Some requirements from the Official Controls Regulation

Annual meeting of EURL for fish and crustacean diseases with NRLs

31 May 2021

DG SANTE

Unit G2 – Animal Health

AHL and OCR (Official Controls Regulation)

OCR

- Delegation of tasks to natural and legal persons
- Veterinary checks intra EU and borders
- Laboratories (including EURLs and NRLs)
- Sampling and diagnostic methods (“cascade”)
- IMSOC
- Etc…

https://ec.europa.eu/food/animals/health/regulation_en

European Commission

EU Regulations

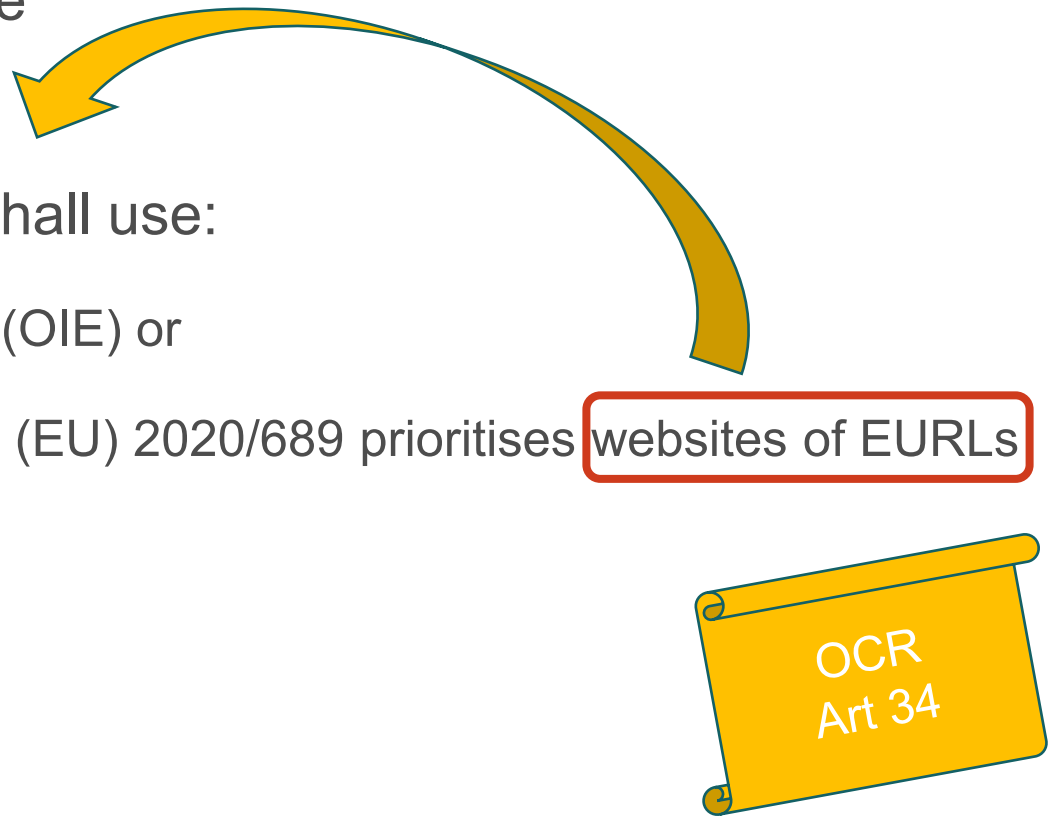
- Binding legislative act
- Must be applied in its entirety across the EU
- Regulations of the European Parliament and of the Council
- Commission Regulations:
  - Delegated Regulations: non-essential elements
  - Implementing Regulations: technical details, lists, etc.
- „Member States shall…”
- „Competent authorities shall/may …”
- „National reference laboratories shall…”

Regulation (EU) 2017/625 – OCR

- Article 1(2): „official controls … for the verification of compliance with…”
- Article 1(2)(d): animal health requirements
- Article 1(5): „…shall also apply to other official activities…”
- Official controls to verify
  - Compliance by the operators with animal health requirements
  - Animals or goods meet the animal health requirements
- Other official activities:
  - anything else done by competent authorities, e.g. surveillance, disease control, eradication etc.

Cascade of methods for sampling, analyses, tests and diagnosis

- Comply with Union rules establishing those
  - Delegated Regulation (EU) 2020/689
- In the absence of the above, official labs shall use:
  - Internationally recognised rules or protocols (OIE) or
  - Methods by EURLs. BUT Art 6 of Regulation (EU) 2020/689 prioritises websites of EURLs
- In the absence of the above:
  - Nationally recognised rules or NRLs
- In the absence of the above:
  - Official labs



Second expert opinion

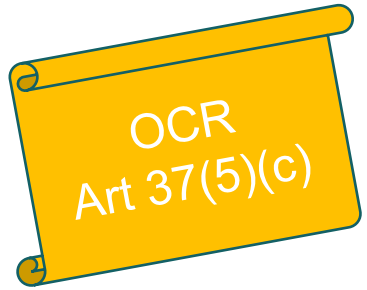
- In the context of official controls only
  - Right of the operator: documentary review by an expert
- Sampling:
  - Where relevant, appropriate and technically feasible: hazards!
  - Sufficient quantity or inform operator
- Dispute: MS may decide: documentary review by another official lab
- Obligation: prompt action to eliminate or contain risks in accordance with:
  - Animal health rules
  - Animal by-product rules

Official labs

- CAs shall designate as official labs:
  - In their own MS
  - official labs of other Member States or EEA States
- In writing with description
- CA must perform their audits and inspections
- CAs may only designate if:
  - Expertise, equipment, infrastructure and sufficient staff
  - Impartial
  - Timely manner
  - Accredited

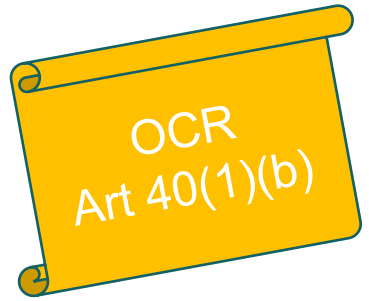
Accreditation in flexible manner

- Modified versions or new versions of methods
- Based on lab's own validation
- National accreditation body:
  - Your experience?
  - What are the limits of flexibility?



Derogation from accreditation for other official activities

- Competent authorities may designate
- Under the supervision of the CA or the NRL
- Participates in ILPT
- Quality assurance is in place to ensure sound and reliable results
- If confirmatory analysis is needed: by an accredited lab

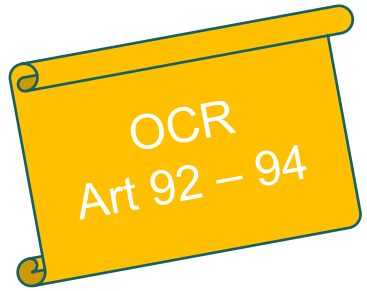


Temporary derogation possibility for official labs

- CAs may temporarily designate
  - When the method is newly required by Union rules
  - Changes in method require new accreditation
  - Need to use method
    - In emergency situation: guidance is in preparation
    - For emerging risk: guidance is in preparation
- Conditions:
  - The lab is already accredited
  - Quality assurance is in place to ensure sound and reliable results
  - Under the supervision of the competent authority or the NRL
- 1+1 year

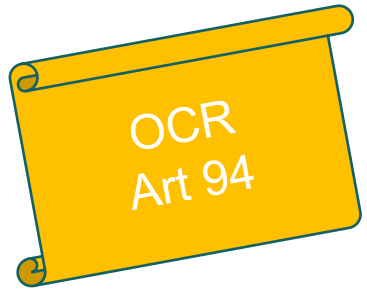
EURLs

- For quality, uniformity and reliability of:
  - methods of analysis, tests or diagnosis employed by the official laboratories
  - the results of those analysis, tests or diagnosis
- Designation is limited in time or reviewed regularly
- Accreditation: no derogation is possible
- Previous requirements in Directive 2006/88/EC repealed:
  - Article 55 + Part I of Annex VI



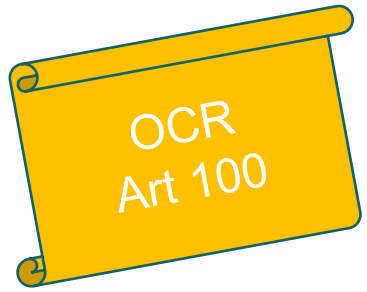
Responsibilities and tasks of EURLs

- Details and guidance on methods
- Reference materials
- Coordinating: e.g. ILPT and follow-up
- Coordination on new methods
- Training of NRLs
- Assistance to the Commission
- Information on research activities
- Collaborating with labs of TCs, EFSA, etc.
- Assist diagnosis of outbreaks in MS
- Tests for the verification of quality of reagents
- Reference collections
- Develop methods of analysis, testing and diagnosis



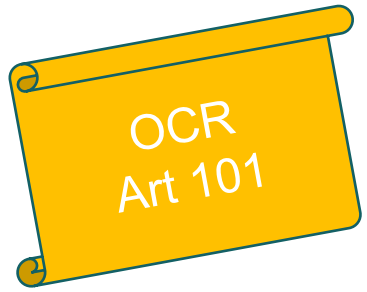
NRLs

- Member States shall designate NRL(s) for each EURL
- In another Member State too
- One lab can be NRL for more Member State
- NRLs are to collaborate with the EURL
- Previous requirements in Directive 2006/88/EC repealed:
  - Article 56 + Part II of Annex VI
- Baseline: accreditation per Art 100(2) in connection with Art 37(4) and (5)
- Temporary derogation is possible in certain, limited cases:
  - Art 100(2) in connection with Art 42(1), 42(2)(a) and (b) and 42(3):



Responsibilities and tasks of NRLs

- Collaborate with EURL
- Coordinate official labs
- ILPTs for official labs
- Dissemination of info from EURL to CAs
- Scientific and technical assistance to CAs
- Reagents and reference materials
- Training for official labs
- Assist the MS CA in diagnosis of outbreaks



Temporary derogation possibility for NRLs

- When the method is newly required by Union rules
- Changes in method require new accreditation
- Need to use method
  - Emergency situation: guidance is coming
  - Emerging risk: guidance is coming
- Conditions:
  - The lab is already accredited
  - Quality assurance is in place to ensure sound and reliable results
- 1+1 year

Key messages

- Comply with obligations
- Explore possibilities, including in other MS
- Liaise with your national accreditation body and with your CA
- Justify within the framework

Thank you

European Commission