

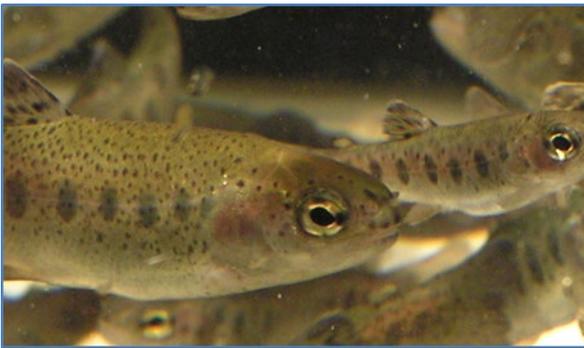


European Union Reference Laboratory for Fish and Crustacean Diseases
NATIONAL INSTITUTE OF AQUATIC RESOURCES, TECHNICAL UNIVERSITY OF DENMARK

Report of
Special session for NRL's on new Animal Health Law

31st of May 2021

**National Institute of Aquatic Resources
Technical University of Denmark
2800 Kgs. Lyngby, Denmark**



Organized by the European Union Reference Laboratory for Fish and Crustacean Diseases,
National Institute of Aquatic Resources, Technical University of Denmark, Kgs. Lyngby

Contents

Introduction and short summary	3
Programme	4
SESSION I: Aquatic animal health legislation	6
Animal Health Law- State of Play	7
Some requirements from the Official Controls Regulation	8
Functions and duties of NRLs in EU	9
Listing of species under the AHL – background and update	11
SESSION II: Diagnostic manuals for listed fish and crustacean diseases	12
DIAGNOSTIC MANUAL FOR LISTED FISH and CRUSTACEAN DISEASES	13
Workshop evaluation	14

Introduction and short summary

On May 31st, a workshop on the new Animal Health Law (AHL) was organised. This session was attended only by the staff of the National Reference Laboratories in EU and EFTA countries.

The aim of this session was to introduce the new legislative framework which was adopted on 21st of April 2021, and to provide an overview of the methods used for diagnostics of the diseases listed in the new AHL.

The first session had the title: “Aquatic animal health legislation” and was opened by a welcome address by Head of the EURL for Fish and Crustacean Diseases, Niels Jørgen Olesen, followed by four presentations. First Fiona Geoghegan from DG Sante, European Commission provided a detailed and extensive overview of Regulation (EU) 2016/429 (‘Animal Health Law’) and the key delegated and implementing acts that have been developed by the European Commission over the past 2 years, to supplement the basic rules which are set out in the AHL. Next, Laszlo Kuster, also from DG Sante, gave a presentation on Regulation (EU) 2017/625 (‘Official Controls Regulation, OCR’), focusing on the rights and obligations of NRLs and other actors in relation to this regulation. Niels Jørgen Olesen then gave an overview of the functions and duties of NRLs in relation to the new AHL. Finally, the session was closed by Fiona Geoghegan presenting the work process of listing susceptible and vector species for the aquatic animal diseases of the new AHL.

The second session had the title: “Diagnostic manuals for listed fish and crustacean diseases“ and consisted of six presentations by Niels Jørgen Olesen, Niccolò Vendramin and Morten Schiøtt from the EURL for Fish and Crustacean diseases providing an overview of the diagnostic manuals for the EU listed fish and crustacean diseases: VHS, IHN, ISA, KHV and EHN for fish, and WSS, TS and YHD for crustaceans.

As for the 25th AW of National reference laboratories for fish diseases and the 12th AW of National reference laboratories for Crustacean diseases a questionnaire based on google forms was delivered to the participants to assess the quality of the meeting and receive inputs for improvements in future. The data collected from the evaluation are attached in the end of this report.

Niccolò Vendramin, Morten Schiøtt and Niels Jørgen Olesen

Programme

Monday May 31st

Annual Workshop of the National Reference Laboratories for Fish and Crustacean Diseases

Shared session for Aquatic animal health legislation

NRL Only:

Chair Niels Jørgen Olesen and minutes Niccoló Vendramin

- | | |
|---------------|---|
| 9:15 – 9:30 | Welcome
<i>Niels Jørgen Olesen</i> |
| 9:30 – 10:10 | Implementation of the new animal health law
<i>Fiona Geoghegan</i> |
| 10:10 – 10:40 | Official Control Regulation - OCR
<i>Laszlo Kuster</i> |
| 10:40 – 11:00 | <i>Coffee break</i> |
| 11:00 – 11:20 | Functions and duties of NRLs in EU
<i>Niels Jørgen Olesen</i> |
| 11:20 – 11:35 | List of susceptible species
<i>Fiona Geoghegan</i> |
| 11:35 – 12:00 | Plenum discussion of the new animal health law |
| 12:00 – 12:30 | <i>Lunch</i> |

Shared session for Diagnostic manuals for listed fish and crustacean diseases

NRL Only:

Chair Niels Jørgen Olesen and minutes Morten Schiøtt

- | | |
|---------------|---|
| 12:30 - 12:50 | Diagnostic manual for VHS and IHN
<i>Niels Jørgen Olesen</i> |
| 12:50 – 13:10 | Diagnostic manual for HPR-del ISAV
<i>Niccoló Vendramin</i> |

- 13:10 - 13:30 Diagnostic manual for KHV
Niccoló Vendramin
- 13:30 - 13:50 **Coffee break**
Chair Niels Jørgen Olesen and minutes Niccoló Vendramin
- 13:50 – 14:10 Diagnostic manual for List A fish diseases
Niels Jørgen Olesen
- 14:10 – 14:30 New diagnostic manual for crustacean diseases: WSSV
Morten Schiøtt
- 14:30-14:50 Diagnostic manual for List A crustacean diseases
Morten Schiøtt
- 14:50-15:10 Final remarks and conclusions
- End of meeting***

SESSION I: Aquatic animal health legislation

Chair: Niels Jørgen Olesen

Animal Health Law- State of Play

Fiona Geoghegan

DG Sante, European Commission

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Abstract

Regulation (EU) 2016/429 ('Animal Health Law') became applicable on 21 April last. An update concerning the key Regulations, which supplement the Animal Health Law was presented as well as an update on ongoing and future work.

All key Regulation have been now been published. The main pillars of these Regulations were described, and details were provided so that participants can access the key pieces of legislation in the Official Journal of the European Union, and understand how the various Regulations are linked with each other. Work is ongoing concerning a small number of Implementing Regulations, and this was described.

The focus has now moved towards providing training for Member States and towards developing other forms of communication, to assist stakeholders with the implementation of the new legislation.

Annex VI of Regulation (EU) 2020/689 is of particular interest to NRLs and a number of issues were highlighted to participants. In particular, it was noted that detailed diagnostic methods are no longer set out in legislation, rather they are to be found on the website of the relevant EURL. Part II of Annex VI sets out the specific requirements to gain and maintain disease-free status, for each of the Category C diseases of aquatic animals, and this is very reflective of the information which was previously set out in Regulation (EU) 2015/1554. Part III of Annex VI deals with surveillance programmes for Category C diseases. These surveillance programmes are new, and were not previously referred to in Regulation (EU) 2015/1554. An explanation was provided concerning the background to these programmes and their purpose.

Some requirements from the Official Controls Regulation
Laszlo Kuster

European Commission DG SANTE Unit G2 Animal Health

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Abstract

Regulation (EU) 2017/625 ('Official Controls Regulation, OCR') became applicable on 14 December 2019. The Regulation covers a number of areas relevant for official laboratories, national reference laboratories and EU reference laboratories. Some of those areas and topics were previously regulated under Directive 2006/88/EC, some others are beyond. Such areas and topics of potential interest to EURLs and NRLs include cascade of methods for official tasks, second expert opinion, designation of official laboratories, accreditation requirements and derogation possibilities therefrom. The presentation outlined those, as the requirements are directly applicable to participants. The objective was to provide participants with an adequate understanding about rights and obligations under the Regulation to assist its implementation and compliance with, as well implementation of related EU animal health rules. For that, operational relations, communication and cooperation between different actors in the official control and animal health public administration is of paramount importance. For example, between EURL and NRLs, between competent authorities and their official laboratory network or between official laboratories and the relevant national accreditation bodies.

A: There will not be 5 categories, as the former category 3 will enter the surveillance program. They will be able to trade between them with self declaration. There will also be the possibility of avoiding to have a health status for small businesses that produce for direct consumption and put and take lakes. The TRACES system will be adopted for the farms in surveillance programs.

Q: In our case, we have accredited screening methods for VHS and IHN but no confirmatory methods are accredited (PCR and sequencing). How should we deal with that?

A: As long as you have one accredited method to conduct surveillance and diagnosis you should fulfill the requirements. There is also the question about diseases in category A and category E

A: For the diseases in category A, the EURL needs to be accredited, so any suspect cases should be forwarded to the EURL for confirmatory diagnostics. For the diseases in category E, the requirement for accreditation will apply for fish moving into KHV free area.

Q: Being free of VHS/IHN in Ireland, could it be interpreted in such a way that occurrence of this disease is an emergency situation and therefore the need for accreditation can be derogated?

A: No, diseases in category C are endemic in EU, they cannot be regarded as emergency situation.

C: In regards to the demands for accreditation, it is very important to have a dialogue with the competent authorities, which in fact are setting the demands for the NRL.

C: To fulfill the demand for accreditation will be even more difficult for the crustacean diseases, considering the limited amount of surveillance and diagnostics performed. Again it is very important to have a dialogue with the Competent authorities.

Listing of species under the AHL – background and update
Fiona Geoghegan

DG Sante, European Commission

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Abstract

Article 8 of Regulation (EU) 2016/429 ('Animal Health Law') sets out the criteria on which species or groups of species which pose a considerable risk for the spread of specific diseases should be listed. This list is set out in the Annex to Regulation (EU) 2018/1882, however, the list as it pertains to aquatic diseases is currently under review, with a view to amending it in the coming months. Background information concerning the need to amend the current list was set out, as well as the approach, which will be taken to this amendment.

SESSION II: Diagnostic manuals for listed fish and crustacean diseases

Chair: Niels Jørgen Olesen

DIAGNOSTIC MANUAL FOR LISTED FISH and CRUSTACEAN DISEASES

Niels Jørgen Olesen, Niccoló Vendramin, Morten Schiøtt

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Abstract:

The new Animal Health Law Regulation (EU) 2016/429 ('Animal Health Law') became applicable on 21 April 2021.

Diseases are now listed in different categories according to COMMISSION IMPLEMENTING REGULATION (EU) 2018/1882 along with lists of susceptible and vector species for each disease.

While Commission Delegated Regulation (EU) 2020/689 supplement 2016/429 providing the actual rules for surveillance, eradication programmes, and disease-free status for listed and emerging diseases, it is the responsibility of the EURL for fish and crustacean diseases to provide the DETAILED diagnostic methods and procedures for the surveillance and confirmation of listed fish and crustacean diseases.

The updated manuals are available on the EURL website

<https://www.eurl-fish-crustacean.eu/fish/diagnostic-manuals>

<https://www.eurl-fish-crustacean.eu/crustacean/diagnostic-manuals>

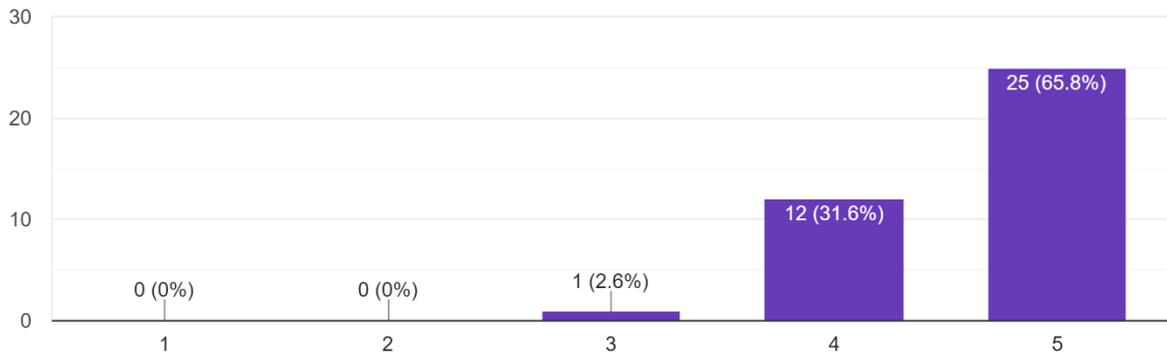
During this session all diagnostic manuals will be presented and discussed.

Workshop evaluation

A questionnaire was delivered to the participants asking to evaluate various aspect of the workshop. An overview of the 38 questionnaires retrieved is shown below. Specific comments are going to be considered for the next annual workshop organization.

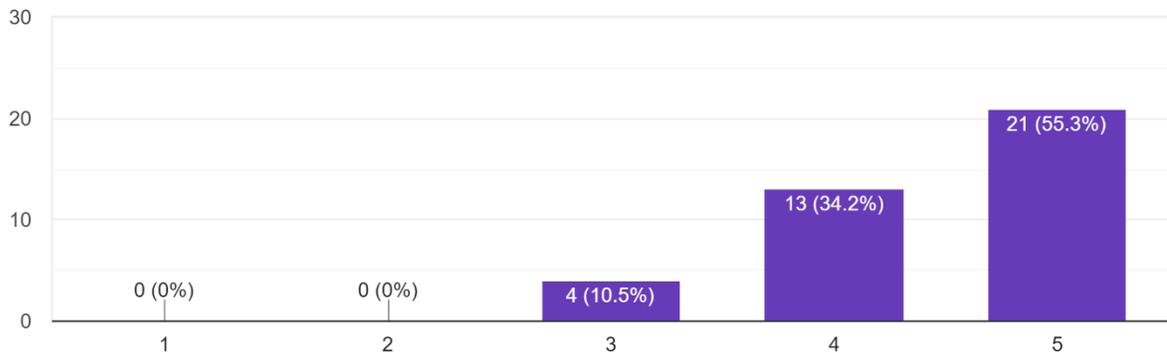
25th AW for NRL for fish diseases and 12th AW for NRL for Crustacean diseases - shared session -
Quality of presentations

38 responses



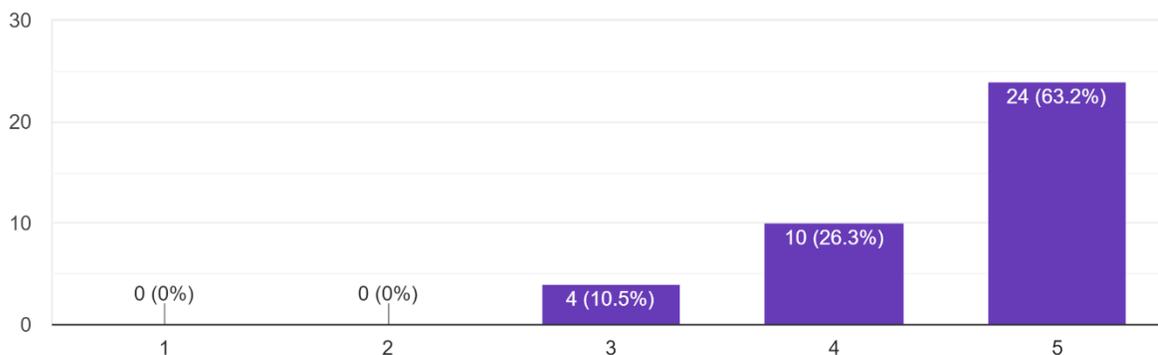
25th AW for NRL for fish diseases and 12th AW for NRL for Crustacean diseases -shared session -
increase of your knowledge

38 responses



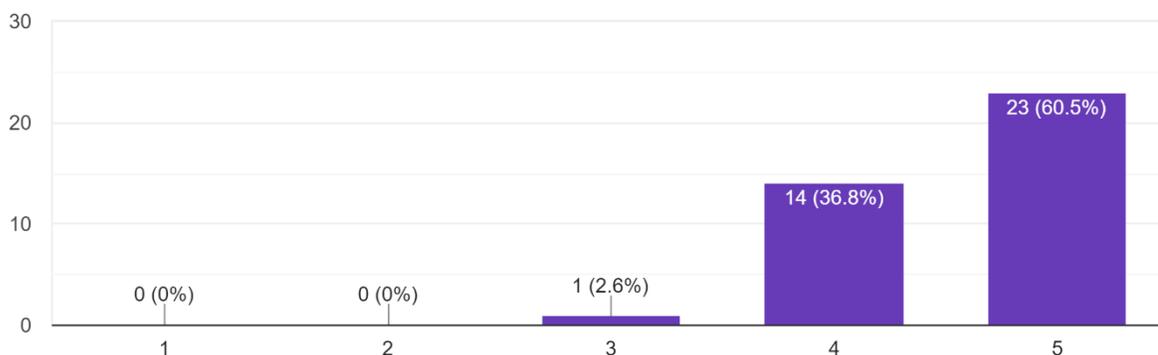
25th AW for NRL for fish diseases and 12th AW for NRL for Crustacean diseases - shared session
-relevance for you

38 responses



25th AW for NRL for fish diseases and 12th AW for NRL for Crustacean diseases -shared session -
overall score

38 responses



25th AW for NRL for fish diseases and 12th AW for NRL for Crustacean diseases -
shared session - comments, feedback, inputs

7 responses

- The breakout rooms in the coffee breaks were really nice, and added much in a personal way. Let's hope we can meet up in real next year! Furthermore the three of you are a bit far from the camera, therefore no nice close-ups made. Thanks!
- Very well done!
- Excellent workshop.
- I think it was a very informative session, thank you!
- Great with the legislation and diagnostic methods presentations

- This was such a helpful session that really helped to breakdown the requirements and obligations of the NRLs under the new AHL and gave us time to clarify issues with regards obligation with all relevant parties. Really enjoyed and very informative. I hope this will be done again next year.
- very useful and well prepared section