



# Experience from inter-laboratory proficiency tests among European national reference laboratories for detection of viral infections in fish

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## 23rd Annual Workshop for National Reference Laboratories for Fish diseases Kgs. Lyngby 27.05.2019

The International Association for Business and Society is a learned society devoted to research and teaching about the relationships between business, government and society.

Conference

**Diagnostics in the veterinary field:**

**The role in health surveillance and disease identification**

May 15 - 17, 2019 Dorinth Pallas Hotel, Wiesbaden, Germany

**The Role of Veterinary Diagnostics in Health Surveillance and Disease, Including New Technologies, Standardization and Quality Assurance**



Keith Bailey DVM, PhD, DACVP  
President, American Association of Veterinary Laboratory Diagnosticians  
Director, Oklahoma Animal Disease Diagnostic Laboratory

# Since 2006 is the legislative basis for Aquaculture animal health surveillance 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

# EU “Diagnostic Manual”: Commission Decision 2015/1554 for sampling and diagnostic procedures:

23.9.2015

EN

Official Journal of the European Union

II

(Non-legislative acts)

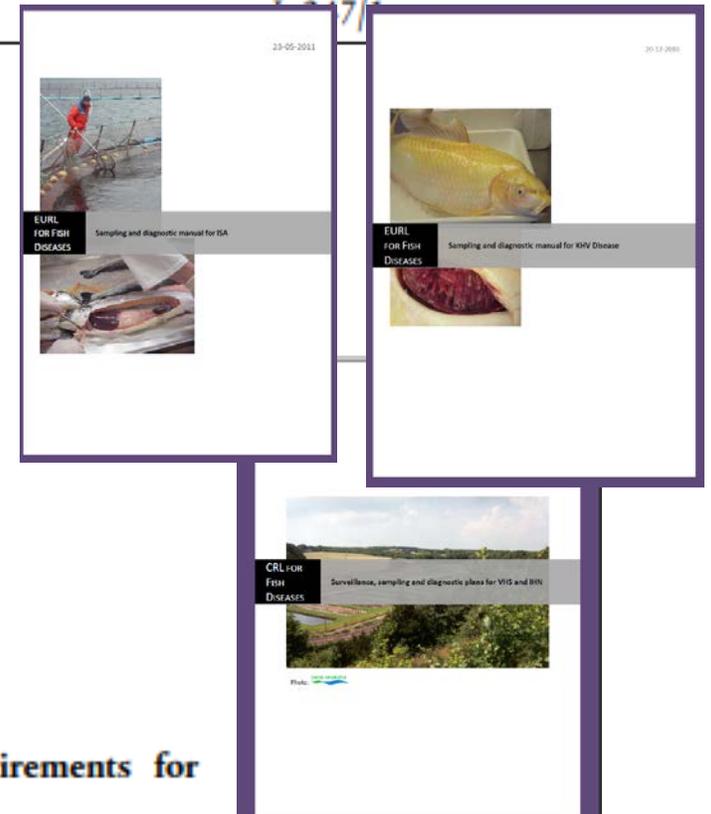
DECISIONS

**COMMISSION IMPLEMENTING DECISION (EU) 2015/1554**

**of 11 September 2015**

**laying down rules for the application of Directive 2006/88/EC as regards requirements for surveillance and diagnostic methods**

*(notified under document C(2015) 6188)*





# The functions and duties of EU and National Reference Laboratories are given in CD 2006/88/EC

ANNEX VI

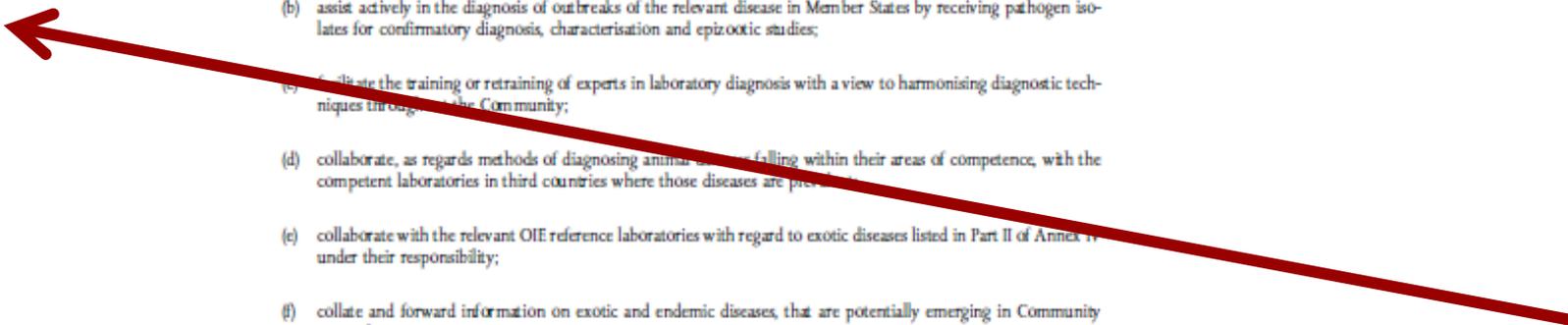
Functions and duties of laboratories

PART I

Community reference laboratories

1. In order to be designated as a Community reference laboratory in accordance with Article 55, laboratories shall fulfil the following requirements. They must:
  - (a) have suitably qualified staff with adequate training in diagnostic and analytical techniques applied in their area of competence, including trained personnel available for emergency situations occurring within the Community;
  - (b) possess the equipment and products needed to carry out the tasks assigned to them;
  - (c) have an appropriate administrative infrastructure;
  - (d) ensure that their staff respect the confidential nature of certain subjects, results or communications;
  - (e) have sufficient knowledge of international standards and practices;
  - (f) have available, as appropriate, an updated list of available reference substances and reagents and an updated list of manufacturers and suppliers of such substances and reagents;
  - (g) take account of research activities at national and Community level.
2. However, the Commission may designate only laboratories that operate and are assessed and accredited in accordance with the following European Standards, account being taken of the criteria for different testing methods laid down in this Directive:
  - (a) EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories';
  - (b) EN 45002 on 'General criteria for the assessment of testing laboratories';
  - (c) EN 45003 on 'Calibration and testing laboratory accreditation system — General requirements for operation and recognition'.
3. The accreditation and assessment of testing laboratories referred to in paragraph 2 may relate to individual tests or groups of tests.
4. For one or more of the diseases under their responsibility, the Community reference laboratories may take advantage of the skills and capacity of laboratories in other Member States or EFTA Member States, provided that the laboratories concerned comply with the requirements laid down in points 1, 2 and 3 of this Annex. Any intention to take advantage of such cooperation shall be part of the information provided as a basis for the designation in accordance with Article 55(1). However, the Community reference laboratory shall remain the contact point for the National reference laboratories in the Member States, and for the Commission.
5. The Community reference laboratories shall:
  - (a) coordinate, in consultation with the Commission, the methods employed in the Member States for diagnosing the disease concerned, specifically by:
    - (i) typing, storing and, where appropriate, supplying strains of the pathogen of the relevant disease to facilitate the diagnostic service in the Community;
    - (ii) supplying standard sera and other reference reagents to the national reference laboratories in order to standardise the tests and reagents used in each Member State, where serological tests are required;

- (iii) organising periodic comparative tests (ring tests) of diagnostic procedures at Community level with the national reference laboratories designated by the Member States, in order to provide information on the methods of diagnosis used and the results of tests carried out in the Community;
- (iv) retaining expertise on the relevant disease pathogen and other pertinent pathogens to enable rapid differential diagnosis;
- (b) assist actively in the diagnosis of outbreaks of the relevant disease in Member States by receiving pathogen isolates for confirmatory diagnosis, characterisation and epidemiologic studies;
- (c) facilitate the training or retraining of experts in laboratory diagnosis with a view to harmonising diagnostic techniques throughout the Community;
- (d) collaborate, as regards methods of diagnosing animal diseases falling within their areas of competence, with the competent laboratories in third countries where those diseases are present;
- (e) collaborate with the relevant OIE reference laboratories with regard to exotic diseases listed in Part II of Annex IV under their responsibility;
- (f) collate and forward information on exotic and endemic diseases, that are potentially emerging in Community aquaculture.



# Accreditation

- Designated laboratories must operate under EU standardized quality assurance schemes and be accredited according to e.g. ISO 17025 for the diseases in question.
- Designated NRL's in EU are obliged to participate in proficiency tests for the listed diseases.
- Participation in inter-laboratory proficiency test mandatory as part of the accreditation.



# Since 1998 the Annual inter-laboratory proficiency tests organized by the EURL include all listed fish diseases and comprised 45 NRLs in 2018

 **European Union Reference Laboratory for Fish and Crustacean Diseases**  
National Institute of Aquatic Resources, Technical University of Denmark

***EURL for Fish Diseases***

**Report of the Inter-Laboratory Proficiency Test 2018**  
for identification and titration of  
VHSV, IHNV, EHNV, SVCV and IPNV (PT1)  
and identification of  
CyHV-3 (KHV), SAV and ISAV (PT2)

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

[www.eurl-fish.eu](http://www.eurl-fish.eu)



Worldwide distribution of the participants in the EURL proficiency test 2018.



# The proficiency testing is accredited according to DS/EN ISO/IEC 17043 and in conformity with requirements for proficiency testing.



Dansk standard

DS/EN ISO/IEC 17025:2017

2017-12-19

## Generelle krav til prøvnings- og kalibreringslaboratoriers kompetence

General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2017)

The standart providing the general requirements for the competences of testing laboratories

Single user license: DTU - Foedevareinstituttet, Moerkhoej Bygade 19, DK-2860 Soeborg



Dansk standard

DS/EN ISO/IEC 17043

1. udgave

2010-02-19

REPRODUCT DS/EN ISO/IEC 17043:2010

## Overensstemmelsesvurdering – Generelle krav til præstationsprøvning

Conformity assessment – General requirements for proficiency testing

and the general requirements for proficiency testing



# ISO 17043 SOP for PT on fish pathogens



SOP

FOR

**Preparation, shipment and reporting of proficiency test for the identification and quantification of fish pathogens.**

(INTER-LABORATORY PROFICIENCY TEST)



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# Design and organization of a PT Technical requirements - planning



## Bilag 1A - Tilrettelæggelse og planlægning af forløbet / Organisation and design of logistics

The team in charge of delivering the proficiency test has to fill the following scheme before starting the work.

År:	2018
Mødedato:	31.01.2018
ISO 17043 udgave nr.:	2
Mødedeltagere:	CFDE, NIVEN, NJOL, TEVK

		Kolonne der skal udfyldes:
a)	Navn og adresse af udbyder af præstationsprøvningen:	EU Reference Laboratory for Fish Diseases Technical University of Denmark National Institute of Aquatic Resources Aquatic Animal Health Unit (From July 2018: Unit for Fish and Shellfish Diseases) <u>Kemitorvet</u> Building 202 2800 Kgs. Lyngby Denmark
b)	Navn, adresse og tilknytning af medarbejdere involveret i designet og udførelsen af testen:	Navn og tilknytning/ Name and affiliation: 1. Niccolò Vendramin – DTU AQUA - EURL 2. Niels Jørgen Olesen – DTU AQUA - EURL 3. Teena Vendel Klinge – DTU AQUA - EURL 4. Argelia Navarro – DTU AQUA - EURL 5. Christina Flink Desler – DTU AQUA - EURL
c)	Formål med præstationsprøvningen:	<b>Standardformål:</b> 1. To test the participating laboratories ability to isolate, quantify and identify the notifiable viruses using cell cultures: <i>Viral haemorrhagic septicaemia virus (VHSV)</i> , <i>infectious haematopoietic necrosis virus (IHNV)</i> and <i>epizootic haematopoietic necrosis (EHNV)</i> or <i>EHNV-like</i> . The test ampoules can contain other viruses (e.g. other <i>rhabdo-</i> , <i>rana-</i> and <i>birna</i> viruses) and participants should be able to carry out differential diagnosis from the other fish viruses. By comparing the quantification of the virus, the participating laboratories are provided with an indication of the relative

**ISO 17043, 4.4.1.3 (item a to u!):**

**The PT provider shall document a plan before commencement of the PT scheme**

*(and where appropriate, reasons for selecting or excluding the items in the plan)*



# Choice of pathogens in the PT-2018

Table 1. Content of each ampoule with reference to culture conditions and major publications of the included viruses.

Code	Specifications/References
Ampoule I: SVCV	<p>SVCV strain 56/70 Genotype Id Spring viraemia of carp virus isolate from carp. The isolate is most likely identical to the S/30 isolate described in <a href="#">Fijan N, Petrinec Z, Sulimanovic D, &amp; Zwillenberg LO (1974). Isolation of the viral causative agent from the acute form of infectious dropsy of carp. Veterinarai Archiv 41, 125-138, (10)</a></p> <p>Received from: Prof. Fijan (January 1979 in a tube named Rhabdo virus carpio 56/70 and given as the reference strain of SVC virus). Genotype: Id GenBank accession numbers: <a href="#">F37505.1</a> [Fijan], <a href="#">AJ338061.1</a> [S30]</p> <p>Reference on sequence (S30) and genotype: <a href="#">Stone DM, Ahne W, Denham KL, Dixon PF, Liu C-TY, Sheppard AM, Taylor GR &amp; Way K (2003). Nucleotide sequence analysis of the glycoprotein gene of putative spring viraemia of carp virus and like fish rhabdovirus isolates reveals four serogroups. Diseases of Aquatic Organisms 53, 203-210, [11]</a></p>
Ampoule II: IPNV	<p>IPNV strain Sp Genotype 5 The Sp (Spjarup) reference strain of Infectious Pancreatic Necrosis (IPN) virus from farmed rainbow trout in Denmark, isolated in 1969 by Dr. Vestergaard Jørgensen.</p> <p>Received from: National Veterinary Institute, Technical University of Denmark. GenBank accession numbers: <a href="#">AM889271</a></p> <p>Reference on isolate: <a href="#">Jørgensen PEV &amp; Bregnballe F (1969) Infectious pancreatic necrosis in rainbow trout in Denmark. Nordisk Veterinærmedicin 21, 142-148. [12]</a> <a href="#">Jørgensen PEV &amp; Grauballe PC (1971) Problems in the serological typing of IPN virus. Acta Veterinaria Scandinavica 12, 143-147. [13]</a></p> <p>References on sequences: <a href="#">P. F. Dixon, G.-H. Ngoh, D. M. Stone, S. F. Chang, K. Way, S. L. F. Kueh (2008) Proposal for a fourth aquabirnavirus serogroup Archives of Virology 153:1937-1941 [14]</a></p>
Ampoule III: IHN	<p>IHN - isolate BLK94 Isolated in 1994 from Sockeye salmon <i>Oncorhynchus nerka</i> smolt, in Washington USA.</p> <p>Received from: Geel Kurath American Genotype U Genogroup U <a href="#">G. Kurath, K. Garver, R. M. Troyer, E. J. Emmenegger, K. Einer-Jensen, E. Anderson</a> <a href="#">Phylogeography of infectious haematopoietic necrosis virus in North America 2003, J. General Virology 84:803-814; [7]</a></p> <p>Mid G USD mG002U refers to Universal sequence designators (USD) defined for North American IHN isolates as described in the MEAP-IHN (Molecular Epidemiology of Aquatic Pathogens) database at <a href="http://gis.nbcsce.org/ihnv">http://gis.nbcsce.org/ihnv</a></p>

Code	Specifications/References
Ampoule IV: EHN	<p>EHN isolate 86/8774 Australian freshwater isolate of epizootic haematopoietic necrosis virus from rainbow trout from Adaminaby Trout Farm, NSW obtained in 1986 by Jeremy Langdon.</p> <p>Received from: Prof. Whittington, The OIE reference laboratory for EHN, University of Sydney, Australia. GenBank accession numbers: <a href="#">F1493873</a>, <a href="#">AY487045</a>, <a href="#">AF147667</a></p> <p>Reference on isolate: <a href="#">Langdon JS, Humphrey JD &amp; Williams LM (1988). Outbreaks of an EHN-like iridovirus in cultured rainbow trout, <i>Salmo gairdneri</i> Richardson, in Australia. Journal of Fish Diseases 11, 93-96, [15]</a></p> <p>References on sequences: <a href="#">Hyatt AD, Gould AR, Zupanovic Z, Cunningham AA, Hengstberger S, Whittington RJ, Kattenbelt J &amp; Couper BEH (2000). Comparative studies of piscine and amphibian iridoviruses. Archives of Virology 145, 301-331, [16]</a> <a href="#">Janovich JK, Brumont M, Touchman JW &amp; Jacobs BJ (2010). Evidence for multiple recent host species shifts among the ranaviruses (family Iridoviridae). Journal of Virology 84, 2636-2647, [17]</a> <a href="#">Marsh JB, Whittington RJ, O'Rourke B, Hyatt AD &amp; Chisholm O (2007) Rapid differentiation of Australian, European and American ranaviruses based on variation in major capsid protein gene sequence. Molecular and Cellular Probes 16, 137-151, [18]</a></p>
Ampoule V: VHS	<p>VHS virus, DK-35928 "Voldbjerg strain". Highly pathogenic Viral Haemorrhagic Septicaemia strain belonging to sero-pattern I isolated from Rainbow trout in 1989. <a href="#">Olesen NJ, Lorenzen N, Jørgensen PEV. Serological differences among isolates of viral haemorrhagic septicaemia virus detected by neutralizing monoclonal and polyclonal antibodies. Dis Aquat Org 1993;16:163-70 [19]</a></p> <p>Genotype: Ia</p> <p>Reference on isolate: <a href="#">Lorenzen N, Olesen NJ, Jørgensen PEV (1993) Antibody response to VHS virus proteins in rainbow trout. Fish Shellfish Immunol 3:461-473 [20]</a></p> <p>References on sequences: N gene <a href="#">MF394520</a> Nv gene <a href="#">DQ129198.1</a> Full Genome <a href="#">KC778774.1</a></p>

Code	Specifications/References
Ampoule VI: KHV	<p>Koi Herpesvirus isolate KHV 1287 Isolate from Common Carp (<i>Cyprinus Carpio</i>), from a river in the Okayama region, Japan in 2012. Received from: Dr. Kei Yuasa, National Research Institute of Aquaculture, Japan. Passages no. in cell culture: 4</p>
Ampoule VII: ISAV	<p>ISAV Glesvaer/2/90 Virulent isolate of Infectious Salmon Anemia Virus, HPR4 isolated from Atlantic salmon HPR Genotype: 2 Received from: Dr. B. Dannevig, OIE Reference Laboratory for ISA, Oslo, Norway GenBank accession numbers: <a href="#">HQ259676</a> or <a href="#">AF220607.1</a> or <a href="#">DQ785248.1</a></p> <p>References on isolate: <a href="#">Dannevig BH, Falk K &amp; Namork E (1995). Isolation of the causal virus of infectious salmon anaemia (ISA) in a long-term cell line from Atlantic salmon head kidney. Journal of General Virology 76, 1313-1328, [27]</a> <a href="#">Falk K, Namork E, Rimstad E, Mjølset S &amp; Dannevig BH (1997). Characterization of infectious salmon anaemia virus, an orthomyxo-like virus isolated from Atlantic salmon [<i>Salmo salar</i> L.]. Journal of Virology 71, 9016-9023, [28]</a></p> <p>References on sequence: <a href="#">Ménour E, LeBerre M, Lamoureux A, Bernard J, Brémont M &amp; Bacciali S (2011). Completion of the full-length genome sequence of the infectious salmon anaemia virus, an aquatic orthomyxovirus-like, and characterization of mAbs. Journal of General Virology 92, 328-333, [29]</a></p> <p>References on genotype: <a href="#">Table 13. Opinion of the Panel on Animal Health and Welfare of the Norwegian Scientific Committee for Food Safety 26.04.07. Which risk factors relating to spread of infectious Salmon Anaemia (ISA) require development of management strategies? Dok.nr.06/804, 68 pages. [30]</a></p>
Ampoule VIII: SAV	<p>Salmonid alpha virus (SAV) 3, Pancreas Disease Virus (PD) Salmonid alphavirus strain Norway - R-1_2007, isolated from Atlantic salmon Received from: Dr. Hilde Sindre, Norwegian Veterinary Institute, Norway</p> <p>Reference on isolate: <a href="#">Taksdal T, Bang Jensen B, Bockerman I, McLoughlin M.F., Hortaas M.J., Ramstad A. &amp; Sindre H. (2012) Mortality and weight loss of Atlantic salmon, <i>Salmo salar</i> L., experimentally infected with salmonid alphavirus subtype 2 and subtype 3 isolates from Norway. Journal of Fish Diseases 33, 1047-1061, [31]</a> Gene Bank Ref. E2 gene: <a href="#">LT630447</a></p> <p>References on the sequences: <a href="#">Hortaas M.J., Bang Jensen B, Taksdal T, Olsen S B, Lillehaug A, Trettenes E. &amp; Sindre H. (2016) Genetic characterization of salmonid alphavirus in Norway. Journal of Fish Diseases 39, 249-257, [32]</a></p>
Ampoule IX: BLANK	BF-2 NON Infected Supernatant

# Example of content of ampoules

Ampoule	Virus	Isolate	Species
I	VHSV	Isolate 1p8. G. Ib	Herring
II	EHNV	Isolate 86/8774	Rainbow trout
III	ECV	European catfish virus 562/9	Catfish
IV	IHNV	First French isolate 32/87 G.E	Rainbow trout
	IPNV	Type strain Sp (Spjarup)	
V	IPNV	Type strain Sp (Spjarup)	Rainbow trout

Ampoule	Virus	Isolate	Species
VI	ISAV Low titer	ISAV Glesvaer 2/90	Atl. salmon
VII	ISAV High titer	ISAV Glesvaer 2/90	Atl. salmon
VIII	KHV (CyHV-3) High titer	KHV 07/108b	Carp
IX	SAV	Salmonid alpha virus (SAV) 3	Atl. salmon
X	KHV (CyHV-3) Low titer	KHV 07/108b	Carp

# Stable long term storage by lyophilization



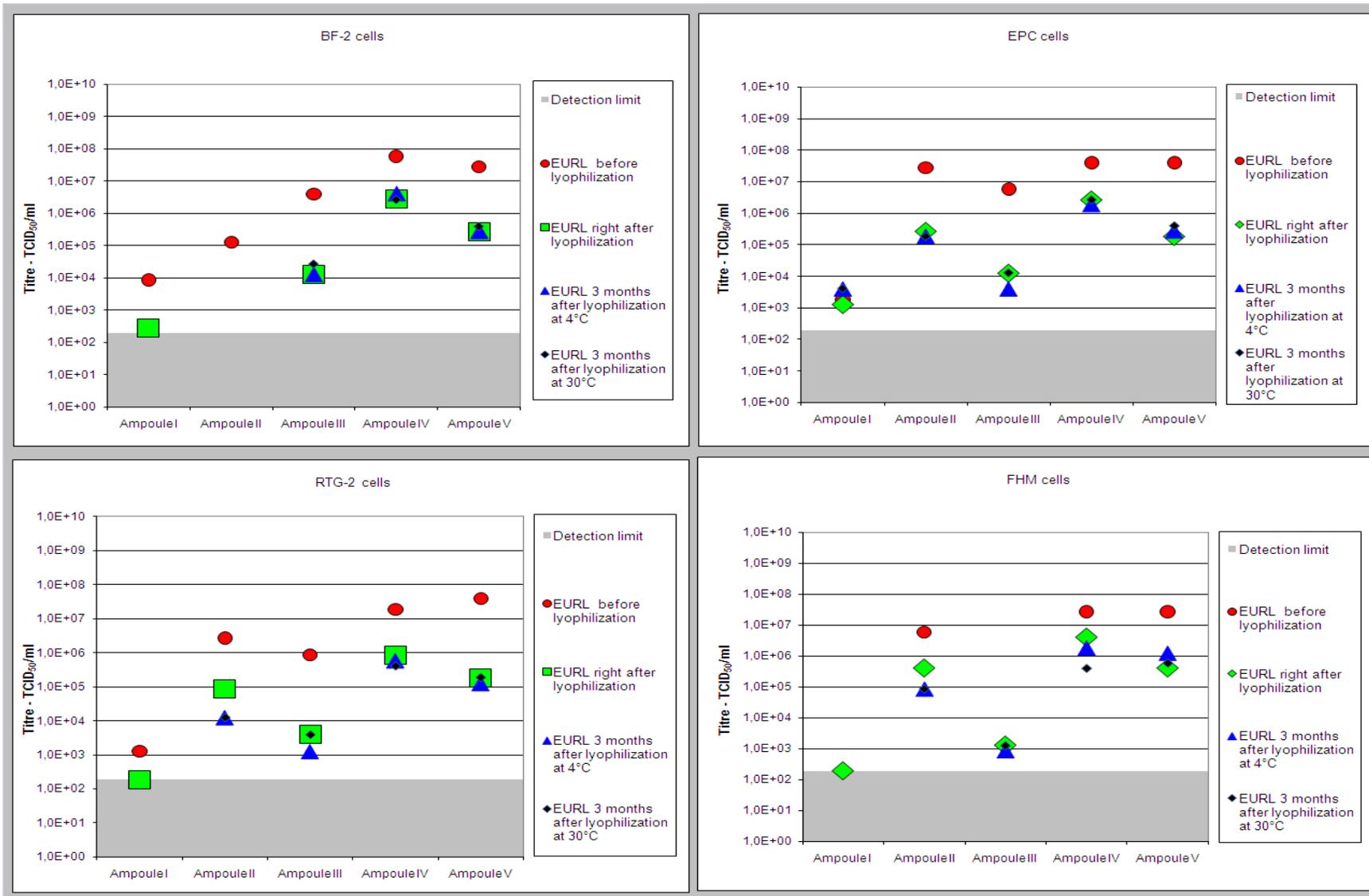


# Lyophilisation of ampoules





# Titres before and after lyophilization



Significant decrease in titre in the lyophilization process- very stable hereafter.

# Testing the test, PT1 and PT2

## Titre, homogeneity and identity

- The titre and homogeneity of the samples is tested prior to sending out the test by *titration of 5 ampoules of each virus preparation in 4 cell lines for PT1 and by qPCR in PT2.*
- The identity of the virus in the ampoules is checked by **ELISA, IFAT, PCR and by sequencing**



# Challenges: Shipment

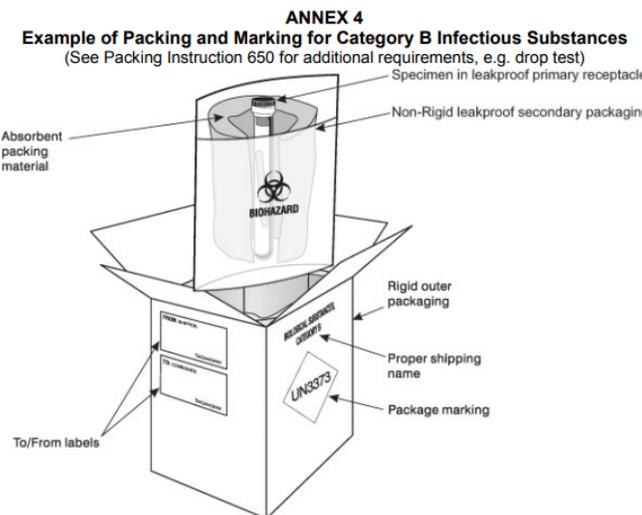
The PTs comprise not-inactivated exotic and non-exotic animal pathogens

The test is shipped according to international regulations for shipment of specimens UN 3373, “Biological Substance, Category B”.

Fish pathogens delisted from UN 3373



BIOLOGICAL SUBSTANCE  
CATEGORY B



Notes:

1. At least one surface of the outer packaging must have a minimum dimension of 100 mm x 100 mm;
2. The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa.



## 1. Introduction and background

This reference document provides a summary of the regulatory requirements and TNT Policy and Procedures for all shipments containing UN3373, Biological Substance, Category B that are shipped by air.

UN3373 Biological Substance, Category B can be human or animal material including (but not limited to) blood and its components, tissue, tissue fluids or body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment or prevention.

Shipments containing UN3373 that are compliant to the relevant IATA DGR requirements are also acceptable for road and sea transport.

## 2. Summary of the regulatory requirements

Complete details of the regulatory requirements can be found in the IATA Dangerous Goods Regulations.

### 2.1 Packaging

The packaging must be fully compliant with IATA DGR – Packing Instruction 650, i.e. it must consist of three components: a primary receptacle, a secondary package, a rigid outer package.

The outer package must have at least one surface of a minimum dimension of 100x100mm.

### 2.2 Person Responsible

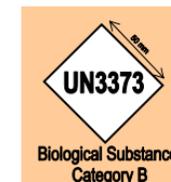
The name and telephone number of a “person responsible” must be provided on the Consignment Note (AWB) or on the package (this can be the shipper or the consignee!).

### 2.3 Markings

The package must bear a diamond shaped mark containing the text “UN3373”. (Each side of the mark must have a minimum length of at least 50mm)

The text “Biological Substance, Category B” must be displayed adjacent to the diamond shape mark

(New) UN3373 labels can be obtained from the Global Purchasing Centre ([GPC.orders.DHO@tnt.com](mailto:GPC.orders.DHO@tnt.com))  
Article number: 11-540 (100 pieces, cost €2,18)



### 2.4 Documentation

#### 2.4.1. (TNT) Consignment Note & Air Waybill

- The “Nature and Quantity of Goods” box must contain;
  - > the text: “Biological Substance, Category B” and “UN3373”
  - > the number of packages
- The Dangerous Goods “YES” box must be ticked.

#### 2.4.2. Itemized list of contents

An itemized list of contents must be enclosed between the secondary and the outer packaging

#### 2.4.3. A Shippers Declaration (DGD) is not required



# Shipment of PT1 and PT2

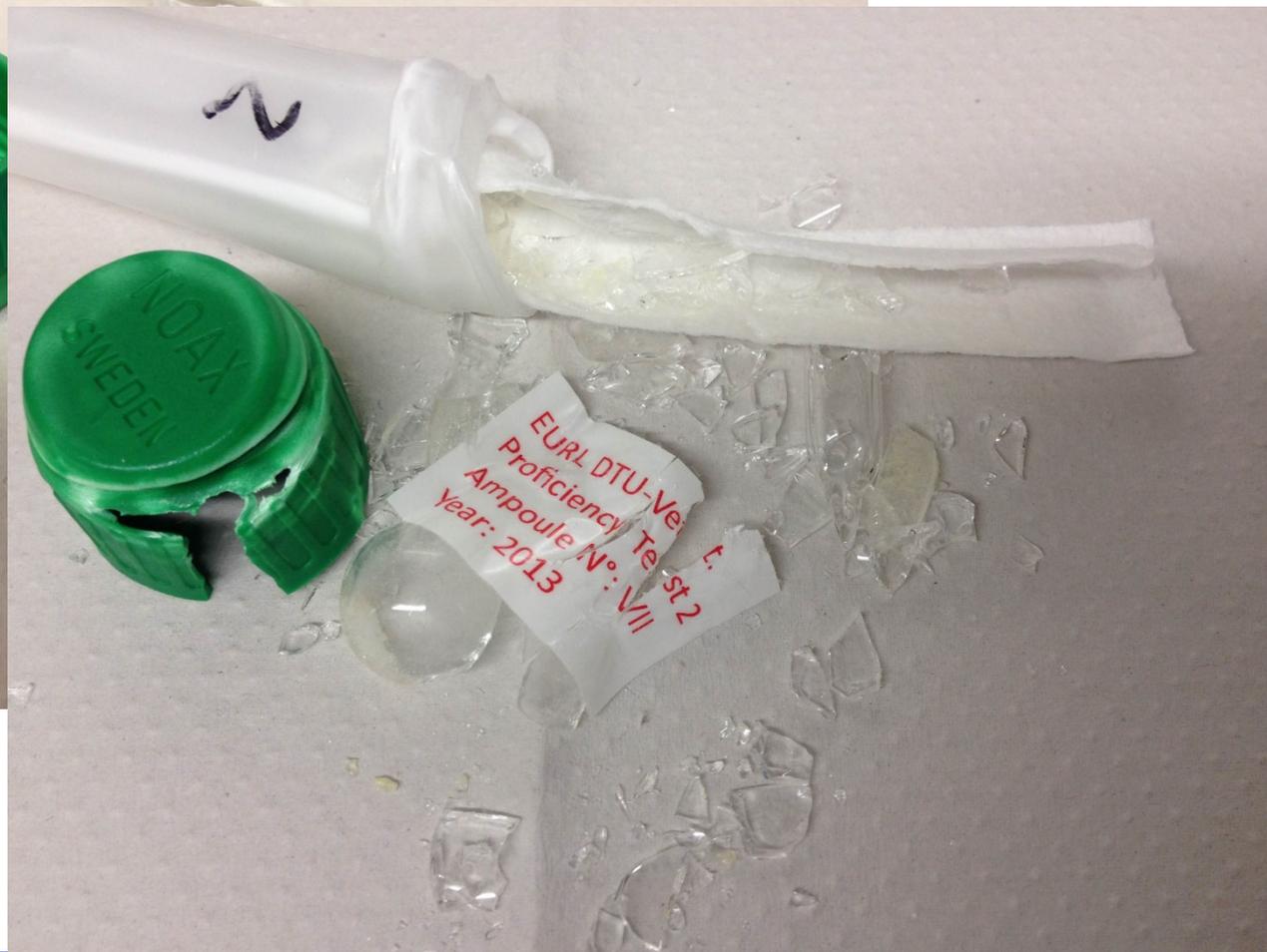
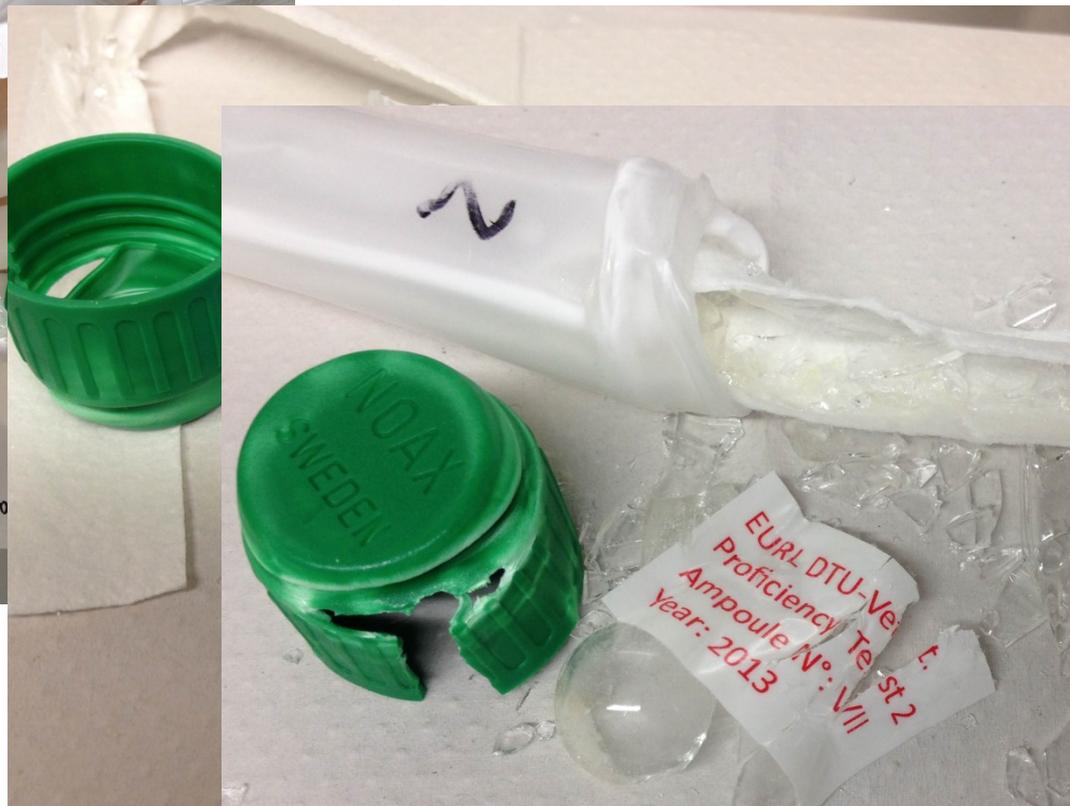
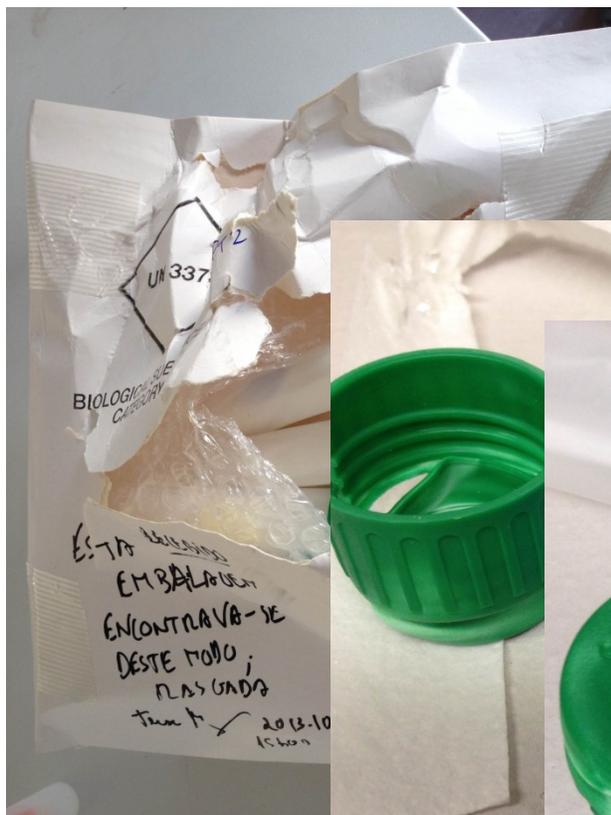
Few cases: Shipping company messed up the shipping- e.g. one lab received 6 parcels.



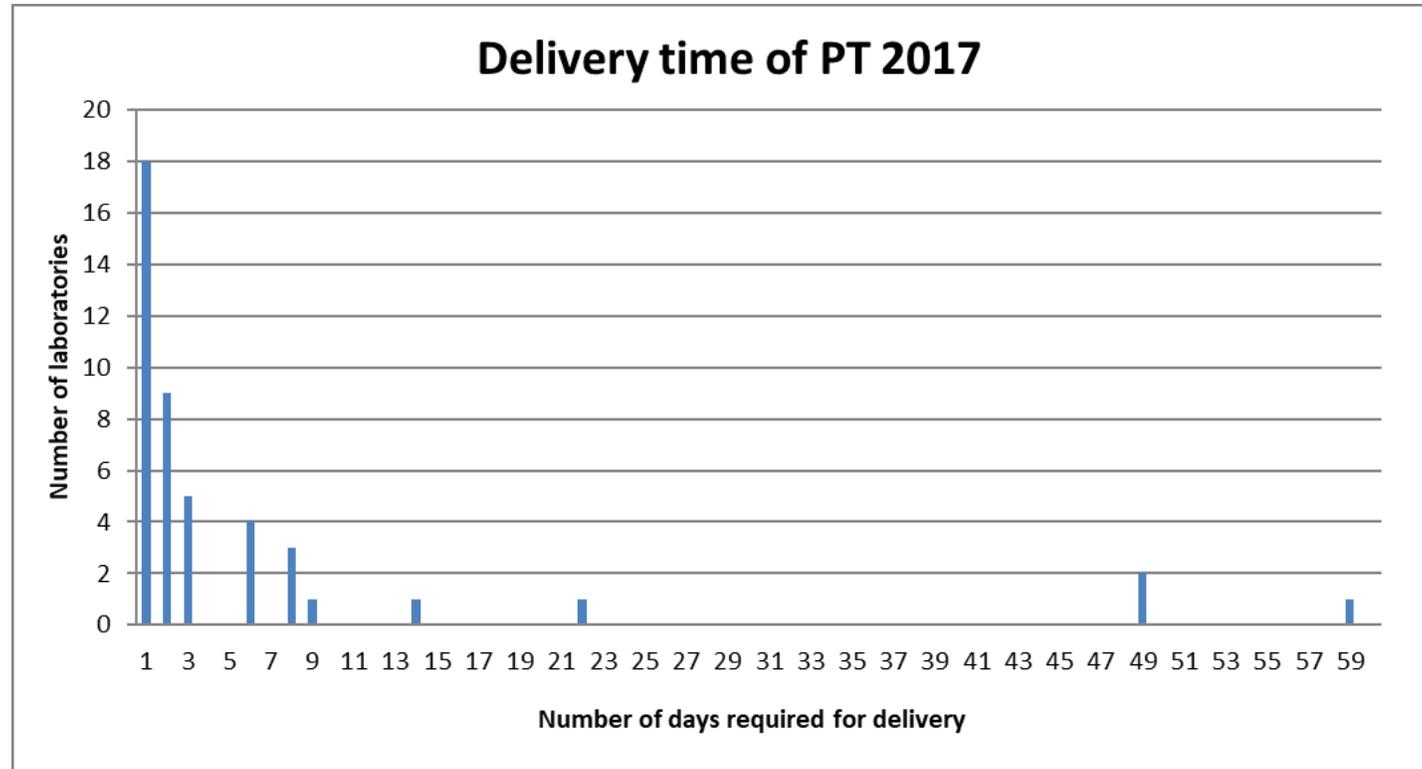
BIOLOGICAL SUBSTANCE  
CATEGORY B



# Shipment: Package smashed by a truck UN 3373 requirements not always enough



# Shipment of PT1 and PT2

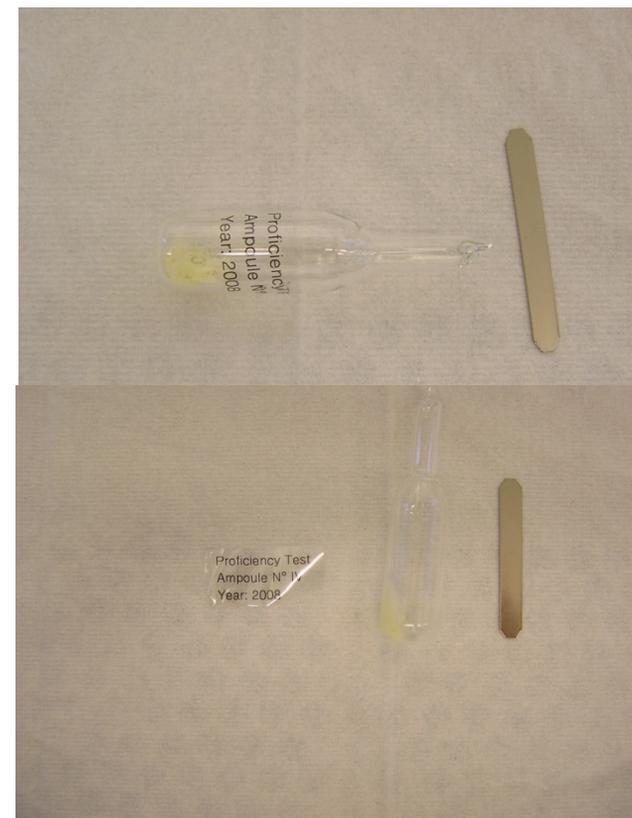
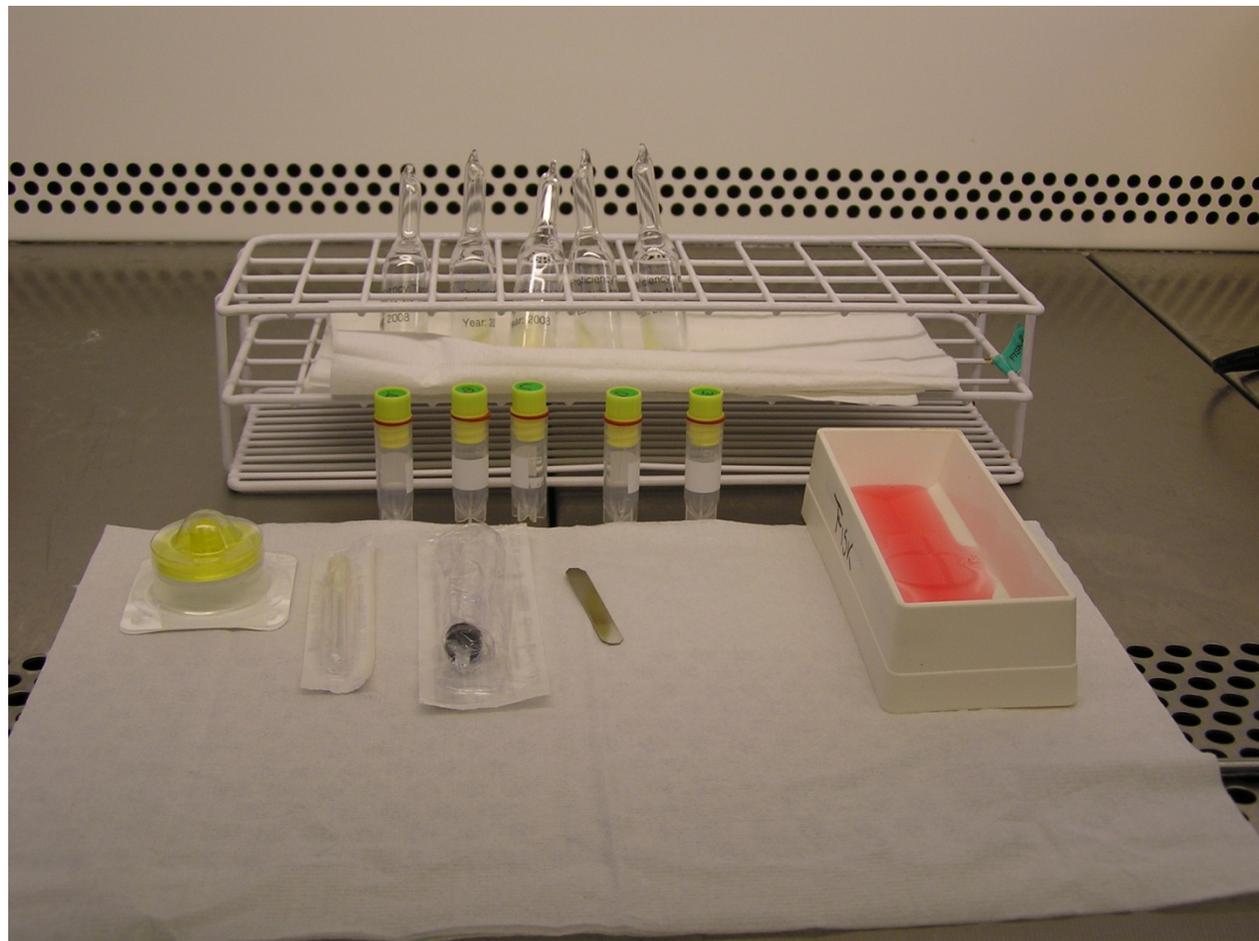


**Within one day, the tests were delivered to 18 participants; 18 more tests were delivered within the first week; 5 more within the first two weeks; 1 further within four weeks; due to delivery problems in the receiving countries 3 tests were 7 – 9 weeks in transit. All the parcels were sent without cooling elements.**



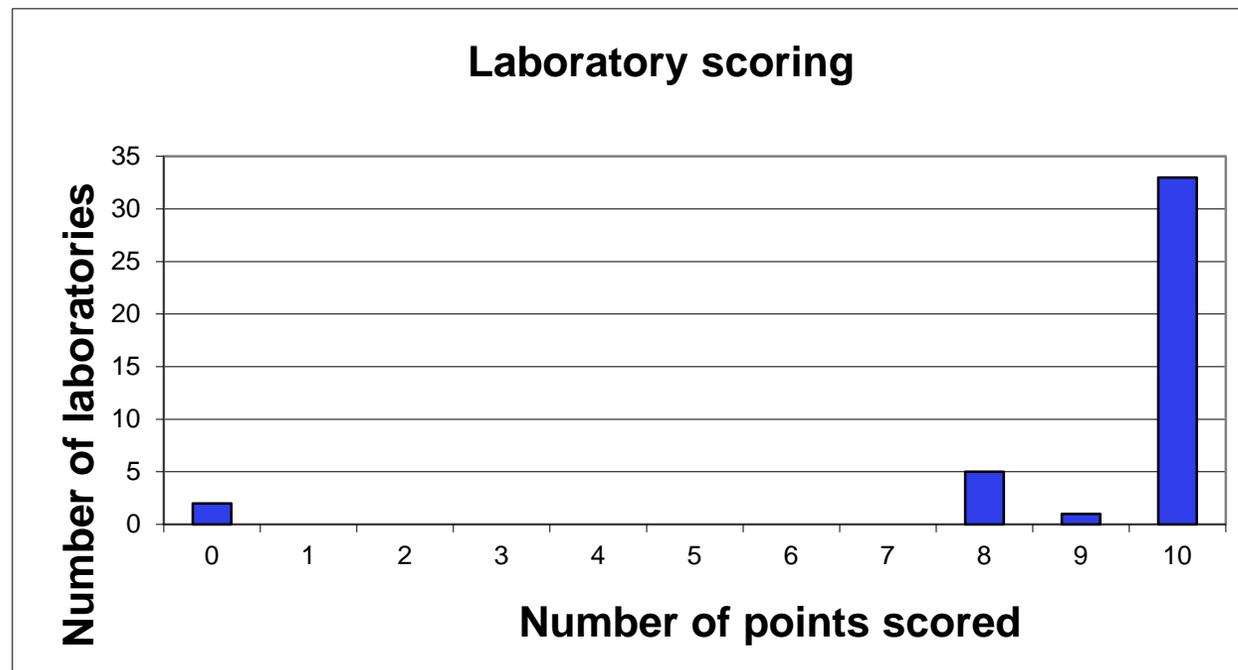
# Procedures at receipt

Detailed procedures on how to open and treat the ampoules are given in cover lettres, videos etc.



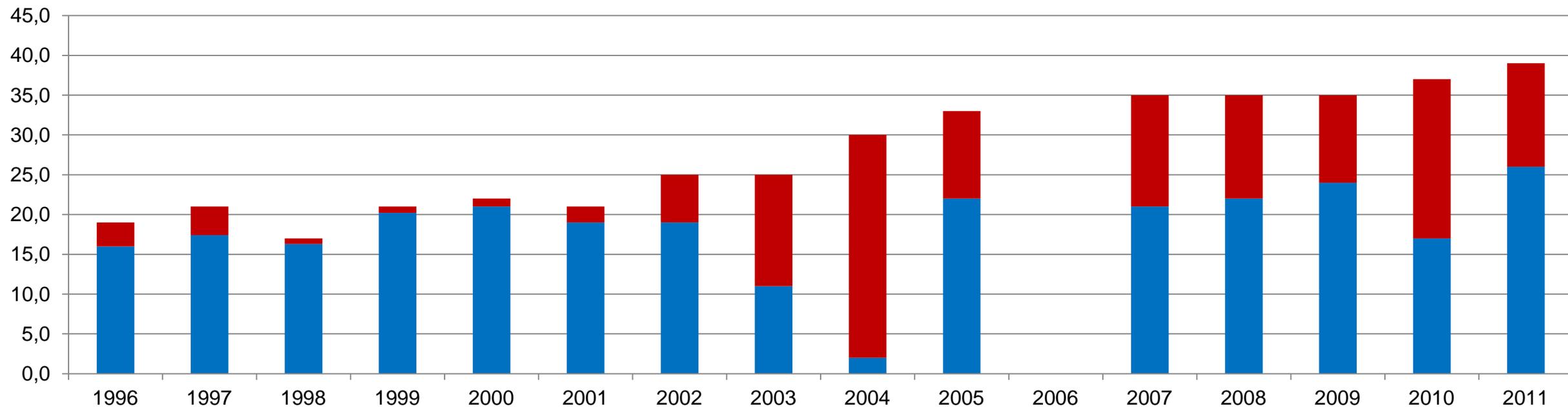
# Qualitative results

Scoring: correct ID: 2; partly correct: 1; not correct: 0





# Success-rate of participating laboratories 1996 - 2011

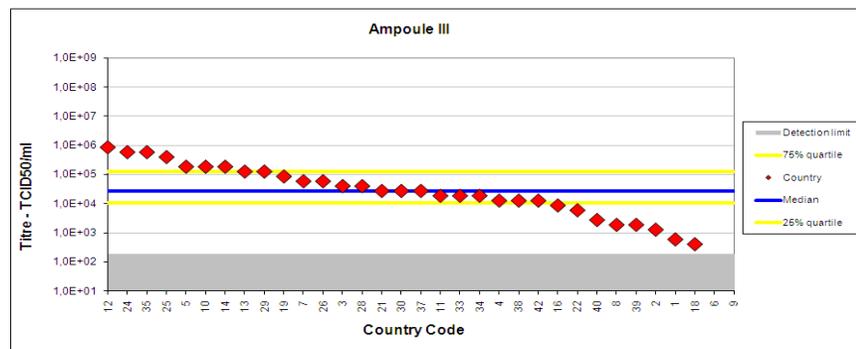
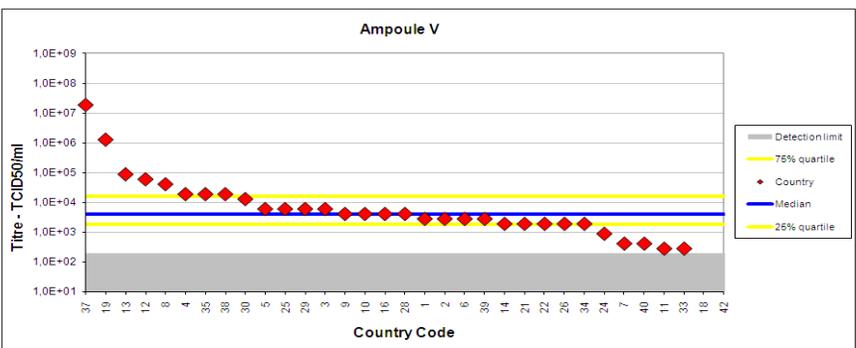
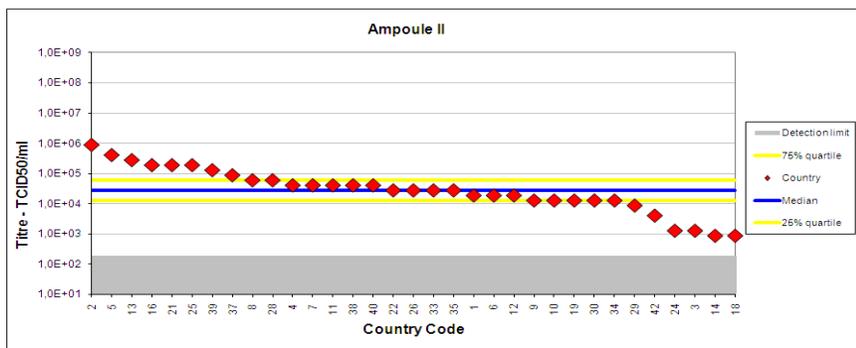
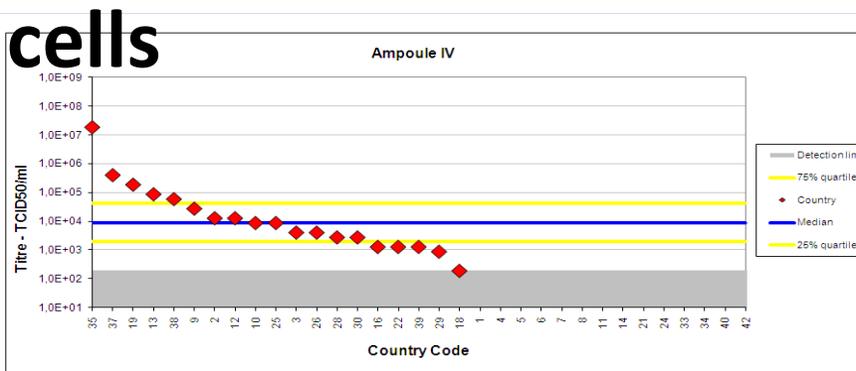
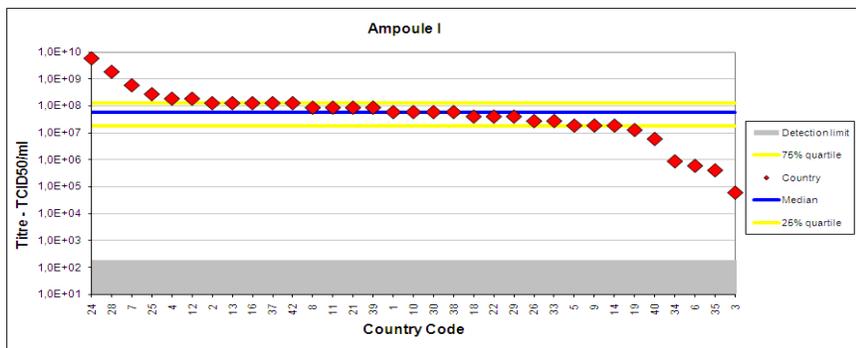


**Blue: Number of labs with score 10**

**Red: Number of labs with score < 10**



# Quantitative results: Assessment of virus titre; BF-2



All labs performing < 75% fractal are encouraged to ask for new cell lines.

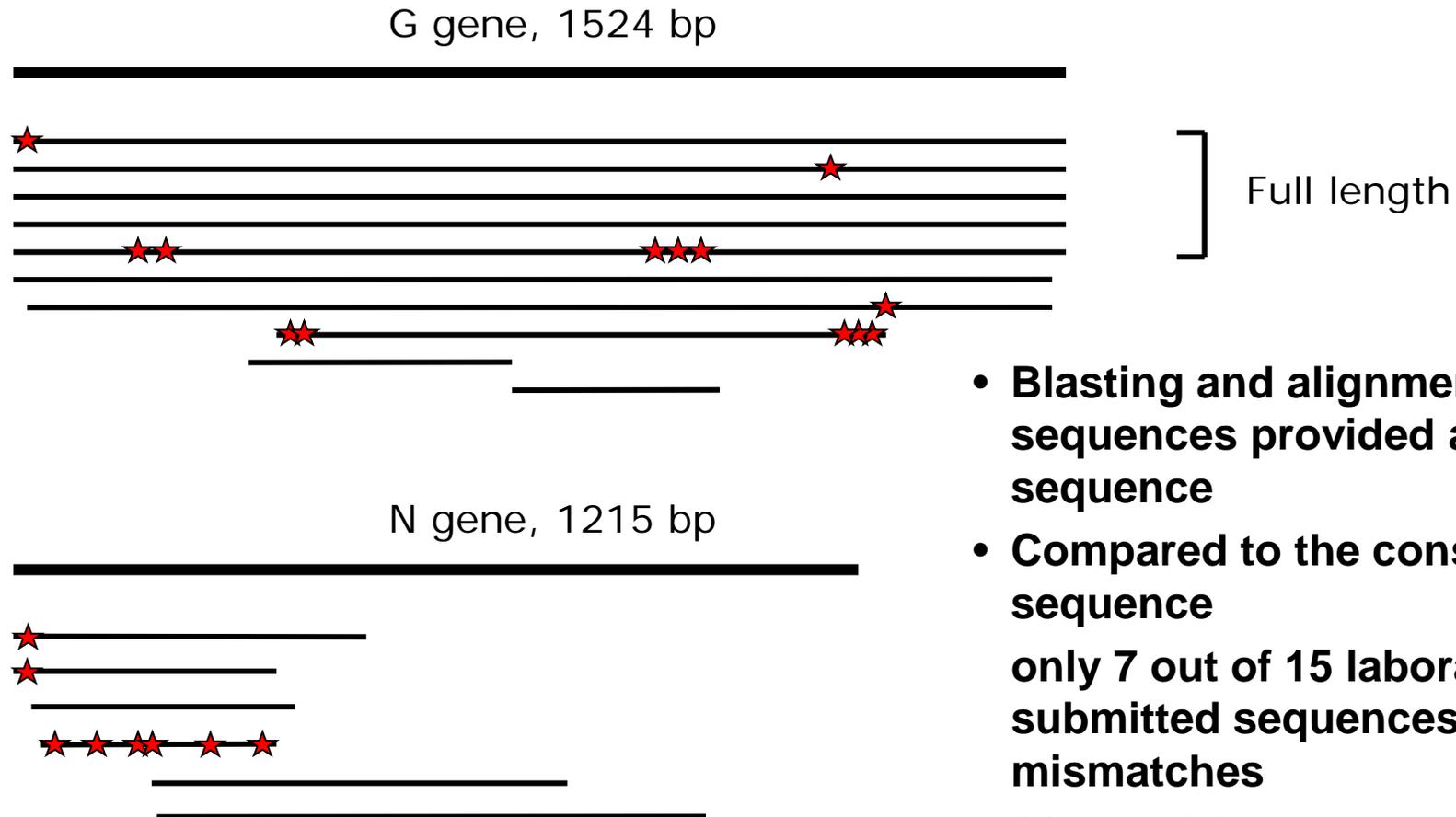
Some outliers with very high titres is more likely due to poor technical performance

# Comparative sequence studies in association with proficiency test

- Unique possibility to assess performance of sequencing and bioinformatics in the respective laboratories.



# Mismatches in sequencing of the VHSV G- and N-gene



- **Blasting and alignment of submitted sequences provided a consensus sequence**
- **Compared to the consensus sequence only 7 out of 15 laboratories submitted sequences containing no mismatches**
- **26 out of 31 mismatches are caused by improper reading of sequence**



# Feedback



Participant feedback form following the Inter-Laboratory Proficiency Test 2017 - PT1 & PT2			
<p>In order to ensure a high quality of future inter-laboratory proficiency tests, we would like if you could provide us with feedback on the tests shipped in 2017, PT1 and PT2. Therefore, if you have any comments, please fill it in.</p>			
Name of the National Reference Laboratory:			
Work area		Specific points to be addressed	Reply
Concerning the ampoules that you received:	1	Were they received safely and under proper conditions?	
	2	Were there enough time to perform the test?	
	3	Were instructions clear?	
	4	Were you able to use daily diagnostic procedures to analyse the content?	
	5	Any other comments?	
Concerning results and report?	6	Was it convenient for you to use the spreadsheet for submission of results?	
	7	Was the report straightforward to understand?	
	8	Was it easy to assess how you performed compared to other participants?	
If you have any other comments please fill in below:	9	Comments	

# Underperformance by NRLs

taken seriously:

**EU Protocol for management of underperformance of NRLs in comparative testing and lack of collaboration with EURL activities**

3

**Previous Training for laboratories with special needs**

- 1 Fact finding missions**
- 2 Workshop on laboratory identification procedures for**
- 3 Follow up missions**
- 4 2 tailored proficiency tests**
- 5 Result 100% performance – satisfying high quality I**

**Fact-finding missions to 5 laboratories**

- Aquaculture
- Buildings, refurbishing and access
- Staff
- Equipment and maintenance of it
- Registration of samples
- Cell culture
- Accreditation
- Past comparative test results
- Training needs

⇒ Proposal of a training schedule

National Veterinary Institute

# Summary

- **Qualitative and quantitative inter-laboratory proficiency tests are very useful for harmonization and standardization of laboratory test**
- **Increased the performances both at laboratory and at National level.**
- **Helped the laboratories to keep awareness and make their performance visible.**
- **Mandatory for keeping up ISO/IEC 17025 quality assurance accreditation.**

## Draw back

- **Expensive to produce**
- **Laborious to perform**



For further information, see:

[http://www.eurl-fish.eu/activities/proficiency\\_tests](http://www.eurl-fish.eu/activities/proficiency_tests)



**European Union Reference Laboratory for Fish and Crustacean Diseases**  
National Institute of Aquatic Resources, Technical University of Denmark

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**What is the EURL for Fish and Crustacean Diseases?**

The European Union Reference Laboratory (EURL) for Fish and Crustacean Diseases is funded by the European Commission and is situated within the Unit for Fish and Shellfish Diseases at DTU Aqua – the National Institute of Aquatic Resources at the Technical University of Denmark. The functions and duties are concerned with harmonizing diagnostic procedures for notifiable fish and crustacean diseases in Europe. The research group for Fish and Shellfish Diseases at DTU Aqua has since 1994 been designated as the EU reference laboratory for fish diseases. From July 2018, the functions and duties were expanded to also include crustacean diseases. The functions and duties are described in Council Directive 2006/88/EC.

A main purpose of the EURL is to ensure the quality of diagnostics of fish and crustacean diseases in Member States and to harmonize the procedures and methodologies applied. The work is mainly concerned with the exotic and non-exotic diseases mentioned in [Council Directive 2006/88/EC](#).

The EURL coordinates those activities of the National Reference Laboratories (NRLs) for Fish and Crustacean Diseases in EU that aim to harmonize diagnostic techniques and disseminate information of mutual interest. Details of our Work Programme is decided at the Annual Workshops of the NRLs for Fish and Crustacean Diseases.

NEWS
All

02 May 2019  
Updated programmes for EURL Annual Workshops 2019

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25 March 2019  
Invitation to EURL Annual Workshops

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**The Fish Pathogen Database**



F I S H P A T H O G E N S

Thanks for your attention!