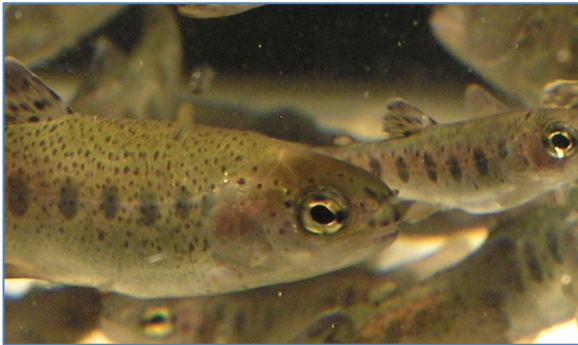


The new legislative basis for sampling and diagnostic procedures for the fish diseases - EHN, Infection with ISAV HPRA, VHS, IHN, and KHV

The 24th Annual Workshop of the National Reference Laboratories for Fish Diseases



Picture: DTU Aqua

COMMISSION DELEGATED REGULATION (EU) 2020/689

of 17 December 2019

supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases

The current legislative basis for aquaculture animal health surveillance is given in

- **COUNCIL DIRECTIVE 2006/88/EC**

L 328/14

EN

Official Journal of the European Union

24.11.2006

COUNCIL DIRECTIVE 2006/88/EC

of 24 October 2006

on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals

Will from 21 April 2021 be replaced by the Animal Health Law (EU) 2016/429

Cover both terrestrial and aquatic animals

Now include BOTH farmed and wild animals in contrast to 2006/88

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')

Rules for categories of diseases and list of susceptible/ vector species is given in Regulation 2018/1882

4.12.2018

EN

Official Journal of the European Union

L 308/21

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1882

of 3 December 2018

on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases

Define the Categories of animal diseases and provide list of categorized diseases and their susceptible and vector species

- **Category A-E:**

The List of susceptible and of vector species is under review

Categorization according to Regulation 2018/1882 from 21.04.2021: 1

(1) '**category A disease**': means a listed disease that **does not normally occur in the Union and for which immediate eradication measures must be taken** as soon as it is detected, as referred to in Article 9(1)(a) of Regulation (EU) 2016/429;

"the exotic to EU diseases" for the Aquatics: **EHN, Infection with Taura Syndrome virus, -Yellow Head Virus**"

(2) '**category B disease**': means a listed disease which must be controlled in all Member States with the goal of eradicating it throughout the Union,

Only Brucella, Tuberculosis and Rabies / **NO Aquatic Animals in B!**

(3) '**category C disease**': means a listed disease which is of relevance to some Member States and for which measures are needed to prevent it from spreading to parts of the Union that are officially disease-free or that have eradication programmes for the listed disease concerned.

VHS, IHN, infection with HPR-deleted ISAV, Infection with White Spot Syndrome Virus

Categorization according to Regulation (EU)2018/1882 2

(4) '**category D disease**': means a listed disease for which measures are needed to prevent it from spreading on account of its entry into the Union or movements between Member States

All listed aquatic animal diseases Except "Infection with KHV"

(5) '**category E disease**': means a listed disease for which there is a need for surveillance within the Union

All listed diseases fall into this category including KHV

List of susceptible and vector fish species in current 2018/1882: EHN and VHS

EHN, A + D + E

VHS C + D + E

Name of listed disease	Category of listed disease	Listed species	
		Species and group of species	Vector species
Epizootic haematopoietic necrosis	A+D+E	Rainbow trout (<i>Oncorhynchus mykiss</i>), redfin perch (<i>Perca fluviatilis</i>)	Bighead carp (<i>Aristichthys nobilis</i>), goldfish (<i>Carassius auratus</i>), crucian carp (<i>Carassius carassius</i>), common carp and koi carp (<i>Cyprinus carpio</i>), silver carp (<i>Hypophthalmichthys molitrix</i>), chub (<i>Leuciscus spp.</i>), roach (<i>Rutilus rutilus</i>), rudd (<i>Scardinius erythrophthalmus</i>), tench (<i>Tinca tinca</i>)
Viral haemorrhagic septicaemia	C+D+E	Herring (<i>Clupea spp.</i>), whitefish (<i>Coregonus spp.</i>), pike (<i>Esox lucius</i>), haddock (<i>Melanogrammus aeglefinus</i>), Pacific cod (<i>Gadus macrocephalus</i>), Atlantic cod (<i>Gadus morhua</i>), Pacific salmon (<i>Oncorhynchus spp.</i>) rainbow trout (<i>Oncorhynchus mykiss</i>), rockling (<i>Onos mustelus</i>), brown trout (<i>Salmo trutta</i>), turbot (<i>Scophthalmus maximus</i>), sprat (<i>Sprattus sprattus</i>), grayling (<i>Thymallus thymallus</i>), olive flounder (<i>Paralichthys olivaceus</i>), marble trout (<i>Salmo marmoratus</i>), lake trout (<i>Salvelinus namaycush</i>), wrasse (<i>Labridae spp.</i>), lumpfish (<i>Cyclopteridae spp.</i>)	Beluga (<i>Huso huso</i>), Danube sturgeon (<i>Acipenser gueldenstaedtii</i>), sterlet sturgeon (<i>Acipenser ruthenus</i>), starry sturgeon (<i>Acipenser stellatus</i>), sturgeon (<i>Acipenser sturio</i>), Siberian sturgeon (<i>Acipenser baerii</i>), bighead carp (<i>Aristichthys nobilis</i>), goldfish (<i>Carassius auratus</i>), crucian carp (<i>Carassius carassius</i>), common carp and koi carp (<i>Cyprinus carpio</i>), silver carp (<i>Hypophthalmichthys molitrix</i>), chub (<i>Leuciscus spp.</i>), roach (<i>Rutilus rutilus</i>), rudd (<i>Scardinius erythrophthalmus</i>), tench (<i>Tinca tinca</i>), North African catfish (<i>Clarias gariepinus</i>), pike (<i>Esox lucius</i>), catfish (<i>Ictalurus spp.</i>), black bullhead (<i>Ameiurus melas</i>), channel catfish (<i>Ictalurus punctatus</i>), pangas catfish (<i>Pangasius pangasius</i>), pike perch (<i>Sander lucioperca</i>), wels catfish (<i>Silurus glanis</i>), European seabass (<i>Dicentrarchus labrax</i>), striped bass (<i>Morone chrysops</i> x <i>Morone saxatilis</i>), flathead grey mullet (<i>Mugil cephalus</i>), red drum (<i>Sciaenops ocellatus</i>), meagre (<i>Argyrosomus regius</i>), shi drum (<i>Umbrina cirrosa</i>), true tuna (<i>Thunnus spp.</i>), Atlantic bluefin tuna (<i>Thunnus thynnus</i>), white grouper (<i>Epinephelus aeneus</i>), dusky grouper (<i>Epinephelus marginatus</i>), Senegalese solea (<i>Solea senegalensis</i>), common sole (<i>Solea solea</i>), common pandora (<i>Pagellus erythrinus</i>), common dentex (<i>Dentex dentex</i>), gilthead seabream (<i>Sparus aurata</i>), white seabream (<i>Diplodus sargus</i>), black spot seabream (<i>Pagellus bogaraveo</i>), red sea bream (<i>Pagrus major</i>), sharpshout seabream (<i>Diplodus puntazzo</i>), common two-banded seabream (<i>Diplodus vulgaris</i>), red porgy (<i>Pagrus pagrus</i>), tilapia spp. (<i>Oreochromis</i>), brook trout (<i>Salvelinus fontinalis</i>), arctic charr (<i>Salvelinus alpinus</i>)

List of susceptible and vector species in current 2018/1882: IHN, infection with HPR-deleted ISAV and KHV disease

IHN C + D + E

HPR-del ISAV
C + D + E

KHV E

Infectious haematopoietic necrosis	C+D+E	Chum salmon (<i>Oncorhynchus keta</i>), coho salmon (<i>Oncorhynchus kisutch</i>), Masou salmon (<i>Oncorhynchus masou</i>), rainbow trout (<i>Oncorhynchus mykiss</i>), sockeye salmon (<i>Oncorhynchus nerka</i>), pink salmon (<i>Oncorhynchus rhodurus</i>), chinook salmon (<i>Oncorhynchus tshawytscha</i>), Atlantic salmon (<i>Salmo salar</i>), lake trout (<i>Salvelinus namaycush</i>), marble trout (<i>Salmo marmoratus</i>), brook trout (<i>Salvelinus fontinalis</i>), arctic charr (<i>Salvelinus alpinus</i>), whitespotted charr (<i>Salvelinus leucomaenis</i>)	Beluga (<i>Huso huso</i>), Danube sturgeon (<i>Acipenser gueldenstaedtii</i>), sterlet sturgeon (<i>Acipenser ruthenus</i>), starry sturgeon (<i>Acipenser stellatus</i>), sturgeon (<i>Acipenser sturio</i>), Siberian sturgeon (<i>Acipenser Baerii</i>), bighead carp (<i>Aristichthys nobilis</i>), goldfish (<i>Carassius auratus</i>), crucian carp (<i>Carassius carassius</i>), common carp and koi carp (<i>Cyprinus carpio</i>), silver carp (<i>Hypophthalmichthys molitrix</i>), chub (<i>Leuciscus spp.</i>), roach (<i>Rutilus rutilus</i>), rudd (<i>Scardinius erythrophthalmus</i>), tench (<i>Tinca tinca</i>), North African catfish (<i>Clarias gariepinus</i>), catfish (<i>Ictalurus spp.</i>), black bullhead (<i>Ameiurus melas</i>), channel catfish (<i>Ictalurus punctatus</i>), pangas catfish (<i>Pangasius pangasius</i>), pike perch (<i>Sander lucio-perca</i>), wels catfish (<i>Silurus glanis</i>), Atlantic halibut (<i>Hippoglossus hippoglossus</i>), flounder (<i>Platichthys flesus</i>), Atlantic cod (<i>Gadus morhua</i>), haddock (<i>Melanogrammus aeglefinus</i>), noble crayfish (<i>Astacus astacus</i>), signal crayfish (<i>Pacifastacus leniusculus</i>), redswamp crayfish (<i>Procambarus clarkii</i>)
Infection with HPR-deleted infectious salmon anaemia virus	C+D+E	Rainbow trout (<i>Oncorhynchus mykiss</i>), Atlantic salmon (<i>Salmo salar</i>), brown and sea trout (<i>Salmo trutta</i>)	
Koi herpes virus disease	E	Common carp and koi carp (<i>Cyprinus carpio</i>)	Goldfish (<i>Carassius auratus</i>), grass carp (<i>Ctenopharyngodon idella</i>)

New health "categorization" to be implemented

Regulation 2020/689

- There will be no more cat. III (expected to be transient status)

Health Category	Intro from	Dispatch to
I Approved Disease Free	I	I, II, III
II Approved Eradication program (surveillance or eradication program)	I or II 6 year max	II, III
III Non approved disease free	I-II	III

Poll 1

- In the [Regulation \(EU\) 2018/1882](#) :
 - HPR-deleted ISAV is listed as Category A + D + E disease?
 - VHS is listed as Category C + D + E disease?
 - KHV is listed as Category D + E disease?
 - Are all listed diseases in Category E?
 - [Regulation \(EU\) 2018/1882](#) include only Aquatic Animals?

Poll 1

- In the [Regulation \(EU\) 2018/1882](#) :
 - HPR-deleted ISAV is listed as Category A + D + E disease? **No C + D + E**
 - VHS is listed as Category C + D + E disease? **Yes**
 - KHV is listed as Category D + E disease? **No (E only)**
 - Are all listed diseases in Category E? **Yes**
 - [Regulation \(EU\) 2018/1882](#) include only Aquatic Animals? **No (both terrestrial and aquatics)**

COMMISSION DELEGATED REGULATION (EU) 2020/689

COMMISSION DELEGATED REGULATION (EU)
2020/689

of 17 December 2019

supplementing Regulation (EU) 2016/429 of the
European Parliament and of the Council as regards
rules for surveillance, eradication programmes, and
disease-free status for certain listed and emerging
diseases

**Rule for surveillance, eradication programmes, and disease-free status
for certain listed and emerging diseases**

**Replace Commission Decision 2015/1554 on Surveillance and
Diagnostic Methods.**

COMMISSION DELEGATED REGULATION (EU) 2020/689

Refer to aquatic animal list C diseases:

Fish: VHS, IHN, Infection with HPR-deleted ISAV

Molluscs: *Bonamia exitiosa*, *Bonamia ostrea*, *Martelia refringens* infection

Crustacean: Whitespot syndrome virus infection (WSS)

The List A diseases EHN, Taura syndrome and Yellow head NOT included Diagnostic methods referred to the OIE Aquatic Manual

The list E disease KHV Not included

COMMISSION DELEGATED REGULATION (EU) 2020/689

Divided in 4 Chapters:

1: Rules for Surveillance

2: Rules for Eradication programme terrestrials

3: Rules for Eradication programme Aquatic Animals

4: Rules for Disease-free status

And 6 Annexes:

Annex VI: Giving the specific requirements for Diseases of Aquatic Animals

COMMISSION DELEGATED REGULATION (EU) 2020/689

Chapter 1.3.: Rules for Surveillance for Aquatics

1.3.2.:General rules for design of surveillance for category E or emerging diseases (= all AA diseases)

(Notification, investigation of increased mortality and suspicion of Cat. E disease, targeted population, disease control measures.)

Specific rules: Risk ranking, eradication program or maintaining disease free status or demonstrating that establishments are not infected, movement etc.

Targeted Animal production

Diagnostic methods

Disease confirmation

COMMISSION DELEGATED REGULATION (EU) 2020/689

Chapter 3.: Eradication programmes for category C diseases of aquatic animals

Max 6 year

upon request, extend the period of application of the eradication programme for an additional 6-year period.

Disease control measures in the event of suspicion of certain diseases including restrictions of movements.

Official confirmation of certain diseases and disease control measures
Including epidemiological investigations, removal of animals, cleaning and disinfection, fallowing etc.

COMMISSION DELEGATED REGULATION (EU) **2020/689**

Chapter 4.: Disease-free status

Historical freedom not applicable

Disease-free status based on eradication programmes

Maintenance, suspension and withdrawal of disease-free status

A Member State with an approved disease-free status before the date of application of this Regulation shall remain its status!

Annex VI Part I

SPECIFIC REQUIREMENTS AS REGARDS DISEASES OF AQUATIC ANIMALS

CHAPTER 1 Minimum requirements for risk-based surveillance in approved aquaculture establishments with focus on a) increased mortality; (b) listed diseases; and (c) emerging diseases

CHAPTER 2 Risk ranking to be applied in approved aquaculture establishments

- a) possibility of the direct spread of pathogens via water;
- b) movements of aquaculture animals

CHAPTER 3 Frequency of risk-based animal health visits

- a) at least once per year in high risk establishments; (b) at least once every two years in medium risk establishments; (c) at least once every three years in low risk establishments

COMMISSION DELEGATED REGULATION (EU) 2020/689

PART II DISEASE- SPECIFIC REQUIREMENTS FOR DISEASE-FREE STATUS OF AQUATIC ANIMALS

CHAPTER 1

Eradication, disease-free status and diagnostic methods for viral haemorrhagic septicaemia (VHS) and infectious hematopoietic necrosis (IHN)

CHAPTER 2

Eradication, disease-free status and diagnostic methods for infection with HPR-deleted infectious salmon anaemia virus (HPR-deleted ISAV)

CHAPTER 6

Eradication, disease-free status and diagnostic methods for infection with white spot syndrome virus (WSSV)

Infection with KHV no longer in text

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PART III REQUIREMENTS FOR DEMONSTRATING THE IMPLEMENTATION OF SURVEILLANCE PROGRAMMES FOR CATEGORY C DISEASES AND FOR RESTARTING THOSE PROGRAMMES AFTER A DISEASE OUTBREAK

**Rules If an outbreak in approved free zone / compartment how to
regain status**

COMMISSION DELEGATED REGULATION (EU) 2020/689

1 CHAPTER 1

Eradication, disease-free status and diagnostic methods for **VHS and IHN**

Section 1 Health visits and sampling-

When? Temperature < 14° C,

species: Rainbow trout

All year classes, all sites



VHS infected RBT
Photo: N.J. Olesen

COMMISSION DELEGATED REGULATION (EU) 2020/689

2 CHAPTER 1

Eradication, disease-free status and diagnostic methods for **VHS and IHN**

Section 2 Granting status from unknown health status (former health cat 3 to cat 1) Health visits and sampling-

Model A - 2 year scheme large sampling 2 x 75 fish/year

Model B – 4 year scheme smaller sampling 1 x 30 yr1&2 2 x 30 yr 3&4

Table 1.A

Scheme for Member States, zones and compartments for the 2-year control period referred to in point (a)(i) which precedes the achievement of status free from VHS and status free from IHN

Type of establishment	Number of health visits per year to each establishment	Number of samplings per year in each establishment	Number of fish in the sample ⁽¹⁾	
			Number of growing fish	Number of broodstock fish ⁽²⁾
(a) Establishments with broodstock	2	2	50 (first visit) 75 (second visit)	30 (first or second visit)
(b) Establishments with broodstock only	2	1	0	75 (first or second visit)
(c) Establishments without broodstock	2	2	75 (first AND second visit)	0

Maximum number of fish per pool: 10

Scheme for Member States, zones or compartments using a reduced sample size for the 4-year control period referred to in point (a)(ii) which precedes the achievement of status free from VHS and status free from IHN

Type of establishment	Number of health visits per year to each establishment	Number of samplings per year in each establishment	Number of fish in the sample ⁽¹⁾	
			Number of growing fish	Number of broodstock fish ⁽²⁾
First 2 years				
(a) Establishments with broodstock	2	1	30 (second visit)	0
(b) Establishments with broodstock only	2	1	0	30 (first or second visit)
(c) Establishments without broodstock	2	1	30 (first or second visit)	0
Last 2 years				
(a) Establishments with broodstock	2	2	30 (first visit)	30 (second visit)
(b) Establishments with broodstock only	2	2		30 (first AND second visit)
(c) Establishments without broodstock	2	2	30 (first AND second visit)	

Maximum number of fish per pool: 10

COMMISSION DELEGATED REGULATION (EU) 2020/689

3 CHAPTER 1

Eradication, disease-free status and diagnostic methods for **VHS and IHN**

Section 3 Granting status from *infected* health status (former Category 5 to 1) zoning, emptying disinfection, fallowing, restocking and following sampling program for achievement of disease free status

Restriction zones: Protection zone/ surveillance zone

5 / 10 km radius or entire water catchment area(with derogations)

Cleaning/disinfecting

Min 6 weeks fallowing (3 weeks synchronized) before repopulation



IHNV infected RBT photo NJO

COMMISSION DELEGATED REGULATION (EU) 2020/689

4 CHAPTER 1

Eradication, disease-free status and diagnostic methods for **VHS and IHN**

Section 4 Maintenance of status free from VHS and free from IHN.

All disease free compartments are high risk

Minimum 3 weeks after transfer to saltwater

Table 1.C

Scheme for Member States, zones or compartments to maintain status free from VHS or status free from IHN

Risk level ⁽¹⁾	Number of health visits per year to each establishment	Number of fish in the sample ⁽²⁾ , ⁽³⁾
High	1 every year	30
Medium	1 every 2 years	30
Low	1 every 3 years	30

Maximum number of fish per pool: 10

COMMISSION DELEGATED REGULATION (EU) 2020/689

5 CHAPTER 1

Eradication, disease-free status and diagnostic methods for **VHS and IHN**

Section 5 Diagnostic and sampling method

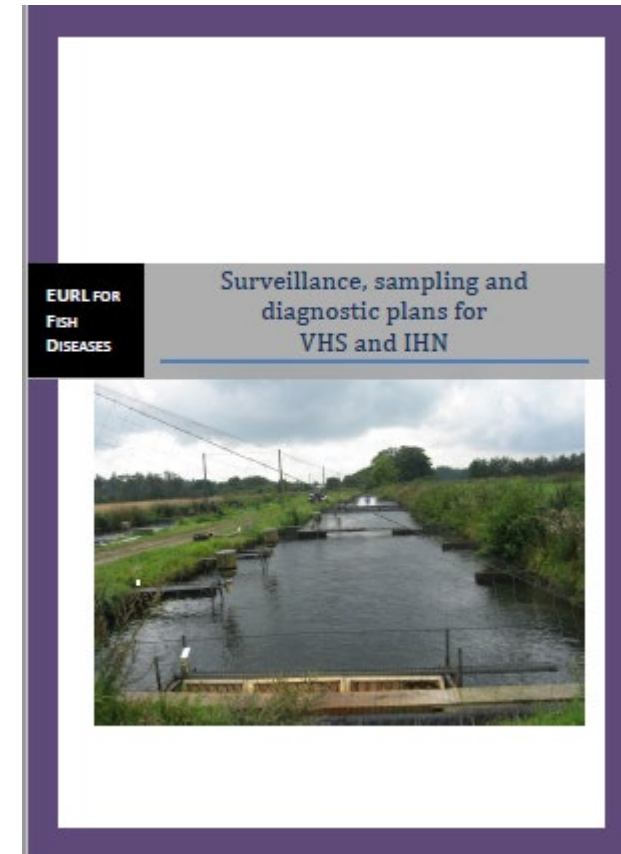
Organs to be sampled: **spleen, kidney, heart and or encephalon**

10 fish pool maximum

Virus isolation in cell cultures or real-time RT-PCR

The detailed procedures to carry out these diagnostic methods must be those approved by the EURL for fish diseases

Can be found on [www.eurl fish and crustacean diseases](http://www.eurl-fish-and-crustacean-diseases.eu)



COMMISSION DELEGATED REGULATION (EU) 2020/689

5 CHAPTER 1

Eradication, disease-free status and diagnostic methods for **VHS and IHN**

Detailed diagnostic and sampling method approved by the EURL for fish diseases

No significant changes from 2015/1554 (still based on detection of virus not necessarily disease)

News:

New Conventional RT-PCR for detection of VHSV

Validation of a novel one-step reverse transcription polymerase chain reaction method for detecting viral haemorrhagic septicaemia virus

Hyoung Jun Kim^a, Argelia Cuenca^b, Niels Jørgen Olesen^{b,*}

Universal reverse-transcriptase real-time PCR for infectious hematopoietic necrosis virus (IHNV)

Maureen K. Purcell^{1,*}, Rachel L. Thompson¹, Kyle A. Garver², Laura M. Hawley², William N. Batts¹, Laura Sprague³, Corie Sampson³, James R. Winton¹

Analytical validation of one-step real-time RT-PCR for detection of infectious hematopoietic necrosis virus (IHNV)

Argelia Cuenca^{1*}, Niccolò Vendramin¹, Niels Jørgen Olesen¹

Serum neutralization test will be taken out as outdated

More focus on genotyping and sequencing

COMMISSION DELEGATED REGULATION (EU) 2020/689

PART II DISEASE- SPECIFIC REQUIREMENTS FOR DISEASE-FREE STATUS OF AQUATIC ANIMALS

CHAPTER 2

Eradication, disease-free status and diagnostic methods for infection with HPR-deleted infectious salmon anaemiaa virus (HPR-deleted ISAV**)**

Section 1 Health visits and sampling- When? No Temperature
requirement, species: Atlantic salmon, diseased fish All year classes, all sites

**Section 2 Granting status from unknown health status (former cat 3
to cat 1) Health visits and sampling- 2 yr program**

Table 2.A

Scheme for Member States, zones and compartments for the 2-year control period which precedes the achievement
of status free from infection with HPR-deleted ISAV

Year of surveillance	Number of health visits per year to each establishment	Number of laboratory examinations per year ⁽¹⁾	Number of fish in the sample
Year 1	6	2	75
Year 2	6	2	75



DIAGNOSTIC METHODS FOR THE SURVEILLANCE AND
CONFIRMATION OF INFECTION WITH HPR-DELETED INFECTIOUS
SALMON ANEMIA VIRUS (ISAV)



COMMISSION DELEGATED REGULATION (EU) 2020/689

CHAPTER 2

Eradication, disease-free status and diagnostic methods for **HPR deleted ISAV**

Section 3 Granting status from infected health status: zoning, emptying, disinfection, following minimum 3 months, restocking and following sampling program for achievement of disease free status

Section 4 Maintenance of status free from **HPR-deleted ISAV**

Table 2.B

Scheme for Member States, zones or compartments to maintain status free from infection with HPR-deleted ISAV ⁽¹⁾

Risk level ⁽²⁾	Number of health visits per year	Number of laboratory examinations per year ⁽³⁾ , ⁽⁴⁾	Number of fish in the sample
High	2	2	30
Medium	1	1	30
Low	1 every 2 years	1 every 2 years	30

COMMISSION DELEGATED REGULATION (EU) 2020/689

CHAPTER 2

Eradication, disease-free status and diagnostic methods for **HPR deleted ISAV**

Section 5 Diagnostic and sampling method for HPR deleted ISAV

Organs to be sampled: mid-kidney, and heart for RTqPCR.

If need for finding HPR0 ISAV

5 fish pool maximum

Confirmatory (clinical manifestation no longer necessary)

RT-qPCR for ISAV detection targeting segment 8 and One-step conventional RT-PCR targeting segment 6 including the HPR region with sequencing of amplicon or

IHC or

Cell cultivation

The detailed procedures to carry out these diagnostic methods must be those approved by the EURL for fish diseases

Can be found on [www.eurl fish and crustacean diseases](http://www.eurl-fish-and-crustacean-diseases)



DIAGNOSTIC METHODS FOR THE SURVEILLANCE AND
CONFIRMATION OF INFECTION WITH HPR-DELETED INFECTIOUS
SALMON ANEMIA VIRUS (ISAV)



COMMISSION DELEGATED REGULATION (EU) 2020/689

CHAPTER 2

Eradication, disease-free status and diagnostic methods for **HPR deleted ISAV**

Detailed diagnostic and sampling method approved by the EURL for fish diseases for detection of **HPR deleted ISAV** [www.eurl.fish and crustacean diseases](http://www.eurl.fishandcrustacean.org)

Few changes from 2015/1554

RT-qPCR for ISAV detection targeting segment 8 (Snow et al., 2006)

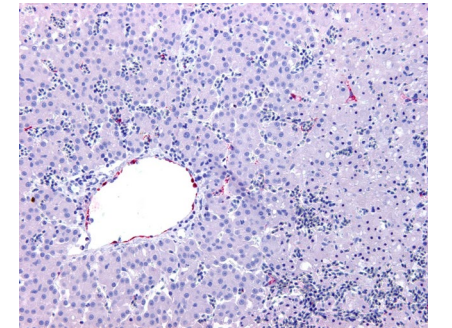
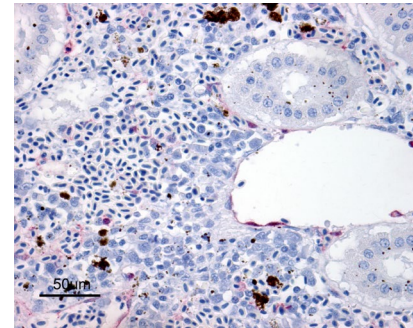
New sensitive One-step conventional RT-PCR targeting segment 6 including HPR region (Christensen et al.)

Cell culture: ASK L-15 medium with 2%FBS

Gross pathology and IHC

Reference list

Annex



Koi Herpes virus infection

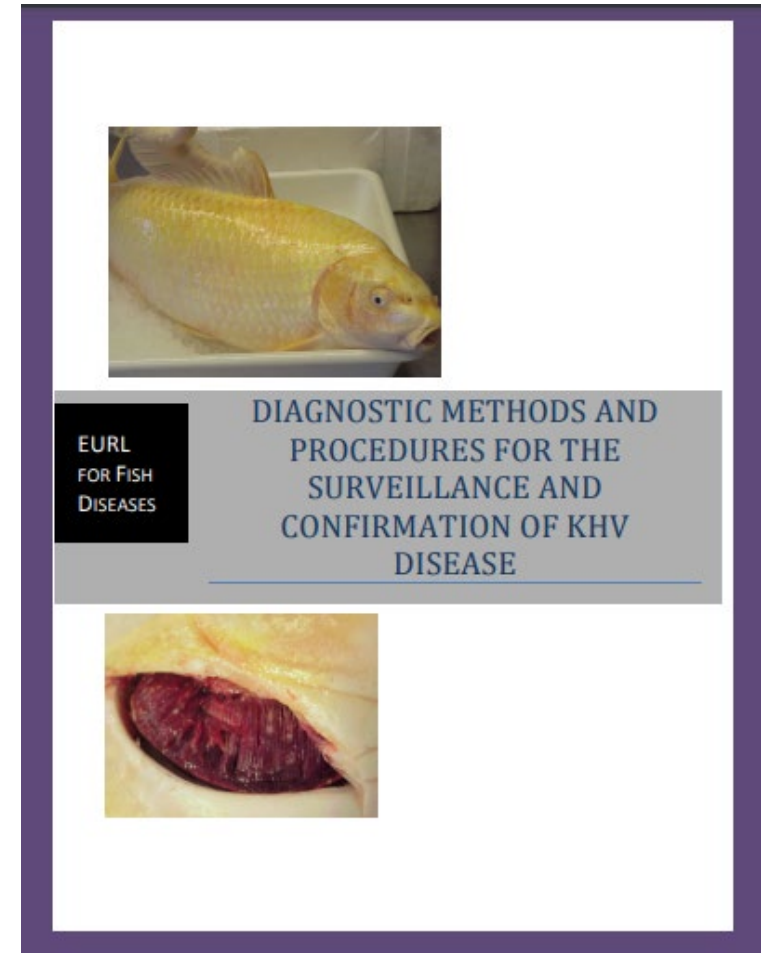
Down-listed to category E.

Diagnostic methods based on former EURL
WG recommendations

BUT

**23rd AW: Deficiencies in the current
assays for the detection and
identification of DNA viruses of carp:
an assay redesign and evaluation.**
David Stone

To be updated accordingly



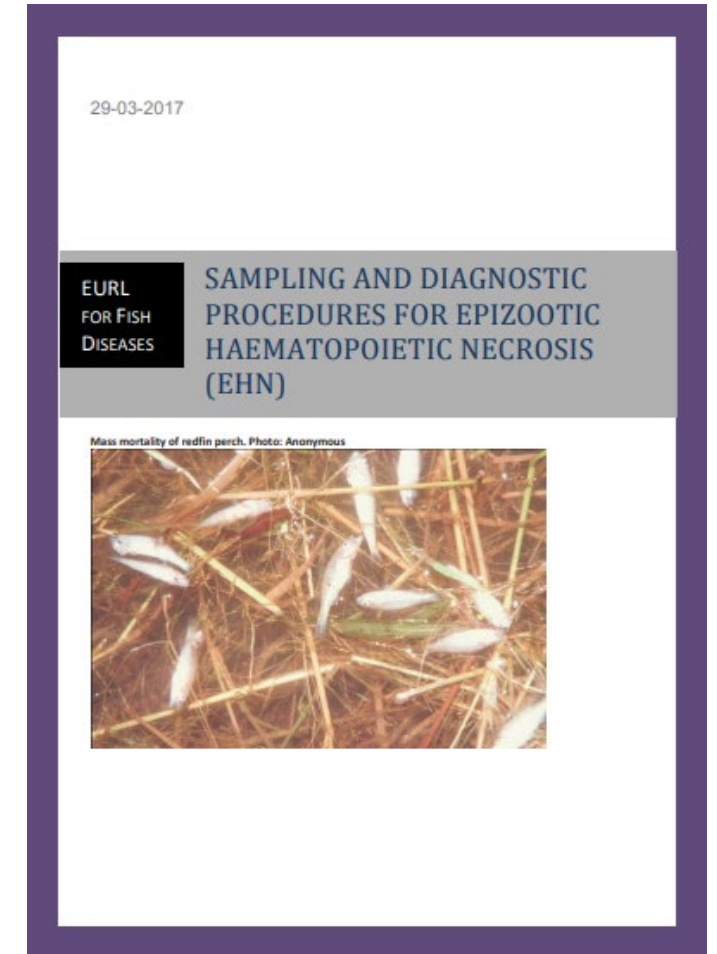
Epizootic haematopoietic necrosis (EHN)

EHN a Category A disease.

EU rely on the relevant chapters of the OIE Manual, sampling and diagnostic procedures in EU have however to be clarified (e.g. strain differentiation of RANA viruses)

New EURL Manual created and to be uploaded.

Will include a new and validated real-time PCR



Listed Crustacean Diseases

See next presentation by Morten



Poll 2

- 1: In the [COMMISSION DELEGATED REGULATION \(EU\) 2020/689](#) you will find:
 - **Requirements for health visits and sampling for IHN?**
 - **Requirements for health visits and sampling for KHV?**
 - **Detailed diagnostic procedures for VHS ?**

Poll 2 answers

- 1: In the [COMMISSION DELEGATED REGULATION \(EU\) 2020/689](#) you will find:
 - Requirements for health visits and sampling for IHN? **Yes**
 - Requirements for health visits and sampling for KHV? **No**
 - Detailed diagnostic procedures for VHS ? **No detailed procedures on EURL website**

Poll 3 Sampling and diagnostic procedures

- All samples for detection of VHSV or IHN (PCR / cell culture) can be tested in pools of max 10?
- Sampling for HPR-del ISAV shall include spleen, kidney, gill, and heart and or encephalon?
- Procedures for eradication of Infection with Koi Herpes Virus are given in regulation 2020/689?

Poll 3 Sampling and diagnostic procedures

- All samples for detection of VHSV or IHN (PCR / cell culture) can be tested in pools of max 10? Yes
- Sampling for HPR-del ISAV shall include spleen, kidney, gill, and heart and or encephalon? **No Gills are not obligatory**
- Procedures for eradication of Infection with Koi Herpes Virus are given in regulation 2020/689? **No after down listing to E no specific procedures**

Finally please pay attention to

Regulation on official controls (EU) 2017/625:

general rules across sectors

Date of application: 14 December 2019

Concern Official Control, welfare, antibiotics etc.

CHAPTER IV Sampling, analyses, tests and diagnoses

Article 37 Designation of official laboratories (including “operates in accordance with the standard EN ISO/IEC 17025 and is accredited in accordance with that standard”)

Article 38 Obligations of official laboratories

Article 39 Audits of official laboratories

Regulation on official controls (EU) 2017/625:

TITLE III REFERENCE LABORATORIES AND REFERENCE CENTRES

Article 93 Designation of European Union reference laboratories

Article 94 Responsibilities and tasks of European Union reference laboratories

Article 100 Designation of national reference laboratories

Article 101 Responsibilities and tasks of national reference laboratories

Obligation for all to be ISO 17025 accredited for all the listed pathogens!
Dispensation for 6 year possible but it is not decided yet to include Aquatic Animal NRLs

Obligation to work under QA system

Participation in PT obligatory

If not possible to delegate task to another accredited NRL

Final remarks

- The new Animal Health Law 2016/429 is almost adopted (21.April 2021 final)
- The Diagnostic manuals 2015/1554 will soon be replaced by Commission regulation (EU) 2020/689 but the principles are very much the same.
- The detailed diagnostic procedures no longer in legal text but «those approved by the EURL» and given on the web (now with references)
- KHV down listed to E- diagnostic procedures still on EURL web
- No new diseases listed
- NRL obligation to be accredited
- No health categorization any longer (disease free establishment, eradication program and «the rest»)
- Please read them! Make your competent authorities and your directors aware of the rules.
- These are not guidelines but mandatory procedures to follow