

## WORK PROGRAMME of EURL for

# FISH DISEASES

PERIOD: 2018

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# EURL for fish diseases

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## SUMMARY

INTRODUCTION .....	page 3
ACTIVITIES	
1. TO ENSURE AVAILABILITY AND USE OF HIGH QUALITY METHODS AND TO ENSURE HIGH QUALITY PERFORMANCE BY NRLs .....	page 4
2. TO PROVIDE SCIENTIFIC AND TECHNICAL ASSISTANCE TO NRLS .....	page 7
3. TO PROVIDE SCIENTIFIC AND TECHNICAL ASSISTANCE TO THE EUROPEAN COMMISSION AND OTHER ORGANISATIONS .....	page 9
4. REAGENTS AND REFERENCE COLLECTIONS.....	page 10
5. REQUIREMENTS RELATED TO OTHER LEGISLATION.....	page 12
REMARKS.....	page 13

# EURL for fish diseases

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## INTRODUCTION

(Regarding relevant regulations and functions)

DTU-Vet has since 1994 been designated as the EU reference laboratory for fish diseases, and was last approved as such by Grant decision for an action regarding the EU Reference Laboratory for Fish Diseases - SI2.725290 of 18/02/2016 (Ref. Ares(2016)854560). The following proposal for a Work Programme 2018 has been developed based on the function and duties of the Community reference laboratories given in council directive 2006/88/EC annex VI, PART I.

# EURL for fish diseases

## Regulation (EU) 625/2017 Art 94(2):

European Union reference laboratories designated in accordance with Article 93(1) shall be responsible for the following tasks insofar as they are included in the reference laboratories' annual or multiannual work programmes that have been established in conformity with the objectives and priorities of the relevant work programmes adopted by the Commission in accordance with Article 36 of Regulation (EU) No 652/2014:

*(taking into account Art 147 of (EU) 625/2017)*

1

## TO ENSURE AVAILABILITY AND USE OF HIGH QUALITY METHODS AND TO ENSURE HIGH QUALITY PERFORMANCE BY NRLs.

Please, provided activities related to Regulation (EU) 2017/625:  
(Number of Sub-activity boxes can be adjusted by EURL)

- **Art. 94.2.a** *Providing national reference laboratories with details and guidance on the methods of laboratory analysis, testing or diagnosis, including reference methods.*
- **Art. 94.2.b** *Providing reference materials to national reference laboratories*
- **Art. 94.2.c** *Coordinating the application by the national reference laboratories and, if necessary, by other official laboratories of the methods referred to in point (a), in particular, by organising regular inter-laboratory comparative testing or proficiency tests and by ensuring appropriate follow-up of such comparative testing or proficiency tests in accordance, where available, with internationally accepted protocols, and informing the Commission and the Member States of the results and follow-up to the inter-laboratory comparative testing or proficiency tests.*
- **Art. 94.2.l** *Where relevant for their area of competence, cooperate among themselves and with the Commission, as appropriate, to develop methods of analysis, testing or diagnosis of high standards.*

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## Sub-activity 1.1 (*Annual workshop*)

**Objectives:** To ensure knowledge dissemination and sharing between the Member State NRLs on existing and emerging fish diseases and to agree on the future priorities of the EURL, by holding the 22<sup>nd</sup> annual workshop of the National Reference Laboratories (NRLs) for fish diseases in 2018.

**Description:** These workshops are organised as annual events and all Member State NRLs are strongly recommended to participate in them as it is an important opportunity to get updated on the newest scientific knowledge of fish pathogens, diagnostics, legislation, etc. Several talks of high scientific standard will be given and discussions at group and plenum level will be facilitated during the two days of the workshop.

**Expected Output:** Successful preparation and completion of the 22<sup>nd</sup> annual workshop comprising 2 full days (May 30<sup>th</sup> and 31<sup>st</sup> 2018). A technical and financial report of the workshop produced. The technical report will contain abstracts and minutes from all presentations and discussions and will after acceptance be made publicly available through the EURL website.

**Duration:** The workshop is to be held ultimo May 2018. Preparation in February – April and finalizing of the reports in May – August.

## Sub-activity 1.3 (*Scientific working group*)

**Objectives:** To ensure that all EU Member States can rely on consultancy from international experts to a broad range of problems that existing or emerging fish disease may be causing in Europe.

**Description:** In case of critical fish disease related problems within EU Member States, we will organize specific scientific meetings by collating international experts.

**Expected Output:** Two-three day scientific meeting in Denmark. A scientific report including recommendations will be delivered to the relevant Member State NRL and the European Commission and will be available on our website [www.eurl-fish.eu](http://www.eurl-fish.eu).

**Duration:** 2-3 day meeting in Copenhagen in 2018 and time for organising and reporting.

# EURL for fish diseases

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## Sub-activity 1.4 (*Proficiency test*)

**Objectives:** To assess the capabilities of all Member State NRLs to detect fish disease causing pathogens and to harmonize the procedures used by an inter-laboratory proficiency test.

**Description:** The EURL is going to prepare the Annual Inter-laboratory Proficiency Tests for 2018 for the NRLs. The tests will include the viral fish disease pathogens viral haemorrhagic septicaemia virus (VHSV), infectious haematopoietic necrosis virus (IHNV), epizootic haematopoietic necrosis virus (EHNV), infectious salmon anemia virus (ISAV) and koi herpes virus (KHV), and will also address other common viral pathogens in fish farming (infectious pancreatic necrosis virus (IPNV), spring viraemia of carp virus (SVCV), salmonid alphavirus (SAV), Ranaviruses, etc.). The participation is mandatory for all NRLs in EU. After submission of test results from the NRLs to the EURL, we will collate and analyse information gained from the proficiency test and publish the anonymous data to all participants as a report on our website [www.eurl-fish.eu](http://www.eurl-fish.eu). A non-coded version will be provided to the EU Commission with information on performances and under performances. The results will be presented and discussed at the Annual Workshop 2019. The tests are accredited according to ISO 17043 and are indispensable for maintaining accreditations at the NRLs.

**Expected Output:** Preparation and shipping the test and subsequently provide a report on the proficiency test 2018.

**Duration:** January – December. The samples included in the test will be shipped from the EURL in the fall of 2018 and the final report will be submitted February 2019.

## Sub-activity 1.5 (*Novel molecular methods*)

**Objectives:** For the EURL to have molecular diagnostic methods of the highest scientific standards and to be able to provide these methods to all Member State NRLs.

**Description:** Novel molecular methods are highly sensitive and specific tools for diagnosis and surveillance of a number of listed pathogens. The EURL will assess and standardize real-time PCR, fluidigm, multiplex (PCR and ELISA) tests for the diagnosis, identification and typing of emerging and the listed non-exotic and exotic fish diseases, e.g. a diagnostic package comprising relevant pathogens for the respective fish species like VHSV, IHNV, ISAV, EHNV, PRV3, IPNV, SAV2, R. salmoninarum (BKD) for rainbow trout VHS, IHN, ISA, SAV1-6, PMCV, PRV1, Pox virus for Atlantic salmon,

**Expected Output:** Diagnostic molecular methods that are validated according to the recommendations given by the OIE to be used by the relevant Member State NRLs.

**Duration:** January - December

### TO PROVIDE SCIENTIFIC AND TECHNICAL ASSISTANCE TO NRLs

Please, provided activities related to Regulation (EU) 2017/625:  
(Number of Sub-activity boxes can be adjusted by EURL)

- **Art. 94.2.d** *Coordinating practical arrangements necessary to apply new methods of laboratory analysis, testing or diagnosis, and informing national reference laboratories of advances in this field.*
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- **Art. 94.2.e** *Conducting training courses for staff from national reference laboratories and, if needed, from other official laboratories, as well as of experts from third countries.*
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- **Art. 94.2.g** *Providing information on relevant national, Union and international research activities to national reference laboratories.*

#### Sub-activity 2.1 (Training)

**Objectives:** To ensure that employees of the Member State NRLs have the highest scientific and excellent skills in diagnosis of fish diseases.

**Description:** The EURL yearly provides two training courses in methods used for diagnosis of fish diseases. These courses are primarily offered to participants of the Member State NRLs. The content is mainly based on the opinion of the EURL on what is required in the Member State NRLs, e.g. in 2017 we emphasised the training of the NRLs in blast results reading to be included in the course on diagnostic procedures. However, the course contents are also discussed during the annual workshop, where the Member State NRLs are able to provide specific input.

**Expected Output:** Two training courses of 3-5 days, with 8-10 participants in each course.

**Duration:** September – October.

#### Sub-activity 2.2 (Webpage)

**Objectives:** To provide the Member State NRLs with a fast entrance to information from the EURL.

**Description:** The EURL are administrating the webpage, [www.eurl-fish.eu](http://www.eurl-fish.eu), by uploading relevant material such as updated lists of NRLs, annual workshop presentations, training course reports, sampling and diagnostic procedures, newest update on legislation, general news from the community, etc. The website has daily visitors from a great number of countries from around the world and are, therefore, a substantial part of disseminating the work of the EURL for fish diseases.

**Expected Output:** A constantly updated webpage for the Member State NRLs.

**Duration:** January - December

# EURL for fish diseases

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## Sub-activity 2.3 (*FishRefLabNet*)

**Objectives:** To ensure that relevant and important information rapidly can get from the EURL directly to the Member State NRLs.

**Description:** FishRefLabNet is a mailing list which all interested in the work of the EURL can subscribe to. The EURL use the mailing list for important notifications i.e. meeting calls, training course calls and other relevant information such as information on upcoming conferences, new research findings and relevant reports and publications, emergency situations etc. Often the notifications will include links to the Webpage or other sites for further and detailed information. All Member State NRLs have subscribed to the list, plus a number of fish disease scientists both within and outside Europe.

**Expected Output:** The EURL usually prepare and submit around 5-10 notifications per year via FishRefLabNet to ca. 80 subscribers.

**Duration:** January – December.

## Sub-activity 2.4 (*Molecular epidemiology*)

**Objectives:** To improve knowledge on disease spreading mechanisms within the EU.

**Description:** To prevent diseases from spreading within the EU, it is important for the EURL to have excellent knowledge on the spreading mechanisms and the actual spreading patterns of the listed and emerging viral fish diseases. A study involving highly important isolates and disease outbreaks, in EU will be conducted. As this/these pathogen(s) are also found outside the EU and are putative threats to EU, data from non-EU countries will also be included in the study. Data from these studies are expected to provide better understanding of fish diseases spreading mechanisms within the EU Member States

**Expected Output:** Reports, publications and oral presentations generated. from these studies will be given.

**Duration:** January - December

## Sub-activity 2.5 (*Producing virtual teaching material (e-learning)*)

**Objectives:** To provide the Member State NRLs with “hands on” videos to be used for teaching of staff members.

**Description:** The training courses offered by the EURL are only available for participation one time per year, generally during the fall and for a limited number of participants. A set of e-learning videos will provide fast and effective learning for NRLs employees when needed.

**Expected Output:** A series of English instructional videos for conducting proficiency test, fish sampling and other laboratory techniques related to the EURL.

**Duration:** January - December. The videos will be available via our website during November – December.

## Sub-activity 2.6 (*Missions*)

**Objectives:** To ensure a high standard of diagnostic capabilities of all Member State NRLs.

**Description:** Member State countries chosen for a mission are primarily based on performance in the yearly proficiency test. However, if missions to other countries, both EU Member States but also 3<sup>rd</sup> countries, will be able to provide important scientific knowledge for the EURL to pass on to Member State NRLs, missions to such countries will be conducted. This will ensure EU Member States to be updated with excellent scientific skills and knowledge.

**Expected Output:** As the decision for appointing target laboratories for missions is based on performances of the proficiency test- no final decision can be taken at this stage- but a preliminary

## EURL for fish diseases

indication would point at 2 missions with one mission to the NRL of France (due to their plan for final eradication of VHS and IHN from France) and one mission to Portugal.

Duration: April and/or November

# EURL for fish diseases

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## Sub-activity 2.7 (*International meetings*)

**Objectives:** To keep the EURL updated on the newest scientific information on emerging and listed exotic and non-exotic fish diseases, and to disseminate knowledge and scientific data provided by the EURL.

**Description:** The EURL staffs is able to provide consultancy to Member State NRLs on emerging and listed fish diseases, and attending conferences are an important way of the EURL to keep the excellence of this function. Conference participation therefore ensures up-to-date knowledge within the EURL.

**Expected Output:** The EURL expect to participate in 2 to 3 international conferences e.g. Eighth International Symposium on Aquatic Animal Health, Prince Edward Island, 2-6 September 2018. <https://isaah2018.com/>. [EAFP UK & Ireland Branches Third Meeting](#) "Connecting Academia with Industry for improved Aquatic Animal Health" Galway 11-12 September 2018

Duration: January - December

3

## TO PROVIDE SCIENTIFIC AND TECHNICAL ASSISTANCE TO THE EUROPEAN COMMISSION AND OTHER ORGANISATIONS

Please, provided activities related to Regulation (EU) 2017/625:  
(Number of Sub-activity boxes can be adjusted by EURL)

- *Art. 94.2.f Providing scientific and technical assistance to the Commission within the scope of their mission.*
- *Art. 94.2.h Collaborating within the scope of their mission with laboratories in third countries and with the European Food Safety Authority (EFSA), the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC).*
- *Art. 94.2.i Assisting actively in the diagnosis of outbreaks in Member States of foodborne, zoonotic or animal diseases, or of pests of plants, by carrying out confirmatory diagnosis, characterisation and taxonomic or epizootic studies on pathogen isolates or pest specimens.*

### Sub-activity 3.1 (*Diagnostic manuals*)

Objectives: To have updated diagnostic manuals for all listed fish diseases available for Member State NRLs on the EURL website [www.eurl-fish.eu](http://www.eurl-fish.eu).

Description: The diagnostic manual for sampling and detection of listed non-exotic diseases was finally adopted in 2015. But as the diagnostic procedures for identification and surveillance of the listed diseases is rapidly evolving new procedures will be assessed and validated for inclusion in the first revision of the diagnostic manuals.

Expected Output: Updated sampling and diagnostic manual for the viral fish diseases viral haemorrhagic septicaemia (VHS), infectious hematopoietic necrosis (IHN), infectious salmon anaemia (ISA), koi herpes virus (KHV) and epizootic haematopoietic necrosis (EHN) on the EURL website.

Duration: January - December

### Sub-activity 3.2 (*Survey and diagnosis*)

Objectives: As part of our duties given in given in C.D. 2006/88/EC Annex VI, Part I.5 (f) to “collate and forward information on exotic and endemic diseases, that are potentially emerging in Community aquaculture” data on emerging and endemic fish diseases and fish health surveillance in Europe will be collated in order to ensure that the EU Commission, the Member State NRLs and the EU in general are updated on the fish diseases situation in aquaculture and natural fish populations in Europe.

# EURL for fish diseases

Description: The EURL collect data on emerging and endemic fish diseases outbreaks from NRLs in all European countries by submitting a questionnaire in January 2018 and disseminating the information gathered in a report and at the 2018 annual workshop. The data are collated in a “Survey and diagnosis” report, which is made available for the Commission, Member State NRLs and for public use on our website. This report includes information on the presence of all the listed non-exotic fish diseases given in Council Directive 2006/88/EC Annex IV Part 2, on emerging diseases, and on all surveillance programmes on fish diseases conducted in EU. This is the only comprehensive overview on fish diseases and fish health management in Europe that is published.

Expected Output: A report on “Surveillance and diagnosis of fish diseases in Europe 2017”, will be published on the EURL website [www.eurl-fish.eu](http://www.eurl-fish.eu) and presented at the annual workshop in 2018.

Duration: January – June.

## Sub-activity 3.2 (*Emerging diseases*)

Objectives: For the EURL to have the most updated and highest scientific knowledge of emerging and re-emerging fish diseases in Europa.

Description: Due to increased international trade of fish, focus will be given to emerging diseases and rapid response to Member State NRLs and EU in case of outbreaks. An assessment of risk for contracting and spreading specific emerging and re-emerging diseases in EU will be conducted in 2018. In collaboration with specialised experts the EURL foresee to work e.g. with the emerging viral fish pathogens piscine orthoreovirus3 (PRV3) in rainbow trout in Europe to be able to assess their potential listing as exotic or non-exotic diseases in the future. Diseases like

Expected Output: The EURL will have relevant and updated scientific knowledge on emerging fish diseases in EU and be able to provide immediately consultancy to all Member State NRLs and the European Commission and stakeholders. Scientific knowledge on specific emerging diseases like PRV3 will be disseminated through oral and written presentations in scientific journals, at Annual workshops, conferences etc.

Duration: January - December

## REAGENTS AND REFERENCE COLLECTIONS

Please, provided activities related to Regulation (EU) 2017/625:  
(Number of Sub-activity boxes can be adjusted by EURL)

- **Art. 94.2.j**      ***Coordinating or performing tests for the verification of the quality of reagents and lots of reagents used for the diagnosis of foodborne, zoonotic or animal diseases and pests of plants.***
  
- **Art. 94.2.k**      ***Where relevant for their area of competence, establishing and maintaining:***
  - i. reference collections of pests of plants and/or reference strains of pathogenic agents;***
  - ii. reference collections of materials intended to come into contact with food used to calibrate analytical equipment and provide samples thereof to national reference laboratories;***
  - iii. up-to-date lists of available reference substances and reagents and of manufacturers and suppliers of such substances and reagents.***

### Sub-activity 4.1 (*Pathogen library*)

Objectives: For the EURL to have an updated library of fish pathogens relevant for the EURL and Member State NRLs.

Description: The EURL are going to update and maintain a library of isolates of the viral fish pathogens infectious salmon anaemia virus (ISAV), viral haemorrhagic septicaemia virus (VHSV), infectious hematopoietic necrosis virus (IHNV), koi herpes virus (KHV), enzootic hematopoietic necrosis virus (EHNV) and other relevant putative emerging fish pathogens.

Expected Output: The library will be updated with around 10 to 20 pathogen isolates in 2018.

Duration: January - December

### Sub-activity 4.2 (*Pathogen characterization*)

Objectives: For the EURL to be able to identify and characterize isolates of listed viral fish pathogens on request from the Member State NRLs.

Description: The EURL every year receive strains of fish pathogens for corroboration of diagnostic results in the EU Member States. Regularly these strains must be characterized properly as an emergency response to avoid unwanted spreading of new pathogens in EU. The EURL describe these strains by pathogenicity testing in-vivo and in-vitro and by serological and genetic characterization.

Expected Output: The EURL expect to describe and characterize around 5-10 fish pathogen strains in 2018.

Duration: January - December

# EURL for fish diseases

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## Sub-activity 4.3 ([www.fishpathogens.eu](http://www.fishpathogens.eu))

Objectives: To have an updated database of all serious viral fish pathogens in the EU.

Description: The database [www.fishpathogens.eu](http://www.fishpathogens.eu) is a valuable tool for all Member State NRLs for virus characterisation and molecular epidemiology of listed and non-listed fish pathogens viruses. The more isolates included the stronger the tool for the EURL and Member State NRLs.

Expected Output: The EURL expect to update the database with salmonid alphavirus (SAV) in 2018, and to expand the existing database with more isolates (30-50 isolates).

Duration: January - December

## Sub-activity 4.4 (*Production and supply of reagents*)

Objectives: For the EURL to be able to quickly provide Member State NRLs with diagnostic reagents.

Description: Diagnostic reagents (i.e. polyclonal antibodies raised in rabbit, monoclonal antibodies from stored hybridoma cells or in situ hybridization (ISH probes) will be produced according to demand from the Member State NRLs.

Expected Output: The EURL expect request of diagnostic reagents from around 15 Member State NRLs in 2018. However, we are able to provide more reagents if there is a need from more Member State NRLs.

Duration: January - December

5

## REQUIREMENTS RELATED TO OTHER LEGISLATION

Please specify applicable legislation:  
(Number of Sub-activity boxes can be adjusted)

### Sub-activity 5.1 (*New animal health law*)

Objectives: To prepare regulations related to the new animal health law.

Description: The EURL expect to assist the EU Commission in preparing regulations for the new animal health law in 2018.

Expected Output: Depending on requests from the EU Commission.

Duration: January - December

### Sub-activity 5.2 (*Listing susceptible species*)

Objectives: For the EU Member States to have an updated list of susceptible species for the listed fish diseases.

Description: With implementation of the new Animal Health Law there is an acute demand for scientifically assessing the fish species susceptible to the listed diseases. Therefore, an increased workload for the EURL in 2018 will be to assess the listing of susceptible fish species, e.g. assess susceptibility of cleaner fish (wrasse and lumpfish), sea bass and sea bream to VHS and IHN, etc.

Expected Output: Provide a report with a list of which fish species are susceptible to the listed fish diseases, to be recommended for adaptation in the new legislation.

Duration: January -March

# EURL for fish diseases

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<b>REMARKS</b>
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(if necessary)
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