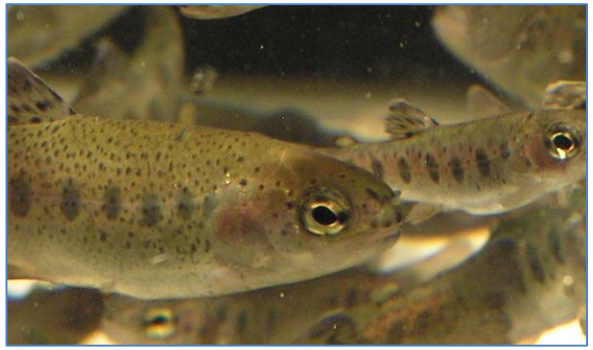
Function and duties of NRLs in EU

The 25th Annual Workshop of the National Reference Laboratories for Fish and Crustacean Diseases



Picture: DTU Aqua

REGULATIONS

REGULATION (EU) 2017/625 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 March 2017

on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)

Functions and duties of laboratories were given in Annex VI of COUNCIL DIRECTIVE 2006/88/EC with Part II describing the F&D for NRLs (part III for Designated laboratories in Member States

These are now replaced with the **Official control Regulation (EU) 2017/625** of the European parliament and of the council on official controls and other official activities

PART II

National reference laboratories

1. The national reference laboratories designated pursuant to Article 56 shall be responsible for coordinating the diagnostic standards and methods within their field of responsibility in the Member State concerned. These national reference laboratories shall:

(a) undertake to notify, without delay, the competent authority whenever the laboratory is aware of a suspicion of any of the diseases referred to in Annex IV;

(b) coordinate, in consultation with the relevant Community reference laboratory, the methods employed in Member States for diagnosing the diseases concerned under their responsibility;

(c) assist actively in the diagnosis of outbreaks of the relevant disease by receiving pathogen isolates for confirmatory diagnosis, characterisation and epizootic studies;

(d) facilitate the training or retraining of experts in laboratory diagnosis with a view to harmonising diagnostic techniques throughout the Member State;

(e) ensure confirmation of positive results of all outbreaks of exotic diseases listed in Part II of Annex IV, and of primary outbreaks of non-exotic diseases listed in that Annex;

(f) organise periodic comparative tests (ring tests) of diagnostic procedures at national level with the laboratories designated by the Member States in accordance with Article 57, in order to provide information on the methods of diagnosis used and the results of tests carried out in the Member State;

(g) cooperate with the Community reference laboratory referred to in Article 55 and participate in the comparative tests organised by the Community reference laboratories;

(h) ensure a regular and open dialogue with their national competent authorities;

(i) operate and be 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:

(i) EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories';

(ii) EN 45002 on 'General criteria for the assessment of testing laboratories';

(iii) EN 45003 on 'Calibration and testing laboratory accreditation system — General requirements for operation and recognition'.

2. The accreditation and assessment of testing laboratories referred to in point 1(i) may relate to individual tests or groups of tests.

3. The Member States may designate national reference laboratories which do not comply with the requirements referred to in point 1(i)(i) of this Part, where operation under EN ISO/IEC 17025 is practically difficult, provided the laboratory operates under quality assurance in line with the guidelines in ISO 9001.

4. Member States may authorise a national reference laboratory situated on their territory to take advantage of the skills and capacity of other laboratories designated pursuant to Article 57, for one or more of the diseases under their responsibility, provided that these laboratories comply with the relevant requirements of this Part. However, the national reference laboratory shall remain the contact point for the central competent authority of the Member State, and for the Community reference laboratory.

OCR Regulation (EU) 2017/625

- Article 100 describe how to designate national reference laboratories

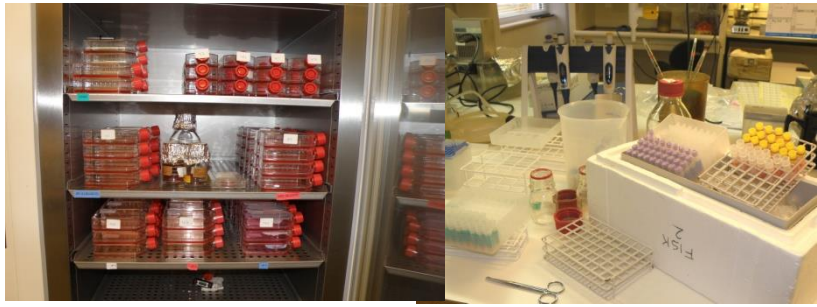
- **MS shall designate one or more NRL for each EURL.**
- **MS may designate a laboratory situated in another MS or in a third country**
- **A single laboratory may be designated as a NRL for more than one MS. (Case for Italy, Belgium, Ireland, Netherland etc.)**

- An updated list of NRLs and contact persons is given on the EURL Website

OCR Regulation (EU) 2017/625 Art.100

National reference laboratories shall:

- (a) Be impartial, free from any conflict of interests,
- (b) have suitably qualified staff with adequate training
- (c) possess, the infrastructure, equipment and products needed
- (d) ensure that staff have good knowledge of international standards and practices



OCR Regulation (EU) 2017/625 Art.101

Responsibilities and tasks of NRLs:

Very much the same as in 2006/88 annex VI

Collaborate with EURL, training course and PT participation

Assistance to CA and Multi-annual national control plans (MANCP)

Validate reagents, coordinate official laboratories with PT training etc.

Article 101

Responsibilities and tasks of national reference laboratories

1. National reference laboratories shall, in their area of competence:

(a) collaborate with the European Union reference laboratories, and participate in training courses and in inter-laboratory comparative tests organised by these laboratories;

(b) coordinate the activities of official laboratories designated in accordance with Article 37(1) with a view of harmonising and improving the methods of laboratory analysis, test or diagnosis and their use;

(c) where appropriate, organise inter-laboratory comparative testing or proficiency tests between official laboratories, ensure an appropriate follow-up of such tests and inform the competent authorities of the results of such tests and follow-up;

(d) ensure the dissemination to the competent authorities and official laboratories of information that the European Union reference laboratory supplies;

(e) provide within the scope of their mission scientific and technical assistance to the competent authorities for the implementation of MANCPs referred to in Article 109 and of coordinated control programmes adopted in accordance with Article 112;

(f) where relevant, validate the reagents and lots of reagents, establish and maintain up-to-date lists of available reference substances and reagents and of manufacturers and suppliers of such substances and reagents;

(g) where necessary, conduct training courses for the staff of official laboratories designated under Article 37(1); and

(h) assist actively the Member State having designated them in the diagnosis of outbreaks of foodborne, zoonotic or animal diseases or of pests of plants and in case of non-compliance of consignments, by carrying out confirmatory diagnoses, characterisation and epizootic or taxonomic studies on pathogen isolates or pest specimens.

2. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the establishment of responsibilities and tasks for national reference laboratories in addition to those provided for in paragraph 1 of this Article. Such delegated acts shall be limited to ensuring coherence with any additional responsibilities and tasks adopted in accordance with Article 99(2).

New enforcement:
Quality assurance of Official laboratories

- NRL operates in accordance with the standard EN ISO/IEC 17025 and is accredited in accordance with that standard by a national accreditation body.
- Demand for accreditation of diagnostic method for at least VHS, IHN, HPR-del ISA, WSSV
- No real possibility for derogation.
- Is it realistic to achieve this??
- How can we help each other in fulfilling the requirements? Sharing SOP´s? Provide guidelines for minimum validations at laboratory level. Distribution of patogen panels for validations.
- The PTs are important for maintenance of QA

Thank you for your attention