate

Mortality is influenced by a wide range of biotic and abiotic factors, including water temperature, geographical location, age of fish, population density and other stressors such as poor physiological condition in fish after winter. These contributing factors make it difficult to compare mortality rates between outbreaks that have occurred under different conditions. Mortality can reach as high as 70% to 90% in young carp, but levels are more frequently from 1% to 40%. Older fish tend to have mortality rates below 30% (Ahne et al., 2002; Su and Su, 2018; 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)

SVC is not a zoonotic disease. There is no evidence in the literature that SVCV infects humans.

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

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

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

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

#### Animal population

#### Parameter 1 – Duration of infectious period in animals

There is limited availability of information regarding the infectious period in individuals or populations of fish. Under experimental infection in adult fish, the virus remained in the incubation phase for 7 days, followed by 23 days where clinical signs of infection were present (Ahne et al., 2002). In this experiment, the first death occurred at 20 days, with 20% mortality at 30 days. The temperature of the water has an impact on the speed at which host antibodies are produced, and also impacts the antibodies' ability to clear the fish of virus (Ahne et al., 2002). At 13°C, carp developed a subclinical infection that persisted for 10 weeks, at which point the fish were considered as carriers. Adult fish began shedding virus in faeces around 11 days after infection in an experimental infection (Ahne et al., 2002).

Poor health or immune status will increase susceptibility to infections and disease. Fish that survive a disease incidence may develop various degrees of immunity (no specific information was found in the literature); however, they may also shed virus and this shedding period is not predictable. These animals can be a significant source of virus (Pyecroft et al., 2022).

#### Parameter 2 – Presence and duration of latent infection period

The latent period following initial exposure to SVCV is likely to be 7 days or less, depending on the water temperature. Laboratory studies using a reverse genetics approach can identify key genes for SVCV replication repression in zebrafish, suggesting that genetics of the fish may play a role in the duration of SVCV latency (Pan et al., 2023).

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

SVCV has been detected in healthy wild common carp and koi carp in China, and in common carp in Canada (WOAH, 2021). The virus has been detected using RT-PCR for at least 167 days post infection in koi, however, the maximum duration of virus latency within these fish species has not been quantified (Zheng et al., 2018).

#### 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)

SVCV remains infectious for 5 weeks in river water at  $10^{\circ}$ C and for more than 6 weeks in pond mud at  $4^{\circ}$ C, reducing to 4 days in pond mud at  $10^{\circ}$ C (Ahne et al., 2002; WOAH, 2021).

# **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 is the main route of SVCV infection and occurs directly between fish or via water contaminated with faeces and urine of infected individuals. Vectors, including *A. foliaceus* and *P. geometra* can also spread the virus between individuals in laboratory trials, but the relevance to spread in wild or farmed fish is not clear. Transmission of the virus via the heron *A. cinerea* has also been suggested, but this has not been proven in the field (Peters and Neukirch, 1986; WOAH, 2021). Vertical transmission via gametes has been reported once, but not confirmed since (WOAH, 2021). Other studies have further downplayed the importance of vertical transmission (Ahne et al., 2002).

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

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

# Speed of transmission

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

There is very limited research reporting the incidence of SVCV among animals within an infected population, either in farmed fish or in the wild. SVCV can rapidly infect fish, replicate and be shed into the environment, leading to rapid spread through populations, especially when in small, enclosed spaces such as fish farms (Ahne et al., 2002; WOAH, 2021). There have been no reports of transmission of SVCV between animals and humans.

# $\frac{Parameter \ 4 - Transmission \ rate \ (beta) \ (from \ R_0 \ and \ infectious \ period) \ between \ animals \ and, \ when \ relevant, \ between \ animals \ and \ humans$

There is no information in the literature on the transmission rate and the infectious period of SVC. It is common that not all the fish in a population that is positive for SVCV become infected or show clinical signs of infection, further complicating parameter estimates (Ahne et al., 2002; WOAH, 2021). The incubation period of SVCV in common carp is between 7 and 14 days (Ahne et al., 2002), the virus can be detected using RT-PCR for at least 167 days post infection in koi; however, the maximum length of the viraemia is unknown (Clouthier et al., 2021b). It is unclear how factors such as host species or temperature affect the transmission rate and infectious period of SVCV.

The maximum infectious period is unknown and could potentially be the lifetime of the animal as in the case for koi herpes virus (EFSA AHAW Panel, 2017b).

There have been no reports of transmission of SVCV between animals and humans.

# **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

The geographical distribution of SCVC occurrence in European Continent based on historical data from 1970 to 2016 by Perchun et al. (2022), the annual reports of the MSs by the European Union Reference Laboratory for Fish and Crustacean Diseases (EURL)<sup>3</sup> (2014–2021) and the WOAH reports is presented in the map below (Figure 1).



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

**Figure 1:** Countries in European Continent where SVCV was detected between 1970 and 2021 (red colour) based on Perchun et al. (2022) and WOAH (2021). Source of map: map produced through QGIS (free and open-source Geographic Information System). According to Annex I to Commission Implementing Decision (EU) 2021/260 as amended, Denmark, Finland, Hungary, Ireland, Sweden and the United Kingdom (Northern Ireland) are currently free from SVC

According to annual reports from EURL for fish and crustaceans diseases, during the period 2014 to 2021, SVCV has been reported in the following countries: Austria (2016), Bulgaria (2016), Belgium (2014, 2019), Czechia (2015, 2016, 2019), Germany (2015, 2016, 2017, 2018, 2019), Italy (2016, 2017, 2019), Lithuania (2019), Poland (2015, 2016, 2017, 2019), Romania (2016, 2017), Slovakia (2015, 2019) and the UK (2017) (see Figure 1). The outbreaks all seemed to be in common carp, including the outbreak in wild population in Italy (Dixon, 2019; WOAH, 2021).

The reports for SVCV to the WOAH indicate presence of SVC in the following EU member states: Croatia, Czechia, Denmark, France, Germany, Hungary, Italy, Lithuania, the Netherlands, Poland, Romania, Slovakia, Slovenia, Spain (Dixon, 2019; WOAH, 2021).

The current status of MSs with respect to SVC is set out in Annex I to Commission Implementing Decision (EU) 2021/260<sup>4</sup> as amended and according to this Annex Denmark, Finland, Hungary, Ireland, Sweden and the United Kingdom (Northern Ireland) are characterised as free from SVC.

<sup>&</sup>lt;sup>3</sup> European Union Reference Laboratory for Fish and Crustacean Diseases: https://www.eurl-fish-crustacean.eu/

<sup>&</sup>lt;sup>4</sup> Commission Implementing Decision (EU) 2021/260: https://eur-lex.europa.eu/eli/dec\_impl/2021/260/oj

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

The EURL annual reports from 2014 to 2021 indicate that SVC has sporadic occurrence in EU and that SVCV has been detected in the following countries: Austria (2016), Bulgaria (2016), Belgium (2014,2019), Czech Republic (2015, 2016, 2019), Germany (2015, 2016, 2017, 2018, 2019), Italy (2016, 2017, 2019), Lithuania (2019), Poland (2015, 2016, 2017, 2019), Romania (2016, 2017), Slovakia (2015, 2019) and the UK (2017) (see Figure 2). All the reported outbreaks were in common carp, including the outbreak in Italy (WOAH, 2021).

'Sporadic' here means that EU MSs have reported the detection of SVCV since 2014. This is not annual occurrence and is not widespread within the MS. The level of monitoring and control for SVCV varies greatly between EU MSs. It is therefore not possible to have a representative and complete picture of the epidemiological situation in the EU.

# Risk of introduction

#### Parameter 3 – Routes of possible introduction

Movement of live fish is thought to be the main route of spreading the virus. This can be trade for purposes of aquaculture and restocking (e.g. common carp), ornamentals (e.g. koi carp) or accidental movement. Spread into new regions is likely to have occurred through movements of infected fish in which SVCV was not detected, and SVCV has now been reported in at least 20 different countries (Perchun et al., 2022). Biosecurity measures for aquaculture and ornamentals have increased over time. The risk of introduction via fish that are introduced in open systems remains a persistent threat (Taylor et al., 2011). The most detailed investigation of the routes of transmission of SVCV using the UK data suggests that the main route of introduction is movement of fishes between farms, followed by wholesalers. Nevertheless, given that SVCV has been frequently detected in the UK in ornamental and sport fish, the transmission of the virus via the import of ornamental and sport fish should be considered a serious risk (Taylor et al., 2013).

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

Movement of live fish between registered farms in EU MSs must be recorded by both the exporter and the receiver of live animals, helping to provide a history of fish that are implicated in disease outbreaks. Detailed data on imports between 2000 and 2007 in the UK highlights that imports of ornamental fish from non-EU countries was significantly higher when compared to imports from EU countries and these generally have less robust biosecurity (Taylor et al., 2013). Fish shipments from countries outside the EU (4,648 total shipments) tended to be for the ornamental trade, whereas fish shipments from the EU countries (93 total shipments) were exclusively for aquaculture, though no information on the actual number of fish imported in each shipment was available (Taylor et al., 2013).

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

SVCV infection develops rapidly, and fish can become infectious within 7 days and remain infectious until death, which can occur rapidly i.e. within 30 days (Ahne et al., 2002). SVCV can be detected in koi carp for at least 167 days after infection (Clouthier et al., 2021b). The maximum infectious period is unknown and could potentially be the lifetime of the animal (typically 13 to 20 years in the wild) as in the case for koi herpes virus (EFSA AHAW Panel, 2017b). The influence of host species may also be an important factor.

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

To minimise the spread of SVCV, inspectors at the place of destination (MS/zone/compartment) listed in Annex I or Annex II of the Commission Implementing Decision 2021/260<sup>5</sup>, should check that the consignments of susceptible/reservoir fish have a health certificate provided by the authorities of the place of origin that confirms they originate from a disease-free area. Fish destined for direct consumption are exempt from this requirement and may pose a risk if stocked or held in non-biosecurity systems prior to slaughter. Fish business operators are obliged to adopt good biosecurity practices (such as quarantine) and that they have complete details on the traceability of the stock. Nevertheless, knowledge gap exists relating to how frequently these recommendations are adhered to.

18314732, 2023, 10, Downloaded from https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochranettalia, Wiley Online Library on [04/02/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.con/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

<sup>&</sup>lt;sup>5</sup> Commission Implementing Decision (EU) 2021/260 of 11 February 2021: https://eur-lex.europa.eu/eli/dec\_impl/2021/260/oj

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

As discussed previously, it is unclear how long the virus can remain latent within the fish that survive infection, but potentially up to the lifetime of the fish (Clouthier et al., 2021b). It is unclear whether the virus can become infectious after latency.

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

The higher incidence rate in fish farms may suggest that the risk of spreading SVCV per shipment is higher in aquaculture than in trade in ornamental fish, but there is insufficient research to estimate risk factors of SVCV introduction (Taylor et al., 2013).

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

#### Diagnostic tools

#### Parameter 1- Existence of diagnostic tools

A range of diagnostic tools are available (WOAH, 2021). Confirmation of SVCV infection is achieved using virus isolation in cell culture followed by virus identification either by molecular methods such as RT-PCR and sequence analysis (WOAH, 2021) or immunochemical methods such as IFAT and ELISA (Reschova et al., 2007). The downside of these techniques is that they require specialist equipment and training, which is usually unavailable on fish farming sites, and can also take a relatively long time to give a result. Virus isolation using cell culture is generally achieved using flathead minnow and epithelioma papulosum cyprinid cell lines, although cell lines isolated from a range of species are susceptible to infection with SVCV.

PCR-based approaches available include RT-PCR combined with nested PCR, multiplex real-time quantitative RT-PCR and one-step TaqMan real-time quantitative RT-PCR, with high specificity. There are reports of simplified RT-PCR protocols that could potentially be used on fish farms for more routine testing, which would increase the accuracy of rapid detection methods, which may help to detect sub-clinical infections more reliably (Taylor et al., 2013; Pyecroft et al., 2022).

Using multiple different methods of SVCV detection increases the likelihood of accurate diagnosis. Virus detection tends to be greater in the liver and kidney than in spleen, gills and brain, but for smaller fish the whole body can be sampled, but pooling fish should be avoided where possible (Pyecroft et al., 2022).

Reverse transcription loop-mediated isothermal amplification (RT-LAMP) can also be used to detect SVCV based on nucleotide sequences of specific genes, with encouragingly high-success rates (Su and Su, 2018). Antibodies may also offer rapid and highly accurate detection of SVCV, but this remains in the early stages of use (Su and Su, 2018). Serology is not generally used due to cross reaction with closely related viruses.

WOAH manual of Diagnostic Tests for Aquatic Animals includes a chapter on SVCV (chapter 2.3.9) that has been updated in 2021 (WOAH, 2021).

# **Control tools**

#### Parameter 2 – Existence of control tools

No effective treatments are available for SVCV so preventing introduction of SVCV is the main method of protecting populations from infection. Biosecurity focussed on ensuring fish movements include only non-infected fish and preventing movement of fish from populations where infection is present is central to these efforts. Additionally, culling and removal infected populations quickly and effectively is used to prevent further spread of the virus. Based on research into koi herpes virus, the ornamental trade may be a significant risk in terms of introducing SVCV so could potentially justify similar biosecurity controls (Taylor et al., 2011; Taylor et al., 2013). Treatments for SVCV are being developed and may become more effective in the future (Ashraf et al., 2016).

# 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

According to the annual EURL reports from 2018 to 2021 SVCV has been detected in 2019 in Czech Republic, Germany, Italy, Lithuania, Poland and Slovakia. Countries that reported being free from SVCS in specific annual reports include England and Wales (2020), Finland (2021), Hungary (2021) and Ireland (2020). Samples were tested for SVCV and the virus was not detected in Austria (2019), Bulgaria (2021), Denmark (2021), France (2021), Greece (2019), Latvia (2019), the Netherlands (2019), Portugal (2019), Romania (2019), Serbia (2019), Slovenia (2019), Spain (2019), Sweden (2021), Switzerland (2019) and Turkey (2019). Countries not listed had no mention of SVCV in EURL reports since 2018.

It should be highlighted that surveillance activities are not implemented all over the EU countries since there is no legal obligation. Therefore, underreporting should be expected.

#### The loss of production of the disease

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

A total of 4.3 million tons of common carp were produced for food in 2018, representing 7.5% of the global freshwater fish production in 2018, with an increasing production annually. Common carp is particularly important in Europe where it accounts for over 30% of freshwater fish production (Machat et al., 2021). Mortality rate of young carps due to SVCV infection fluctuates but can be as high as 70% during springtime outbreaks (Ahne et al., 2002). Estimated losses of carp due to SVCV have been reported between 10% and 15% for year old fish, which is equivalent to 4,000 tons per annum (Teng et al., 2007).

### 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 SVCV infects humans.

Parameter 2 – Incidence of zoonotic cases

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

Parameter 4 – Sporadic, endemic, epidemic or pandemic potential

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

Parameter 5 – Disability-adjusted life year (DALY)

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

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

There is no evidence in the literature that SVCV 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

SVCV infection is generally associated with non-specific clinical signs, such as exophthalmos, abdominal distension, oedema of the vent region, swelling of tissues, lesions and inflammation (Ahne et al., 2002). Fish often appear darker with pale gills. Additional clinical signs include lethargy, degeneration of the gill lamellae, persistent faecal casts, swollen and fluid filled internal organs, swollen and coarse-textured spleen, hepatic necrosis, enteritis and pericarditis (Ashraf et al., 2016). Acute SVCV infection may not lead to any clinical sign of SVCV before death (Phelps et al., 2012). Clinical disease and pathological signs of infection may be observed approximately after 8 days from the virus inoculation. Mortality then tends to occur around 30 days post infection (Ahne et al., 2002). Welfare impacts of SVCV on an individual level can range from insignificant to serious based on the severity of the clinical signs and the deaths.

# **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 SVCV 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

In 2002, an outbreak of SVCV killed an estimated 1,500 common carp in a lake in Wisconsin, USA (Dikkeboom et al., 2004). Mortality in wild common carp, koi carp, bluegill and largemouth bass has been reported in the USA, but the mortality rate was not reported, although described as 'significant' (Phelps et al., 2012). It is difficult to estimate the mortality rate in wild species as the size of the population and its disease status is often unknown. This is compounded by the highly variable nature of SVCV, such that considerations must be made for influential factors like temperature, host species, population density, overall health and many more. Knowledge gaps remain in this area.

# Environment

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

SVCV that has been excreted by infected fish remains infective in water for up to 4 weeks, and for up to 6 weeks in mud at temperatures ranging from 4 to 10°C (Ahne et al., 2002). SVCV may also be transmitted by animal vectors (see above), but this has not been confirmed in the wild and the viral persistence in vectors has not been investigated. There is a knowledge gap for persistence of SVCV in the environment, and the influence of variables such as temperature has not been widely studied. Some farmed populations that became infected with SVCV were destroyed and the environment decontaminated (WOAH, 2021). This is essential for biosecurity but prevents studying how the virus persists after infection.

**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

SVC is listed by the Centre for Food Security and Public Health (CFSPH).<sup>6</sup> SVC is listed as notifiable disease by the WOAH.<sup>7</sup>

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

SVC is not listed in the Encyclopaedia of Bioterrorism Defence of Australia Group.<sup>8</sup>

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

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

<sup>&</sup>lt;sup>6</sup> https://www.cfsph.iastate.edu/diseaseinfo/disease/?disease=spring-viremia-of-carp&lang=en

<sup>&</sup>lt;sup>7</sup> https://www.woah.org/en/home/

<sup>&</sup>lt;sup>8</sup> https://www.australiagroup.net/en/human\_animal\_pathogens.html

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

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

# Availability

# $\label{eq:parameter 1} Parameter \ 1 - Officially/internationally \ recognised \ diagnostic \ tool, \ WOAH \ certified$

The SVCV chapter in the WOAH manual gives a detailed overview of the methods used to detect the virus. The key methods used are cell culture, conventional PCR, immunohistochemistry, antibody or antigen enzyme-linked immunosorbent assay and immunofluorescent antibody test. Visible clinical signs of the disease are not consistent and are not guaranteed in infected individuals, making diagnostic laboratory tests essential. Positive result by conventional RT-PCR or identification via cell culture challenge is required for confirmation of SVC by the WOAH (Stone et al., 2003; Dixon, 2019; WOAH, 2021).

Kidney, spleen, gill and encephalon should be selected from apparently healthy fish. For clinically affected fish: whole fry (body length  $\leq$  4 cm), entire viscera including kidney and brain (> 4 cm body length  $\leq$  6 cm) or, for larger fish, liver, kidney, spleen and encephalon should be selected.

# Effectiveness

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

The sensitivity and the specificity of the diagnosis tests provided by the WOAH are not available (WOAH, 2021).

# Feasibility

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

Cell culture supernatant or fish tissue can be used for molecular tests. According to the WOAH manual, kidney, spleen, gill and encephalon should be selected from apparently healthy fish. For clinically affected fish: whole fry (body length  $\leq$  4 cm), entire viscera including kidney and brain (> 4 cm body length  $\leq$  6 cm) or, for larger fish, liver, kidney, spleen and encephalon should be selected (WOAH, 2021).

# 3.1.4.2. 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 SVCV. There have been several experimental trials with vaccines against SVCV but with the vaccines demonstrating poor efficacy.

DNA vaccines containing the SVCV G gene have been developed, with experiments showing an increase in survival of vaccinated fish up to a maximum of 48% in carp, and up to 88% in koi (Pyecroft et al., 2022). Experimental data suggested these were less effective than DNA vaccines containing the infectious haemopoietic necrosis virus G gene. Injection of DNA plasmid encoding SVCV glycoprotein has also been shown experimentally to provide protection against SVCV, but oral vaccine trials were not successful (Pyecroft et al., 2022).

Inactivated virus has also been demonstrated experimentally to offer some protection to SVCV. Attenuated virus vaccines have not been successfully developed; improper attenuation of the virus, lack of quantitative assessment and the limited market does not encourage further development (Ashraf et al., 2016). Genetically engineered Lactobacillus plantarum expressing SVCV G protein and koi herpesvirus ORF81 protein have been shown to provide protection against SVCV (Embregts et al., 2019). DNA vaccination is difficult to administer on a large scale, and there is not enough evidence to support its efficacy (Su and Su, 2018). Using rotifers to deliver SVCV G and BD3 genes enhanced survival to SVCV from around 50% to around 90% in Yellow river carp (Li et al., 2023). Overall, vaccines so far offer limited protection against SVCV, but effort to improve this continues.

Parameter 2 – Availability/production capacity (per year)

There are currently no authorised vaccines for SVCV.

# Effectiveness

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

There are currently no authorised vaccines for SVCV.

#### Parameter 4 – Duration of protection

There are currently no authorised vaccines for SVCV. The vaccines developed under experimental trials are not authorised yet due to the poor level of protection offered, and the limited number of studies (Ashraf et al., 2016; Su and Su, 2018).

#### Feasibility

Parameter 5 – Way of administration

There are currently no authorised vaccines for SVCV.

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

#### Availability

#### Parameter 1 – Types of drugs available on the market

There are no antiviral treatments that are sufficiently effective to be recommended for suppression of SVCV in infected fish (WOAH, 2021). There are no medicines available to treat SVCV. Natural compounds have been experimentally shown to have antiviral properties against SVCV, such as arctigenin from the plant *Arctium lappa*. Small interfering RNAs have similarly been shown to limit replication of the virus (Pyecroft et al., 2022).

#### Parameter 2 – Availability/production capacity (per year)

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

#### Parameter 3 – Therapeutic effect in the field (effectiveness)

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

#### Feasibility

#### Parameter 4 – Way of administration

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

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

#### Availability

#### Parameter 1 – Available biosecurity measures

The basic strategies for controlling SVCV involve strict hygienic measures and elimination of SVCV infected fish in a controlled way (Ahne et al., 2002). Controlling the disease once it is established is extremely difficult. Vaccination or other forms of immune priming are also currently ineffective at preventing spread of SVCV. Carp eggs can be disinfected using iodophor treatment prior to transportation (WOAH, 2021).

Infection with SVCV is a notifiable disease, meaning that detection should be reported to the WOAH within 48 h (WOAH, 2021). Every animal identified as infected with SVCV should be destroyed appropriately following the EU legislation (see Section 3.1.4.6 on Article 7(d)(vii) Disposal of carcasses and other relevant animal by-products).

Equipment and surfaces in contact with fish directly or indirectly can be sterilised using a range of approaches: formalin, ozone, bleach, iodophor, gamma and UV radiation, pH below 4 or above 10, or heating to above 60°C for 15 min. Water temperature above 19–20°C may stop or prevent outbreaks of infection with SVCV, but it is very difficult to completely remove all SVCV from an environment without destroying fish (Ahne et al., 2002).

Management of an aquaculture facility during and after an SVCV outbreak depends upon a number of factors but particularly the type of fish-holding facility, its design and operational requirements. All

1022021; See the Terms and Conditions (https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia

areas of the farm and facilities in contact with infected stock need to be cleansed and disinfected in order to inactivate the virus (Pyecroft et al., 2022).

#### Effectiveness

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

Biosecurity is the main protection against SVCV, but measures have failed to totally prevent the spread of SVCV to new areas. However, it is essential that these measures are upheld to prevent reintroduction into areas where the disease has been eradicated, such as the UK and Hungary (WOAH, 2021).

Methods to control infection with SVCV rely on avoiding exposure to the virus coupled with good hygiene and biosecurity practices. Reducing fish stocking density during winter and early spring will reduce the spread of the virus (Pyecroft et al., 2022).

Ensuring that all fish to be moved are free from SVCV based on diagnostic tests is not feasible since only PCR- and cell culture-based approaches are thoroughly reliable but are expensive and time consuming (WOAH, 2021).

#### Feasibility

#### Parameter 3 - Feasibility of biosecurity measure

Biosecurity measures, particularly tracking of fish, can be hindered or aided by the regional requirements of fish farms. When appropriate biosecurity measures and traceability are in place, the likelihood of an outbreak is reduced and consequently the impact of the disease is reduced as well (Taylor et al., 2011, 2013). When fish are moved between regions where regulations are weaker, it may be necessary to test fish, with no guarantee that all the fish will be checked, and for tests where the Se and Sp are not really known. New developments into SVCV testing may facilitate this in the future, as there is an active effort to improve monitoring and diagnosis of SVCV (Ashraf et al., 2016; Su and Su, 2018).

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

#### Availability

# Parameter 1 – Available movement restriction measures

Regulation (EU) 2016/429 (AHL) foresees several measures including restriction of movements in case of SVC outbreaks in order to prevent the spread of the virus. In the UK, movement requires notifying the fish health inspectorate, which can block movement based on the disease status of the site. The status of 'disease free' is outlined by the WOAH (WOAH, 2021). The disease status and history of sites can be useful to provide information on the best course of action where movements occur, such as quarantine or increased disinfection processes. It is not clear how frequently quarantine is used as a biosecurity measure. Accurate monitoring and reporting of SVCV is crucial to the success of this approach.

#### Effectiveness

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

The spread of SVCV to new areas including the USA and China shows that efforts to control and restrict fish dispatch have not been effective (Su and Su, 2018). It was unclear how SVCV was spread between farms despite the biosecurity protocols. The available evidence for the spread of SVCV into the USA and China suggests that the virus was transferred to the USA from China either directly or via a third country. China was considered SVCV free until the virus was detected in the UK in Chinese imports in 1998. Subsequent testing in China confirmed that that SVCV was present in the Chinese fish population. Had the testing been effective at source the transfer could have been prevented by restriction of animal movements. Restriction of animal movement or culling was effective in the UK's eradication programme (Taylor et al., 2013).

# Feasibility

#### Parameter 3 – Feasibility of restriction of animal movement

Expanding global trade in fish farmed for food increases the risk of spreading SVCV and other pathogens. Additionally, the intensity of fish farming is also trending upwards, further increasing risk (Su and Su, 2018). The feasibility of animal movement restrictions will depend largely on the legislative

framework, the authorities and the willingness of the business operators to enforce and comply with available measures. The example above demonstrates that restricting animal movement is reliant on testing in the countries of destination (Taylor et al., 2013).

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

# Availability

#### Parameter 1 – Available methods for killing animals

A range of methods is available for killing carp, commonly used are asphyxia and percussion, electrical stunning, percussion alone, overdose with anaesthetic and slitting of gills. Multiple methods are often used to ensure quick and humane killing. As well as the method of dispatching fish, the process by which fish get from ponds is important to consider preventing unnecessary stress, such as draining water versus individual netting. Slaughtered fish should be disposed following existing biosecurity protocols (Algers et al., 2009).

#### Effectiveness

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

The main method of SVCV transmission seems to be horizontal, so killing of fish should be effective in stopping spread of the disease. The virus can also persist in water and mud, so the area should be drained and decontaminated (see methods available above). The method of killing can also help to prevent spread by keeping the animals whole and intact, e.g. through anaesthesia.

#### Feasibility

#### Parameter 3 – Feasibility of killing animals

The simplest method of humanely killing fish in an aquaculture setting is to apply an overdose of anaesthetic to a relatively small volume of water with a high density of fish. A knowledge gap exists for comparing the methods used for slaughter (EFSA AHAW Panel, 2017b).

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

#### Availability

#### Parameter 1 – Available disposal option

Carcasses from fish killed or found dead due to SVCV belong to the category II materials and should be disposed and destroyed according to the rules outlined in EC Regulation 1069/2009<sup>9</sup> and EC Regulation 142/2011<sup>10</sup>. 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 premises approved by EU MSs can be found at European Commission webpage.<sup>11</sup>

#### Effectiveness

#### Parameter 2 – Effectiveness of disposal option

Incineration or rendering is an extremely effective disposal method of destroying pathogens. Rendering is additionally beneficial as it can produce useful products (EFSA AHAW Panel, 2017b).

# Feasibility

#### Parameter 3 – Feasibility of disposal option

Incineration or rendering is only feasible where biosecurity measures can be implemented during the transport and an approved establishment is near the farm to process the carcasses (EFSA AHAW Panel, 2017b).

<sup>&</sup>lt;sup>9</sup> Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 as amended: https://eurlex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1069-20191214

<sup>&</sup>lt;sup>10</sup> 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

<sup>&</sup>lt;sup>11</sup> EC list of approved ABM establishments: https://food.ec.europa.eu/safety/animal-products/approved-establishments-abp\_en

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

# Availability

# Parameter 1 – Available breeds resistant to the pathogen

The 'Krasnodar' strain of common carp has been bred for increased resistance to SVCV (Kirpichnikov et al., 1993). Zebrafish SVCV experimental infection studies have revealed additional potential genes for selective breeding resistance to SVCV (Pereiro et al., 2015). Modern advances in molecular genetics may help to elucidate further genes linked to resistance (Houston et al., 2020). Zebrafish reverse genetics is used to identify genes linked to SVCV resistance or tolerance (Pan et al., 2023; Shi et al., 2023).

#### Effectiveness

#### Parameter 2 – Effectiveness of having resistant breeds

Initial experimental challenges of the 'Krasnodar' strain have an improved survival of around 28% compared to around 10%, with 16% healthy fish compared to around 6% in the most susceptible fish strain tested (Kirpichnikov et al., 1993). Similarly, modest differences were reported from a more recent challenge, with a maximum difference of 20% survival between fish strains (Adamek et al., 2019). Both these results were in common carp. The wide range of factors that influence the outcome of SVCV infection make comparing data difficult, but both seem to suggest only a minor increase in survival in the most resistant strain of carp.

#### Feasibility

#### Parameter 3 – Feasibility of having resistant breeds

It is unclear how widely available the most resistant fish are, but the modest protection suggests that using only resistant fish would not have a sufficiently large benefit to be commercially viable, as some fish in the population would likely still be infected resulting in loss of the whole population.

# 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 are no published data on the cost of control measures implemented against SVCV. Biosecurity is the main defence, but this encompasses protection against all pathogens, so the specific costs related to SVCV is difficult to estimate. Measures can be simple and low cost such as footbaths with disinfectant for personnel and visitors, and disinfection of vehicles and equipment. Purchasing stock from approved SVCV-free areas may be more expensive and limit the supply of fish, but there are no data to support this assumption. The value of individual common carp is low, so testing is not likely to be economically viable (EFSA AHAW Panel, 2017b).

# Parameter 2 – Cost of eradication (culling, compensation)

There are no published data for the costs associated with eradication, which depends on the size and structure of a site. Many carp farms in Europe are very large (with ponds covering more than 1 ha). Eradication is technically challenging and very time consuming. Netting and killing the fish would take a team of four qualified staff up to 5 days. Based on the experience in the UK, the total cost including disposal is likely to be in the region of 20,000 euros for a single farm, but it may be less for smaller farms. In the UK, there was no compensation for the costs related to culling and site disinfection. Moreover, common carp produced for food have a low value per fish (EFSA AHAW Panel, 2017b).

#### Parameter 3 – Cost of surveillance and monitoring

There is no evidence in the literature to estimate the cost of surveillance and monitoring activities specifically for SVC. The cost of a single investigation in a farm including diagnostics is ~ 1,000 euros. An estimation performed in the UK, but for KHV which affected the same populations concluded that 30–80 outbreaks of koi herpes virus are investigated each year at a cost of €30–80,000, which is likely to have a similar cost to SVC outbreaks (EFSA AHAW Panel, 2017b).

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

Infection with SVCV is no longer listed under EU legislation (delisted around 2010) but notifiable to the WOAH.

There is no evidence in the literature to estimate the economic impact on trade activities due to SVC occurrence.

# Parameter 5 – Importance of the disease for the affected sector (% loss or $\in$ lost compared to business amount of the sector

The economic impact of SVC is difficult to estimate. The biosecurity measures increase production costs, but these are not related solely to SVC. Individual farms that suffer outbreaks of SVC are likely to have large financial consequences as all fish. The overall average cost to the sector is likely to be lower as outbreaks of SVC are infrequent in EU member states (see Section 3.1.2.1). A recent estimate suggested that in Germany the cost of an outbreak in a farm producing 20 t of fish ranges from  $\notin$ 150,000 to  $\notin$ 250,000 (including disinfection, removal of carcasses, cleaning and partly restocking) (Schlotfeldt, 2004) (EFSA AHAW Panel, 2017b).

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

There are no available studies relating to societal acceptance of disease prevention and control measures for SVC. In the UK, disease control measures on carp fisheries, farms and in ornamental fish retailers are widely accepted by stakeholders. At a societal level, there has been little opposition to destocking of farms or fisheries undertaken as part of a disease control programmes (EFSA AHAW Panel, 2017b).

#### 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

Fish need to be held in a biosecurity system during quarantine or virus testing. This system needs to have sufficient space, food and water, as well as to carefully maintain water conditions such as dissolved oxygen and temperature. When culling stock due to detection of virus, a humane method is needed for all the fish. These requirements may not be available in all regions where SVCV is present (EFSA AHAW Panel, 2017b).

#### Parameter 2 – Wildlife depopulation as control measure

Wild carp live in extensive and interconnected waters, which have a wide range of uses, including drinking and recreation for people. Therefore, depopulation of most sites is unlikely to be possible. Some smaller sites may be depopulated using biocides, individual capture or draining. Any depopulation is likely to have knock on effects on the ecosystem both directly and indirectly (EFSA AHAW Panel, 2017b).

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

#### Environment

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

The use of biocides or medical drugs is not authorised for SVC prevention or treatment. Studies to investigate the use in SVCV prevention or treatment were not found in literature review.

#### Biodiversity

#### Parameter 2 – Mortality in wild species

A wide range of wild species (see Section 3.1.1) can be infected by SVCV. Infections in wild species can cause mortality of up to 90%, particularly in young fish (Ahne et al., 2002). Knowledge gaps remain relating to the influence of factors such as host species and temperature on mortality in wild populations.

www.efsa.europa.eu/efsajournal

# **3.2.** Assessment of spring viraemia of carp according to article 5 criteria of AHL on its eligibility to be listed

# 3.2.1. Detailed outcome on Article 5 criteria

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

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

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

<b>Criteria to be met by the disease:</b> According to the AHL, a disease shall be included in the list referred to in point (b) of paragraph 1 of Article 5 if it has been assessed in accordance with Article 7 and meets all of the following criteria		Outcome			
		Median range (%)	Criterion fulfilment	Number of NA	Number of experts
A(i)	The disease is transmissible	99–100	Fulfilled	0	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	66–90	Fulfilled	0	14
A(iv)	Diagnostic tools are available for the disease	95–100	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	50–90	Uncertain	0	14
At lea In add criteria	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	45–90	Uncertain	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	NA	NA	14	14
B(iii)	The disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union	33–90	Uncertain	0	14
B(iv)	The disease has the potential to generate a crisis, or the disease agent could be used for the purpose of bioterrorism	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	10–33	Not fulfilled	0	14

NA: not applicable.

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



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

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

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

The collective judgement of the experts is non-consensual for the following reasons:

- The current mitigating measures include mainly biosecurity measures focused on ensuring fish movements only from populations free from the diseases and preventing movement of fish from susceptible and reservoir populations where infection is present.
- The effectiveness of the mitigation measures and the surveillance activities varies depending on the countries, the farming systems and the aquatic species involved.
- Risk mitigation measures when they are implemented properly can be effective to control or eradicate the disease (as it happened in the UK); nevertheless this is very difficult and often not feasible due to the farming systems of carp and the involvement of many species. Carp are farmed in lakes or in large, interconnected ponds making them impossible to drain and disinfect. In addition, the control of the disease in wildlife population is not feasible.
- The cost and the resources required for the effective implementation of the mitigated measures and surveillance activities may not be proportional to the risk posed by the disease and the impact to the industry and therefore some MSs do not invest on the prevention and control of the disease. If enough resources are available, then they would be effective.
- SVCV is widespread in the Union, nevertheless it appears to be sporadic in many MSs, without annual reoccurrence and therefore is not endemic. Many countries put efforts to control the disease for years, but they have not managed making the mitigating measures and surveillance activities effective.
- Authorised vaccines or effective treatments are not available. Hence, the only measure to control and eradicate the disease is stamping out of infected farms and cleaning and disinfection of the establishments.

**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 collective judgement of the experts is non-consensual for the following reasons:

- The disease is not zoonotic and consequently the negative effects are related only to animal health.
- Prevalence, morbidity and mortality are very variable. There is limited information on the prevalence, which ranges from low (3%) to high (96%). Morbidity is not consistently observed in infected fish and no information was found in the literature review.
   The mortality in young fish ranges from 1% to 90% (with 1–40% being more frequent) while older fish tend to present mortality rates below 30%. Death of susceptible fish can be rapid. Mortality is influenced by a wide range of biotic and abiotic factors, including water temperature, geographical location, age of fish, population density and other stressors such as poor physiological condition in fish after winter.
- The disease has been present in many areas of continental Europe for many years with only sparse reports of significant losses; nevertheless, for some countries or some areas the impact could be significant.

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

- Both current and potential impacts of SVC have been considered in the assessment of this criterion.
- Carp aquaculture exists only in some countries in the EU and therefore the current impact on aquaculture in the EU may not be significant.
- Common carp production is particularly important in the EU where it accounts for over 30% of freshwater fish production. In case of SVC occurrence if no control measures are implemented and the disease expanded the potential economic impact could be significant.
- The disease is not present in all MSs, and where it exists, it does not seem to have significant impact on the economy.

# 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 5, SVC complies with four criteria of the first set (A(i)–A (iv)), but there is uncertainty (50–90% probability) on the assessment on compliance with criterion A (v). Therefore, it is uncertain whether Spring Viraemia of Carp 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 Spring Viraemia of Carp being eligible to be listed is **45–90%** (see Figure 2).

# **3.3.** Assessment Spring Viraemia of Carp according to criteria in Annex IV for the purpose of categorisation as in Article 9 of the AHL

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

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

# 3.3.1. Detailed outcome on Category A criteria

# **Table 6:**Outcome of the expert judgement related to the criteria of Section 1 of Annex IV of AHL<br/>(Category A of Article 9 of AHL)

<b>Criteria to be met by the disease:</b> 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	5–33	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	95–99	Fulfilled	0	14
2.3	The disease affects multiple species of kept and wild animals or single species of kept animals of economic importance	95–100	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	0–5	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	5–33	Not fulfilled	0	14
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	66–90	Fulfilled	0	14
5(c)	The disease has a significant impact on the environment, due to the direct impact of the disease or due to the measures taken to control it	10–33	Not fulfilled	0	14
5(d)	The disease has a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	5–10	Not fulfilled	0	14

NA: not applicable.



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

**Figure 3:** Outcome of the expert judgement on the criteria of Section 1 of Annex IV of AHL and overall probability of Spring Viraemia of Carp 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):

- Limited knowledge is available for the economic impact of SVC thus increasing the uncertainty of the assessment for this criterion. Approximately 3 million tons of common carp were produced for food in EU in 2018, representing 7.5% of the global freshwater fish production in 2018, with an increasing production annually.
- Both the current and the potential impact of the disease on the economy of the Union were assessed. Since the disease occurs sporadically in some MSs without significant impact on carp production but mainly on the affected farms it was considered that the current impact on the economy of the Union is probably low. Nevertheless, if the disease will spread to more countries or the carp production increases then the potential impact on the economy could be higher.

# 3.3.2. Detailed outcome on Category B criteria

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

		Outcome					
<b>Crite</b> The d	ria to be met by the disease: isease needs to fulfil all of the following criteria	Median range (%)	Criterion fulfilment	Number of NA	Number of experts		
1	The disease is present in the whole or part of the Union territory with an endemic character and (at the same time) several Member States or zones of the Union are free of the disease	66–90	Fulfilled	0	14		
2.1	The disease is moderately to highly transmissible	66–90	Fulfilled	0	14		
2.2	There are possibilities of airborne or waterborne or vector- borne spread	95–99	Fulfilled	0	14		
2.3	The disease affects single or multiple species <sup>(a)</sup>	_	Fulfilled	0	14		
2.4	The disease may result in high morbidity with in general low mortality	33–66	Uncertain	0	14		

#### At least one criterion to be met by the disease:

In addition to the criteria set out above at point 1–2.4, the disease needs to fulfil at least one of the following criteria

3	The disease has a zoonotic potential with significant consequences for public health, including epidemic potential or possible significant threats to food safety	0–3	Not fulfilled	1	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	5–33	Not fulfilled	0	14
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	66–90	Fulfilled	0	14
5(c)	The disease has a significant impact on the environment, due to the direct impact of the disease or due to the measures taken to control it	10–33	Not fulfilled	0	14
5(d)	The disease has a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	5–10	Not fulfilled	0	14

NA: not applicable.

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



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

**Figure 4:** Outcome of the expert judgement on criteria of Section 2 of Annex IV of the AHL and overall probability of the Spring Viraemia of Carp 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):

- There is not enough information on the morbidity rates for SVC. Morbidity is not consistently observed in infected fish and therefore in some cases might be low.
- The mortality rates may vary a lot and they depend mainly on the age of the fish: in young fish ranges from 1% to 90% (with 1–40% being more frequent), while in older fish mortality is below 30%. Death of infected fish can occur rapidly following infection. Mortality is influenced by a wide range of biotic and abiotic factors, including water temperature, geographical location, age of fish, population density and other stressors such as poor physiological condition in fish after winter.

**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 had been described in Section 3.3.1.1.

# 3.3.3. Detailed outcome on Category C criteria

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

			Out	come	
<b>Crite</b> The d	ria to be met by the disease: lisease needs to fulfil all of the following criteria	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 <b>aquatic animals</b> several Member States or zones of the Union are free of the disease	66–90	Fulfilled	0	14
2.1	The disease is moderately to highly transmissible	66–90	Fulfilled	0	14
2.2	The disease is transmitted mainly by direct or indirect transmission <sup>(a)</sup>	-	Fulfilled	0	14
2.3	The disease affects single or multiple species <sup>(a)</sup>	-	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?	10–66	Uncertain	0	14
	ast one criterion to be met by the disease:				

#### Dy

In addition to the criteria set out above at point 1-2.4, the disease needs to fulfil at least one of the following criteria

3	The disease has a zoonotic potential with significant consequences for public health or possible significant threats to food safety	0–1	Not fulfilled	1	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	33–90	Uncertain	0	14
5(a)	The disease has a significant impact on society, with in particular an impact on labour markets	5–33	Not fulfilled	0	14
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	66–90	Fulfilled	0	14
5(c)	The disease has a significant impact on the environment, due to the direct impact of the disease or due to the measures taken to control it	10–33	Not fulfilled	0	14
5(d)	The disease has a significant impact in the long term on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	5–10	Not fulfilled	0	14

NA: not applicable.

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



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

**Figure 5:** Outcome of the expert judgement on criteria of Section 3 of Annex IV of the AHL and overall probability of Spring Viraemia of Carp to be fitting in Category C of Article 9 of AHL

# 3.3.3.1. Reasoning for uncertain outcome on Category C criteria

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

- There is not enough information on the morbidity rates for SVC. Clinical signs are not consistently observed in infected fish and therefore in some cases the morbidity can be underestimated. The prevalence rates in an affected population can vary from 3% to 96%.
- The mortality rates may vary a lot and they depend mainly on the age of the fish: in young fish ranges from 1% to 90% (with 1–40% being more frequent) while in older fish mortality is below 30%. Death of infected fish can occur rapidly after infection. Mortality is influenced by a wide range of biotic and abiotic factors, including water temperature, geographical location, age of fish, population density and other stressors such as poor physiological condition in fish after winter.
- Infection with the less virulent Asian strains (SVCVa) can result in no or low morbidity and mortality. The European strains (SVCV b–d) are generally more virulent for carp and there is limited evidence of virus infection with no or low morbidity in infected animals.
- There is not enough evidence on the effect of the SVC on fish production. The disease has been present in many areas of continental Europe for many years with only sparse reports of significant losses nevertheless for some countries or some areas the impact could be significant.

**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. Since the disease occurs sporadically in some MSs without significant impact to carp production in the Union as a whole, but mainly to the affected farms, it was considered that the current impact to the economy of the Union is probably low. Nevertheless, if the disease will spread to more countries or the carp production increases then the potential impact on the economy could be higher, particularly if it affects the larger carp producers.

# 3.3.4. Detailed outcome on Category D criteria

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

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

NA: not applicable.

#### 3.3.5. Detailed outcome on Category E criteria

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

		Outcome			
Dise Anr	ases in Category E <b>need to fulfil criteria of Section 1, 2 or 3 of</b> lex IV of the AHL and <b>/or the following</b> :	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	45–90	Uncertain		
	(If a disease fulfils the criteria as in Article 5, thus being eligible to be listed, consequently Category E would apply.)				

# **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 SVC as in Article 9, is presented in Table 11 and Figure 5.

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

						Article	9 crite	ria					
		1° se	t of cri	iteria		2° set of criteria							
	1	2.1	2.2	2.3	2.4	3	4	5(a)	5(b)	5(c)	5(d)		
Category	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	D	Article 5 criteria
Α	5–33	66–90	95–99	95–100	66–90	0–5	10-66	5–33	66–90	10–33	5–10		
В	66–90	66–90	95–99	_(a)	33–66	0–3	10–66	5–33	66–90	10–33	5–10		
С	66–90	66–90	_(b)	_ <sup>(b)</sup>	10-66	0–1	33–90	5–33	66–90	10–33	5–10		
D												66–90	
E													45–90

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

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



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

www.efsa.europa.eu/efsajournal

According to the assessment here performed, SVC 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):

- 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, SVC complies 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 SVC complies with 5 (b) criterion. Overall, it was assessed with 5–33% probability that SVC 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, SVC complies 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 SVC complies with 5(b) criterion. Overall, it was assessed with 33–66% probability that SVC 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, SVC complies with four out of five criteria (1, 2.1, 2.2 and 2.3). To be eligible for Category C, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5(a)–(d)) and SVC complies only with 5 (b) criterion. Overall, it was assessed with 10–66% probability that SVC 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. SVC does not comply with criteria of Section 1, 2, 3 or 5 of Annex IV of the AHL but complies with 45–90% probability with criterion D.
- 5) To be assigned to **Category E**, a disease needs to comply with criteria of Section 1, 2 or 3 of Annex IV of the AHL, and/or the surveillance of the disease is necessary for reasons related to animal health, animal welfare, human health, the economy, society or the environment. The latter is applicable if a disease fulfils the criteria as in Article 5, for which the assessment is uncertain with **45–90% probability**.

# 3.4. Assessment of Spring Viraemia of Carp 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 SVC are presented. The Article 8(3) criteria are about animal species to be listed, as it reads below:

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

(a) they are susceptible to a specific listed disease, or scientific evidence indicates that such susceptibility is likely; or (b) they are vector species or reservoirs for that disease, or scientific evidence indicates that such role is likely'.

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

According to the mapping, as presented in Table 5, Section 3.2, of the Scientific Opinion on the ad hoc methodology (EFSA AHAW Panel, 2017a), the animal species to be listed for Spring Viraemia of Carp 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 SVC has been described, but also those animal species from which only the SVC itself has been isolated. The latter makes susceptibility to SVC likely.

Туре	Class	Order	Family	Genus/Species	References
	Actinopterygii	Cypriniformes	Cyprinidae	Abramis brama	Basic et al. (2009)
				Aristichthys nobilis	Stone et al. (2003)
				Carassius auratus	Kanellos et al. (2006)
				Ctenopharyngodon idella	Haenen and Davidse (1993)
				Cyprinus carpio	Fijan et al. (1971)
<b>a</b> )				Cyprinus carpio koi	Ashraf et al. (2016)
ible				Cyprinus rubrofuscus	Ahne et al. (1998)
cept				Danio rerio	Sanders et al. (2003)
Sus				Percocypris pingi	Zheng et al. (2018)
•,				Pimephales promelas	Boonthai et al. (2017)
				Rutilus kutum	Ghasemi et al. (2014)
				Rutilus rutilus	Haenen and Davidse (1993)
			Leuciscidae	Notemingonus crysoleucas	Boonthai et al. (2017)
		Siluriformes	Siluridae	Silurus glanis	Fijan et al. (1971), Jorgensen et al. (1989), Sheppard et al. (2007)
	Actinopterygii	Cichliformes	Cichlidae	Sarotherodon niloticus	Soliman et al. (2008)
		Cypriniformes	Catostomidae	Catostomus commersonii	Misk et al. (2016)
			Cyprinidae	Carassius carassius	Stone et al. (2003), Miller et al. (2007)
				Cirrhinus merigala	Haghighi Khiabanian asl et al. (2008)
				Cyprinella spiloptera	Boonthai et al. (2017)
				Hypophthalmichthys molitrix	Ashraf et al. (2016); Stone et al. (2003)
				Notropis atherinoides	Misk et al. (2016); Su and Su (2018)
				Semotilus atromaculatus	Boonthai et al. (2017)
oirs				Tinca tinca	Miller et al. (2007)
eservo			Poeciliidae Lebistes reticulatus		Pyecroft et al. (2022), Su and Su (2018)
ĸ		Esociformes	Esocidae	Esox lucius	Ahne et al. (1998), Su and Su (2018)
		Perciformes	Centrarchidae	Lepomis gibbosus	Su and Su (2018)
				Lepomis macrochirus	Phelps et al. (2012)
				Micropterus salmoides	Boonthai et al. (2017), Phelps et al. (2012)
			Percidae	Perca flavescens	Goodwin (2002), Emmenegger et al. (2016)
		Salmoniformes	Salmonidae	Oncorhynchus mykiss	Boonthai et al. (2017), Emmenegger et al. (2016), Haenen and Davidse (1993), Stone et al. (2003)
				Oncorhynchus mykiss irideus	Emmenegger et al. (2016)
				Oncorhynchus nerka	Emmenegger et al. (2016)
				Oncorhynchus tshawytscha	Emmenegger et al. (2016), Goodwin (2002)

Table 12:	Animal species to be	listed for SVC according to t	the criteria of Article 8 of AHL			
		house for or o according to				
Туре	Class	Order	Family	Genus/Species	References	
---------	--	----------	---------------	----------------------	-----------------------	--
	Amphibia	Urodela	Salamandridae	Cynops orientalis	Ip et al. (2016)	
	Malacostraca	Decapoda	Penaeidae	Litopenaeus vannamei	Johnson et al. (1999)	
Vectors	There is no evidence in the literature whether other species can transmit the SVCV to susceptible fi					

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 (**45–90% probability**) whether SVC can be considered eligible to be listed for Union intervention as laid down in Article 5 of the AHL.

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

- The AHAW Panel considered with **5–33% probability** (from 'very unlikely' to 'unlikely') that SVC meets the criteria of Category A as in Section 1 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in point (a) of Article 9(1) of the AHL.
- The AHAW Panel was uncertain (**33–66% probability**, 'about as likely as not') whether SVC meets the criteria of Category B as in Section 2 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in point (b) of Article 9(1) of the AHL.
- The AHAW Panel was uncertain (**10–66% probability**, from 'unlikely' to 'about as likely as not') whether that SVC 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 (**45–90% probability**) whether SVC 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 (**45–90% probability**) that SVC meets the criteria of Category E as in Section 5 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in point (e) of Article 9(1) of the AHL.

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

The animal species that can be considered to be listed for SVC 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 SVC 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 the SVCV in different fish species populations,
- ii) research to estimate the impact of SVCV on animal health, animal welfare and the production in EU,
- iii) a better understanding of the implementation and the effectiveness of the mitigating measures and the surveillance activities used by certain MSs to reduce further spread of the virus.

1022021; See the Terms and Conditions (https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia, Wiley Online Library on [04/02/2021]. See the Terms and Conditions (https://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochraneltalia

## References

- Adamek M, Matras M, Dawson A, Piackova V, Gela D, Kocour M, Adamek J, Kaminski R, Rakus K, Bergmann SM, Stachnik M, Reichert M and Steinhagen D, 2019. Type I interferon responses of common carp strains with different levels of resistance to koi herpesvirus disease during infection with CyHV-3 or SVCV. Fish & Shellfish Immunology, 87, 809–819. https://doi.org/10.1016/j.fsi.2019.02.022
- Ahne W, 1985. Viral infection cycles in pike (Esox lucius L.). Applied Ichthyology, 1, 90–91. https://doi.org/10.1111/j. 1439-0426.1985.tb00417.x
- Ahne W, Bjorklund HV, Essbauer S, Fijan N, Kurath G and Winton JR, 2002. Spring viremia of carp (SVC). Diseases of Aquatic Organisms, 52, 261–272. https://doi.org/10.3354/dao052261
- Ahne W, Kurath G and Winton JR, 1998. A ribonuclease protection assay can distinguish spring viremia of carp virus from pike fry rhabdovirus. Bulletin of the European Association of Fish Pathologists, 18, 220–224.
- Algers B, Anil H, Blokhuis H, Fuchs K, Hultgren J, Lambooij B, Nunes T, Paulsen P and Smulders F, 2009. Project to develop Animal Welfare Risk Assessment Guidelines on Stunning and Killing. EFSA Supporting Publications, 6, 11E. https://doi.org/10.2903/sp.efsa.2009.EN-11
- Ashraf U, Lu Y, Lin L, Yuan J, Wang M and Liu X, 2016. Spring viraemia of carp virus: recent advances. Journal of General Virology, 97, 1037–1051. https://doi.org/10.1099/jgv.0.000436
- Basic A, Schachner O, Bilic I and Hess M, 2009. Phylogenetic analysis of spring viraemia of carp virus isolates from Austria indicates the existence of at least two subgroups within genogroup Id. Diseases of Aquatic Organisms, 85, 31–40.
- Boonthai T, Loch TP, Standish I and Faisal M, 2017. Susceptibility of representative great lakes fish species to the North Carolina strain of Spring Viremia of Carp Virus (SVCV). Journal of Aquatic Animal Health, 29, 214–224. https://doi.org/10.1080/08997659.2017.1360410
- Clouthier SC, McClure C, Schroeder T and Anderson ED, 2021a. Bayesian latent class model estimates of diagnostic accuracy for three test methods designed to detect spring viremia of carp virus. Preventive Veterinary Medicine, 190, 105338. https://doi.org/10.1016/j.prevetmed.2021.105338
- Clouthier SC, Schroeder T, Bueren EK, Anderson ED and Emmenegger E, 2021b. Analytical validation of two RTqPCR tests and detection of spring viremia of carp virus (SVCV) in persistently infected koi Cyprinus carpio. Disease of Aquatic Organisms, 143, 169–188. https://doi.org/10.3354/dao03564
- Dikkeboom AL, Radi C, Toohey-Kurth K, Marcquenski S, Engel M, Goodwin AE, Way K, Stone DM and Longshaw C, 2004. First report of Spring Viremia of Carp Virus (SVCV) in Wild Common Carp in North America. Journal of Aquatic Animal Health, 16, 169–178. https://doi.org/10.1577/H03-064.1
- Dixon P, 2019. Spring viraemia of carp. CABI Compendium. https://doi.org/10.1079/cabicompendium.96466
- EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare), More S, Bøtner A, Butterworth A, Calistri P, Depner K, Edwards S, Garin-Bastuji B, Good M, Gortazar Schmidt C, Michel V, Miranda MA, Nielsen SS, Raj M, Sihvonen L, Spoolder H, Stegeman JA, Thulke H-H, Velarde A, Willeberg P, Winckler C, Baldinelli F, Broglia A, Candiani D, Gervelmeyer A, Zancanaro G, Kohnle L, Morgado J and Bicout D, 2017a. Scientific opinion on an ad hoc method for the assessment on listing and categorisation of animal diseases within the framework of the Animal Health Law. EFSA Journal 2017;15(7):4783, 47 pp. https://doi.org/10.2903/j.efsa.2017.4783
- EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare), More S, Bøtner A, Butterworth A, Calistri P, Depner K, Edwards S, Garin-Bastuji B, Good M, Gortazar Schmidt C, Michel V, Miranda MA, Nielsen SS, Raj M, Sihvonen L, Spoolder H, Stegeman JA, Thulke H-H, Velarde A, Willeberg P, Winckler C, Baldinelli F, Broglia A, Zancanaro G, Beltran Beck B, Kohnle L, Morgado J and Bicout D, 2017b. Scientific Opinion on the assessment of listing and categorisation of animal diseases within the framework of the Animal Health Law (Regulation (EU) No 2016/429): Koi herpes virus disease (KHV). EFSA Journal 2017;15(7):4907, 35 pp. https://doi.org/10.2903/j.efsa.2017.4907
- EFSA (European Food Safety Authority) Scientific Committee, Benford D, Halldorsson T, Jeger MJ, Knutsen HK, More S, Naegeli H, Noteborn H, Ockleford C, Ricci A, Rychen G, Schlatter JR, Silano V, Solecki R, Turck D, Younes M, Craig P, Hart A, Von Goetz N, Koutsoumanis K, Mortensen A, Ossendorp B, Martino L, Merten C, Mosbach-Schulz O and Hardy A, 2018. Guidance on uncertainty analysis in scientific assessments. EFSA Journal 2018;16(1):5123, 39 pp. https://doi.org/10.2903/j.efsa.2018.5123
- Embregts CWE, Rigaudeau D, Tacchi L, Pijlman GP, Kampers L, Veselý T, Pokorová D, Boudinot P, Wiegertjes GF and Forlenza M, 2019. Vaccination of carp against SVCV with an oral DNA vaccine or an insect cells-based subunit vaccine. Fish & Shellfish Immunology, 85, 66–77. https://doi.org/10.1016/j.fsi.2018.03.028
- Emmenegger EJ, Sanders GE, Conway CM, Binkowski FP, Winton JR and Kurath G, 2016. Experimental infection of six North American fish species with the North Carolina strain of spring Viremia of Carp Virus. Aquaculture, 450, 273–282. https://doi.org/10.1016/j.aquaculture.2015.07.007
- Fijan N, 1984. Vaccination of fish in European pond culture: prospects and constraints in Symposia Biologica Hungarica, 1984. v. 23.
- Fijan N, Petrinec Z, Sulimanovic D and Zwillenberg LO, 1971. Isolation of the viral causative agent from the acute form of infectious dropsy of carp. The Journal Veterinarski Arhiv, 41, 125–138.

- Ghasemi M, Zamani H, Hosseini SM, Haghighi Karsidani S and Bergmann SM, 2014. Caspian White Fish (Rutilus frisii kutum) as a host for Spring Viraemia of Carp Virus. Veterinary Microbiology, 170, 408–413. https://doi.org/10.1016/j.vetmic.2014.02.032
- Goodwin AE, 2002. First report of Spring Viremia of Carp Virus (SVCV) in North America. Journal of Aquatic Animal Health, 14, 161–164. https://doi.org/10.1577/1548-8667(2002)014<0161:FROSVO>2.0.CO;2
- Haenen OLM and Davidse A, 1993. Comparative pathogenicity of two strains of pike fry rhabdovirus and spring viremia of carp virus for young roach, common carp, grass carp and rainbow trout. Diseases of Aquatic Organisms, 15, 87–92. https://doi.org/10.3354/dao015087
- Haghighi Khiabanian asl A, Haghighi-Khiabanian Asl A, Azizzadeh M, Bandehpour M, Sharifnia Z and Kazemi B, 2008. The First Report of SVC from Indian Carp Specoes by PCR and Histopathologic Methods in Iran. Pakistan Journal of Biological Sciences, 24, 2675–2678. https://doi.org/10.3923/pjbs.2008.2675.2678
- Houston RD, Bean TP, Macqueen DJ, Gundappa MK, Jin YH, Jenkins TL, Selly SLC, Martin SAM, Stevens JR, Santos EM, Davie A and Robledo D, 2020. Harnessing genomics to fast-track genetic improvement in aquaculture. Nature Reviews Genetics, 21, 389–409. https://doi.org/10.1038/s41576-020-0227-y
- Ip HS, Lorch JM and Blehert DS, 2016. Detection of spring viraemia of carp virus in imported amphibians reveals an unanticipated foreign animal disease threat. Emerging Microbes and Infections, 5, 1–7. https://doi.org/10.1038/emi.2016.94
- Jeremić S, Ivetić V and Radosavljevic V, 2006. Rhabdovirus carpio as a causative agent of disease in rainbow trout (Oncorhynchus mykiss Walbaum). Acta Veterinaria, 56, 553–558. https://doi.org/10.2298/AVB0606553J
- Johnson MC, Maxwell JM, Loh PC and Leong J-AC, 1999. Molecular characterization of the glycoproteins from two warm water rhabdoviruses: snakehead rhabdovirus (SHRV) and rhabdovirus of penaeid shrimp (RPS)/spring viremia of carp virus (SVCV). Virus Research, 64, 95–106. https://doi.org/10.1016/S0168-1702(99)00071-4
- Jorgensen PEV, Olesen NJ, Ahne W and Lorenzen N, 1989. SVCV and PFR Viruses: Serological Examination of 22 Isolates Indicates Close Relationship Between the Two Fish Rhabdoviruses. Proceedings of the Viruses of Lower Vertebrates, Berlin, Heidelberg, 1989//s, 349–366 pp.
- Kanellos T, Sylvester ID, D'Mello F, Howard CR, Mackie A, Dixon PF, Chang K-C, Ramstad A, Midtlyng PJ and Russell PH, 2006. DNA vaccination can protect Cyprinus Carpio against spring viraemia of carp virus. Vaccine, 24, 4927–4933. https://doi.org/10.1016/j.vaccine.2006.03.062
- Kirpichnikov VS, Ilyasov I, Shart LA, Vikhman AA, Ganchenko MV, Ostashevsky AL, Simonov VM, Tikhonov GF and Tjurin VV, 1993. Selection of Krasnodar common carp (Cyprinus carpio L.) for resistance to dropsy: principal results and prospects11Final editing by Graham A.E. Gall. In: GAE Gall and H Chen (eds). Genetics in Aquaculture. Elsevier, Amsterdam. pp. 7–20.
- Li C, Zhang Y, Yuan M, Zhu W, Pei C, Zhao X and Kong X, 2023. An oral vaccine against spring viremia of carp virus induces protective immunity in common carp (Cyprinus carpio L.). Aquaculture, 566, 739167. https://doi.org/10.1016/j.aquaculture.2022.739167
- Machat R, Pojezdal L, Piackova V and Faldyna M, 2021. Carp edema virus and immune response in carp (Cyprinus carpio): current knowledge. Journal of Fish Diseases, 44, 371–378. https://doi.org/10.1111/jfd.13335
- Miller O, Fuller FJ, Gebreyes WA, Lewbart GA, Shchelkunov IS, Shivappa RB, Joiner C, Woolford G, Stone DM, Dixon PF, Raley ME and Levine JF, 2007. Phylogenetic analysis of spring virema of carp virus reveals distinct subgroups with common origins for recent isolates in North America and the UK. Diseases of Aquatic Organisms, 76, 193–204. https://doi.org/10.3354/dao076193
- Misk E, Garver K, Nagy E, Isaac S, Tubbs L, Huber P, Al-Hussinee L and Lumsden JS, 2016. Pathogenesis of spring viremia of carp virus in emerald shiner Notropis atherinoides Rafinesque, fathead minnow Pimephales promelas Rafinesque and white sucker Catostomus commersonii (Lacepede). Journal of Fish Diseases, 39, 729–739. https://doi.org/10.1111/jfd.12405
- Pan J, Qin W, Chen Z, Xiao J, Chang H, He K and Feng H, 2023. Analyzing the transmission of SVCV among zebrafish populations by compartment mathematical modeling. Aquaculture, 564, 739076. https://doi.org/10.1016/j. aquaculture.2022.739076
- Perchun AV, Pavlov DK, Melnikov VP, Antonychev AA, Zinyakov NG, Korennoy FI, Moroz NV, Chvala IA and Metlin AE, 2022. Genetic characteristics of spring viraemia of carp virus strains Kirov/08 and Orenburg/14. Archives of Virology, 167, 681–685. https://doi.org/10.1007/s00705-021-05329-y
- Pereiro P, Varela M, Diaz-Rosales P, Romero A, Dios S, Figueras A and Novoa B, 2015. Zebrafish Nk-lysins: First insights about their cellular and functional diversification. Developmental and Comparative Immunology, 51, 148–159. https://doi.org/10.1016/j.dci.2015.03.009
- Peters F and Neukirch M, 1986. Transmission of some fish pathogenic viruses by the heron, Ardea cinerea. Journal of Fish Diseases, 9, 539–544. https://doi.org/10.1111/j.1365-2761.1986.tb01050.x
- Phelps NB, Armién AG, Mor SK, Goyal SM, Warg JV, Bhagyam R and Monahan T, 2012. Spring viremia of carp virus in Minnehaha Creek, Minnesota. Journal of Aquatic Animal Health, 24, 232–237. https://doi.org/10.1080/08997659.2012.711267
- Pyecroft SB, Ryan G and Mahadevan JJ, 2022. Chapter 19 Spring viremia of carp. In: FSB Kibenge, B Baldisserotto and RS-M Chong (eds). Aquaculture Pathophysiology. Academic Press. pp. 267–275.

- Reschova S, Pokorová D, Smržová Z, Hulova J and Vesely T, 2007. Detection of spring viraemia of carp virus (SVCV) with monoclonal antibodies. Veterinarni Medicina, 52, 308–316. https://doi.org/10.17221/2043-VETMED
- Sanders GE, Batts WN and Winton JR, 2003. Susceptibility of Zebrafish (Danio rerio) to a model pathogen, spring viremia of carp virus. Comparative Medicine, 53, 514–521.
- Schlotfeldt HJ, 2004. Severe losses of common carp in Germany due to Koi Herpesvirus (KHV). Bulletin European Association of Fish Pathologists, 24, 216–217.
- Sheppard AM, Deuff RML, Martin PD, Woolford G, Way K and Stone DM, 2007. Genotyping spring viraemia of carp virus and other piscine vesiculo-like viruses using reverse hybridisation. Diseases of Aquatic Organisms, 76, 163–168.
- Shi Y, Chen K, Zhao X, Lu Y, Huang W, Guo J, Ji N, Jia Z, Xiao H, Dang H, Zou J and Wang J, 2023. IL-27 suppresses spring viremia of carp virus replication in zebrafish. Fish and Shellfish Immunology, 133, 108530. https://doi.org/10.1016/j.fsi.2023.108530
- Soliman MK, Aboeisa M, Mohamed S and Saleh WD, 2008. First Record of Isolation and Identification of Spring Viraemia of Carp Virus from Oreochromis Niloticus in Egypt. 8th International Symposium on Tilapia in Aquaculoture, 2.
- Stone DM, Ahne W, Denham KL, Dixon PF, Liu CTY, Sheppard AM, Taylor GR and Way K, 2003. Nucleotide sequence analysis of the glycoprotein gene of putative spring viraemia of carp virus and pike fry rhabdovirus isolates reveals four genogroups. Diseases of Aquatic Organisms, 53, 203–210.
- Su H and Su J, 2018. Cyprinid viral diseases and vaccine development. Fish and Shellfish Immunology, 83, 84–95. https://doi.org/10.1016/j.fsi.2018.09.003
- Taylor NGH, Norman RA, Way K and Peeler EJ, 2011. Modelling the koi herpesvirus (KHV) epidemic highlights the importance of active surveillance within a national control policy. Journal of Applied Ecology, 48, 348–355. https://doi.org/10.1111/j.1365-2664.2010.01926.x
- Taylor NGH, Peeler EJ, Denham KL, Crane CN, Thrush MA, Dixon PF, Stone DM, Way K and Oidtmann BC, 2013. Spring viraemia of carp (SVC) in the UK: The road to freedom. Preventive Veterinary Medicine, 111, 156–164. https://doi.org/10.1016/j.prevetmed.2013.03.004
- Teng Y, Liu H, Lv JQ, Fan WH, Zhang QY and Qin QW, 2007. Characterization of complete genome sequence of the spring viremia of carp virus isolated from common carp (Cyprinus carpio) in China. Archives of Virology, 152, 1457–1465. https://doi.org/10.1007/s00705-007-0971-8
- WOAH, 2021. Manual of diagnostic tests for aquatic animals chapter 2.3.9.
- Zheng LP, Geng Y, Yu ZH, Wang KY, Ou YP, Chen DF, Huang XL, Deng LJ, Gan WX, Fang J, Zhong ZJ and Lai WM, 2018. First report of spring viremia of carp virus in Percocypris pingi in China. Aquaculture, 493, 214–218. https://doi.org/10.1016/j.aquaculture.2018.04.056

## 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
RT-PCR	Reverse transcription polymerase chain reaction
Se	Sensitivity
Sp	Specificity
SVC	Spring Viraemia of Carp
SVCV	Spring Viraemia of Carp Virus
ToR	Term Of Reference
WOAH	World Organisation for Animal Health

18314732, 2023, 10, Downloaded from https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2023.8324 by Cochranettalia, Wiley Online Library on [04/02/2024]. See the Terms and Conditions (https://onlinelibrary.wiley.con/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

A 17 A /21			
Art5: A(I)	1		
			H
			н
	-		н
			н
			н
	1	1	н
		1	H

## 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

efsaJOURNAL



**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

efsa JOURNAL



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



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



**Figure A.8:** 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.9:** Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion B(v) (the disease has or could have a significant negative impact on the environment, including biodiversity, of the Union). The black dotted line on the top indicates the median

efsa JOURNAL



**Figure A.10:** 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.11:** Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion 1B (the disease is present in the whole or part of the Union territory with an endemic character and (at the same time) several Member States or zones of the Union are free of the disease). The black dotted line on the top indicates the median)



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



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



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



**Figure A.15:** Individual probability ranges, after the collective judgement, reflecting the fulfilment of the criterion 2.2AB (there are possibilities of airborne, waterborne or vector-borne spread). 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 2.3A (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.17:** Individual probability ranges, after the collective judgement, reflecting the 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.18:** 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.19:** Individual probability ranges, after the collective judgement, reflecting the uncertain outcome of the criterion 2.4Caqua (the disease usually does not result in high morbidity and has negligible or no mortality and often the most observed effect of the disease is production loss). The black dotted line on the top indicates the median

efsa JOURNAL

How certain are you tha public health, including	t the disease has a epidemic or pander	zoonotic potentia nic potential OR p	with significant co ossible significant	nsequences for threats to food	
Median LB: 0%, Median UB:	5%				
Art9: 3ABC					
			1	1	
H					
H-1					
H					
н					
н					
H					
and the second second					
	1				
1					
0% 5% 10%	33%	50% Certainty	66%	90%	95% 100

**Figure A.20:** 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

rt9: 3AB				
		1		
	1			
1				
4	4			
	1			
	- 1 (1 · · · ·			
F				
e –				
_				
-	1			
	30			

**Figure A.21:** 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

Art9: 3A					
н					
н — —					
н.					
( <b>1</b>					
н					
н					
н					
н					
_					
H					
H					
	C.				
0% 5% 10%	33%	50% Certainty	66%	90%	95% 100

**Figure A.22:** 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.23:** Individual probability ranges, after the collective judgement, reflecting non-fulfilment of the criterion 4AB (current impact) (the disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals). The black dotted line on the top indicates the median



**Figure A.24:** 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.25:** Individual probability ranges, after the collective judgement, reflecting the uncertain outcome of the criterion 4C (current impact) (the disease has a significant impact on the economy of the Union, mainly related to its direct impact on certain types of animal production systems). The black dotted line on the top indicates the median



**Figure A.26:** 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.27:** 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.28:** 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.29:** Individual probability ranges, after the collective judgement, reflecting fulfilment 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.30:** Individual probability ranges, after the collective judgement, reflecting 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.31:** Individual probability ranges, after the collective judgement, reflecting non-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.32:** Individual probability ranges, after the collective judgement, reflecting non-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.33:** Individual probability ranges, after the collective judgement, reflecting non-fulfilment 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.34:** Individual probability ranges, after the collective judgement, reflecting non-fulfilment 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

efs IOURNAL



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



**Figure A.36:** Medians of the judgement replies in questions related to Article 5 (left side) and Article 9 (right side) of AHL