Technical Report

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Extensive literature review on vectors and reservoirs of AHL-listed pathogens of crustaceans

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Abstract

On request of the EU Commission, EFSA carried out an Extensive Literature Review (ELR) to provide a list of vector species or reservoirs species of pathogens of crustaceans, listed in Annex II to the AHL, aiming to update the Annex of Implementing Regulation (EU) 2018/1882. In this Technical Report, the detailed review protocol of the ELR and assessment of potential vector and reservoir species is described of the crustacean pathogens listed in Annex II to the AHL: Taura syndrome virus (TSV), Yellow head virus (YHV) or White spot syndrome virus (WSSV). In total 2,530 research publications were collected for abstract screening and from these, 110 were selected for further full text analysis. In the final data collection and assessment 34 relevant research publications were used for extracting information on vector and reservoir species of the above crustacean pathogens. The results for crustacean species for which scientific evidence indicates that a role as vector species or reservoir species is likely are presented as tables in the supplementary material of this report.

Key words: Vectors, Reservoir, crustacean, Taura syndrome virus (TSV), Yellow head virus (YHV), White spot syndrome virus (WSSV), transport conditions.

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1 Introduction

1.1 Background and terms of reference as provided by the requestor

In accordance with Article 8 of Regulation (EU) 2016/429 (AHL), the disease-specific rules for listed diseases provided in the AHL, and the rules adopted pursuant to that Regulation, apply to listed species. In compliance with that Article, the Commission shall establish a list of animal species or groups of species, which pose a considerable risk for the spread of specific listed diseases based on the capability of those animals to carry those specific diseases. Animal species or groups of animal species shall only be added to the list if they pose a considerable risk for the spread of a specific listed disease because they are vectors or reservoirs for that disease, or scientific evidence indicates that such role is likely.

The list of vector species, which is set out in the fourth column of the table in the Annex to Implementing Regulation (EU) 2018/1882, was carried forward from the list, which was previously set out in Commission Regulation (EU) 1251/2008. The Commission now requires scientific advice to inform an amendment to that list, to ensure that only species, which comply with Article 8 of the AHL are listed. This amendment may involve species, which are currently set out in the fourth column of the Annex to Implementing Regulation (EU) 2018/1882 being removed and/or new species being added to that list.

It should be noted that vector species of aquatic animals are not listed in the OIE Aquatic Code[1] or in the OIE Aquatic Manual[2]. In the disease specific chapters of the OIE Aquatic Manual however, as well as listing susceptible species, other species which have shown incomplete evidence of susceptibility are listed, as are species in which PCR positive results have been reported, but where an active infection has not been demonstrated. In 2020, the EU Reference Laboratories (EURLs) for fish, crustaceans and molluscs, with the assistance of experts, reviewed those non-susceptible species, which are listed in the OIE Manual, in an effort to determine whether or not, they could be considered to be vectors of specific listed diseases. The reports which have been prepared by the EURLs and which have been furnished to the Commission, may be of assistance to the risk assessor in providing the scientific advice, which is currently sought. The three reports (concerning fish, molluscs and crustaceans) accompany this letter. It should, however, be noted that these reports also contain information concerning susceptible species to the listed diseases, which is not pertinent to this request for a scientific opinion.

In addition, for those species and groups of species referred to above, which should be listed in accordance with Article 8 of the AHL, scientific advice is also required concerning the conditions under which these species should be regarded as vectors or reservoirs for the purposes of movements.

The conditions under which these species should be regarded as vectors are set out in Annex I to Commission Delegated Regulation (EU) 2020/990[3] and in Annex XXX to Commission Delegated Regulation (EU) 2020/692[4]. It should be noted that the conditions set out in Annex I to Commission Delegated Regulation (EU) 2020/990 are not identical to the conditions set out in Annex XXX to Commission Delegated Regulation (EU) 2020/692, and both sets of conditions are different to those which were previously set out in columns 3 and 4 of Annex I to Commission Regulation (EC) 1251/2008.

[1] OIE Aquatic Animal Health Code, 2021, 23rd Edition.
[2] OIE Aquatic Manual, 2021, 8th Edition.
[3] Commission Delegated Regulation (EU) 2020/990 of 28 April 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health and certification requirements for movements within the Union of aquatic animals and products of animal origin from aquatic animals (OJ L 221, 28 April 2020, p.42).
[4] Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin (OJ L 174, 3.6.2020, p.379).

Terms of reference

In view of the above, the Commission asks EFSA for a scientific opinion on the listing of vector species of aquatic animals in accordance with Article 8 of Regulation (EU) 2016/429, as follows:

(1) For each of the aquatic diseases listed in Annex II to the AHL, an assessment concerning which species or groups of species of aquatic animals pose a considerable risk for their spread based on the fact that:
   (i) they are vector species or reservoirs for that disease, or
   (ii) scientific evidence indicates that such role is likely.

For each of the species or groups of species, which are assessed to be vector species or reservoirs of the listed diseases, or where scientific evidence indicates that such role is likely, they should be aquatic animals which are not already listed as susceptible to the listed disease.

(2) For each of the species or groups of species, which are assessed to fulfil the requirements for listing by virtue of being a vector or reservoir of a listed disease, or where scientific evidence indicates such a role is likely, an assessment of the suitability of the conditions under which they should be regarded as vectors or reservoirs for the purposes of movements. These conditions are set out in Annex I to Commission Delegated Regulation (EU) 2020/990 and in Annex XXX to Commission Delegated Regulation (EU) 2020/692, however, alternative conditions should be proposed, if the conditions which are set out in those Regulations, are assessed to be unsuitable.

2 Methodology

This ELR aims to assess the role of fish species as vectors or reservoirs species of specific pathogens listed by the AHL, by gathering all scientific evidence available regarding the parameters presented in Annex IV.

Review question:

1. **What is the evidence generated by experimental infection studies or field studies, demonstrating transmission of pathogen 'A' from vector species 'X' on or in which Pathogen A was detected, to a species 'Y'**
2. **What is the evidence generated by experimental infection studies or field studies, demonstrating the detection of Pathogen A on or in species X, without further evidence of transmission of pathogen A to a species 'Y'**

Pathogen A refers to pathogens listed by the AHL, affecting crustaceans, that are listed in Table 1.

Table 1. Listed pathogens affecting crustacean species to be assessed.

AHL listed pathogens of crustaceans
Taura syndrome virus
Yellow head virus
White spot syndrome virus

Eligibility criteria:

The eligibility criteria for experimental and field studies are listed in Table 2 and 3. Detailed forms for eligibility screening per level of screening are provided in Annex III.

Table 2. Study eligibility criteria for experimental infection studies

Element	Criteria	Level of screening
Publication type	Primary research publications (peer reviewed)	Title and abstract
		Full-text
Language	EU language	Title and abstract
		Full-text
Study type	Experimental infections	Title and abstract
Study design	Experimental study design	Title and abstract
	Only one single species X can be included per time per experimental unit	Full-text
Population	Species X and Y are aquatic animal species belonging to fish	Title and abstract
	Species X should not be a known susceptible species listed in Commission implementing regulation (EU) 2018/1882	Full text
Exposure	Exposure to pathogen A (AHL listed pathogens listed in Table 1)	Title and abstract
		Full-text
Outcome	Demonstration of pathogen A present in or on species X	Full-text
	Species Y must be experimentally exposed to pathogen A, either by direct or indirect contact with species X (cohabitation, immersion, ingestion)	
	Remark: these are outcomes used as eligibility criteria. Detailed eligibility screening forms and lists of parameters to be extracted are provided in Annex III and IV	

Table 3. Study eligibility criteria for field studies

Element	Criteria	Level of screening
Publication type	Primary research publications (peer reviewed)	Title and abstract
		Full-text
Language	EU language	Title and abstract
		Full-text
Study type	Field studies	Title and abstract
Study design	Case studies, prevalence studies, surveillance reports, etc.	Title and abstract
Population	Species X is aquatic animal species belonging to fish	Title and abstract
	Species X should not be a known susceptible species listed in Commission implementing regulation (EU) 2018/1882	Full-text
Exposure	Exposure to pathogen A (AHL listed pathogens listed in Table 1)	Title and abstract
		Full-text
Outcome	Demonstration of pathogen A present in or on species X	Full-text
	Remark: these are outcomes used as eligibility criteria. Detailed eligibility screening forms and lists of parameters to be extracted are provided in Annex III and IV	

2.1 Methods for searching the results

- **Information sources**

Information sources used in the review are listed in Table 4

Table 4: Information sources consulted.

Information source	Platform
Scopus	Scopus.com (Elsevier)
CAB Abstracts	Web of Science (Clarivate)
Web of Science Core Collection - Science Citation Index Expanded - Emerging Sources Citation Index	Web of Science (Clarivate)

- **Reference management**

Full references and abstracts were downloaded from Endnote 20 and uploaded into the Literature Review software DistillerSR ® (Evidence Partners) by EFSA.

- **Search strategy**

For each of the aquatic animal group specific combinations of search terms will be applied. The use of Boolean operators (AND, OR, NOT), truncation ($) and wildcard (*) symbols will assure that search terms account for synonyms, abbreviations and spelling variants, enhancing thus the sensitivity of the search strategy.

The search strings will be a combination of 2 elements:

String I: name of the pathogens and diseases listed in Table 1, with alternative names when relevant, and

String II: selection of experimental studies (e*xperiment* OR transmission*) or field detections (detect*)

2.2 Methods for study selection

The reviews were carried out in Distiller®, under the license owned by EFSA. EFSA was responsible to set up the project in distiller, run the search in Endnote and upload the references. Thereafter one team of six reviewers carried out the reviews. An overview of the extensive literature review process is provided in Figure 1.

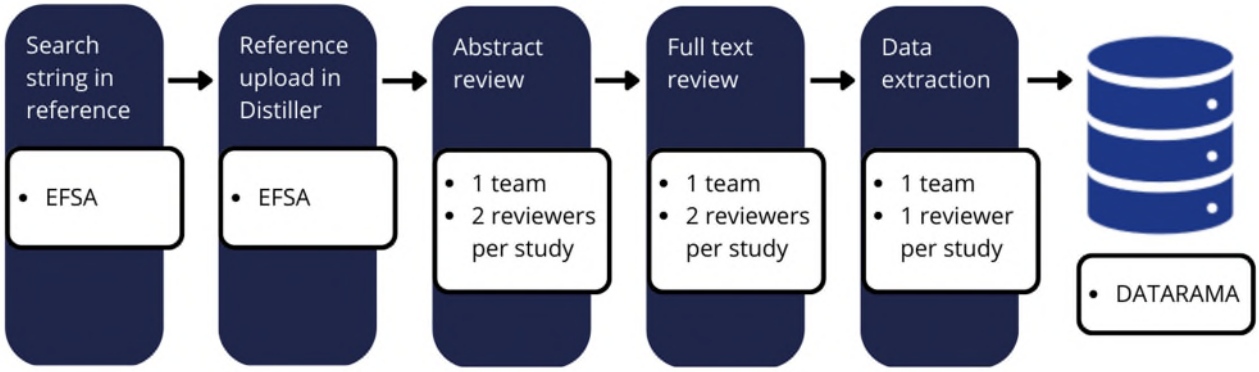

Figure 1. Overview of the extensive literature review process

After the specific search strings were applied in the reference manager (e.g., Endnote in EFSA), duplicates were removed in Endnote, whereafter a reference output file containing all results is uploaded to Distiller.

The review flow is visualised in Figure 2. Level 1 screening for eligibility was performed jointly for both experimental and field studies, while level two screening and data extraction were specific for either experimental infections or field studies.

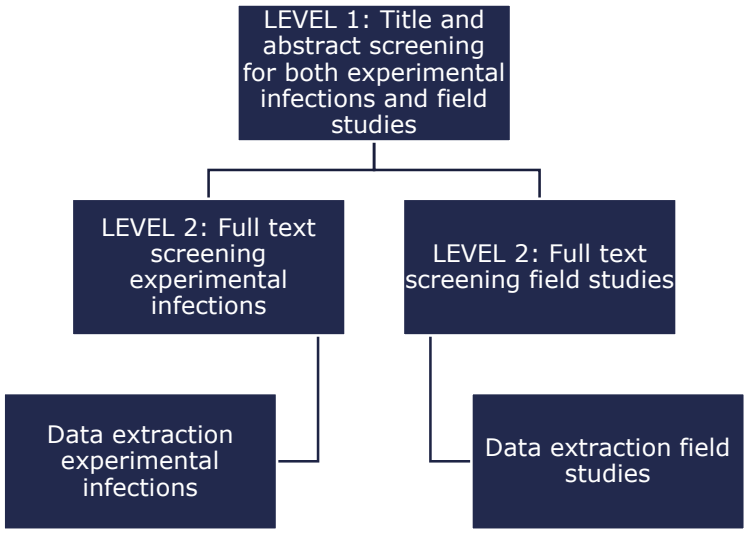

Figure 2. Review workflow to be applied for the output references for each of the aquatic species groups of interest

- **Title and abstract review**

The level 1 selection process involved the screening of title and abstract using a screening check list developed according to the eligibility criteria defined in section 1 above. If the information contained in the title or abstract was not relevant for the research objectives (any of the eligibility criteria are not met), the article was not selected for full text assessment. The first level of screening was performed independently and blindly by two researchers (i.e., two reviewers per study). Conflicts were resolved before going to the second level. To solve conflicts, reviewers discussed their reasoning and reached a consensus decision. Reasons for exclusion were recorded by Distiller.

- **Full text review**

The level 2 selection process involved the screening of full text using a screening checklist developed according to the eligibility criteria defined section 1 above. This step was carried out by two reviewers. Conflicts were resolved before going to the second level. To solve conflicts, reviewers discussed their reasoning and reached a consensus decision. Reasons for exclusion were recorded by distiller.

Both level 1 and level 2 screenings involved an initial phase of harmonisation and training regarding the assessment of study eligibility criteria, across all screeners of each objective. During the selection process, Distiller will record automatically:

- Total number of unique records (title/abstracts) identified through electronic search
- Number of records excluded after level 1 screening
- Records (full text) potentially eligible
- Number of records excluded after level 2 screening (by reason for exclusion)
- Final number of studies included in the review

2.3 Methods for data collection

From those studies that passed both selection levels, data collection was performed using forms set up in Distiller® provided in Annex IV. These forms ensured that data validity checks were performed during data collection, in particular compliance to the data types specified in the forms.

Changes to the existing forms during the review were avoided to ensure that all data collected were compatible with the data already collected in previous SLRs, and were easy to be summarised. However, if adjustments or improvements to the data collection structure provided in Annex IV are shown to be needed during the review process, those will be thoroughly documented during the course of the project.

One reviewer per study individually extracted data from studies that have passed both screenings for relevance, but a quality assurance process was applied, as detailed below.

Authors of primary studies were contacted to provide missing data.

2.4 Data quality assurance

The following data quality assurance practices will be performed

1) New reviewers are always trained by a reviewer experienced in the process

2) Harmonisation rounds are performed in the beginning of each screening level, with reviewers sharing notes and thoughts on 5 papers before working independently

3) A 'helpsheet' is developed for each SLR containing detailing instructions for the screening process. When a reviewer has questions about the eligibility or the format of data collection for any specific paper, the question is shared among the entire group by MS TEAMS, providing the paper refID so that the group can consult the reference in Distiller and discuss the question. If needed, the question is forwarded to the working group. Once consensus is reached, the specific questions and the reached agreement are documented in the helpsheet for future reference in the TEAMS folder.

4) One project leader experienced in the review is responsible for regularly reviewing the progress of the screening and running data validation checks directly in Distiller (using the datarama) or exporting the data.

5) In the data collection step, a free-text box is provided at the end of every form. Reviewers can use this box to take any notes on study quality issues notes, relevant data, which could not be captured, or any other discrepancies or points worth noting. All forms with note in this box are reviewed by the project manager, and if they cannot be solved, they are passed to the EFSA working group.

3 Assessment

3.1 Prisma flow chart

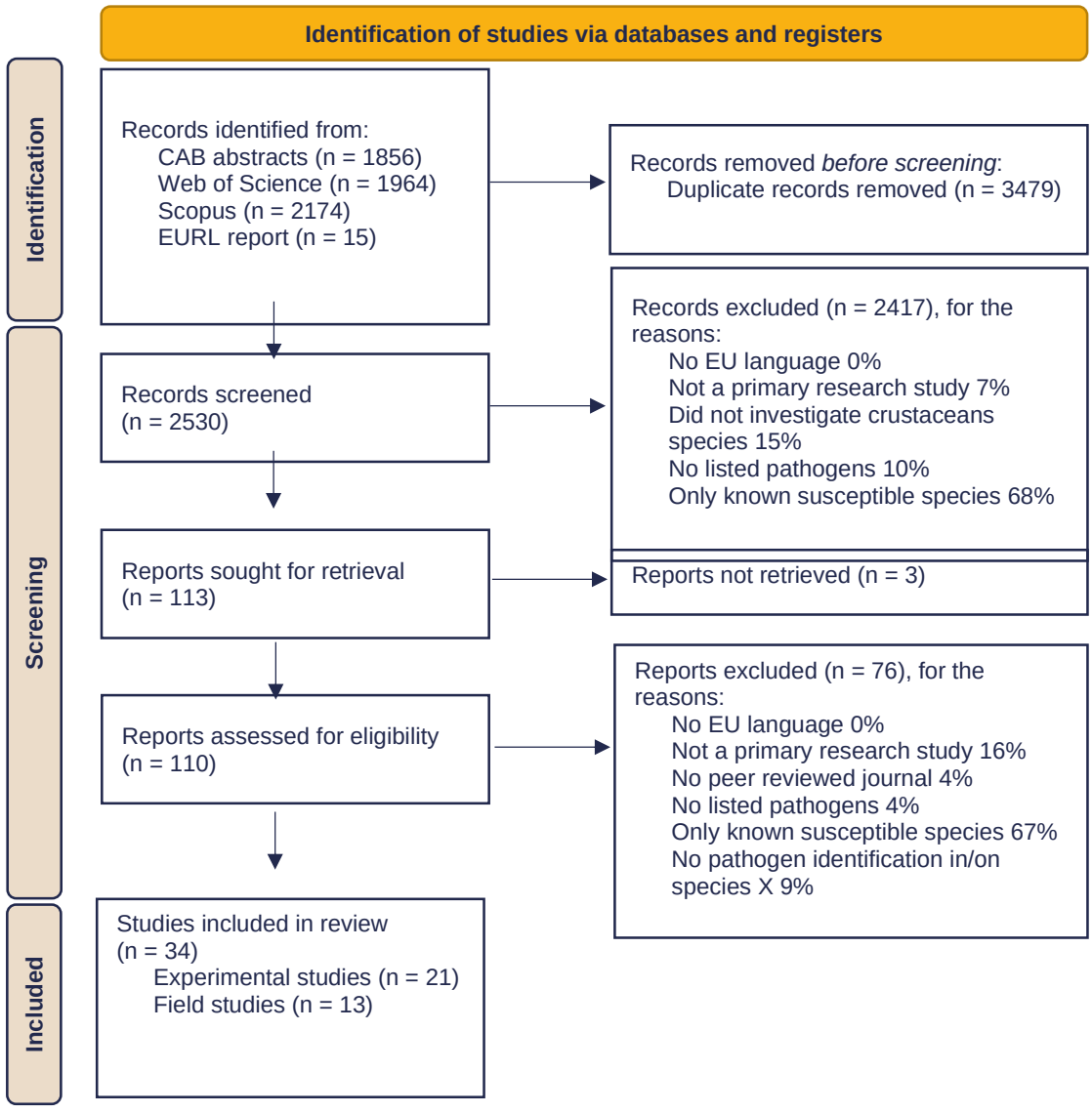

Figure 3: Prisma flowchart documenting the review process

Figure 3 provides an overview of the different steps in the review process. In total 2,530 research publications were collected for abstract screening and from these 110 were selected for further full text analysis. In the final data collection and assessment 34 relevant research publications

were used for extracting information on vector and reservoir species of the above crustacean pathogens.

3.2 Data extraction tables

The results for crustacean species for which scientific evidence indicates that a role as vector species or reservoir species is likely are presented as Annex under the 'Supporting Information' section in the online version of this scientific output.

Annex A - Assessment of potential vectors and reservoir species of pathogens of crustaceans, listed in Annex II to the AHL

Annex A is available under the Supporting Information section on the online version of the scientific output.