The EU approach to Reference Laboratories

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Structure of the presentation

- Introduction
- EURLs and NRLs
- Legal basis: Regulation (EC) No 882/2004
- Revision of the Official Control Regulation
- Role of the European Commission
- In case of underperformance of NRLs
- DG SANTE's goals
- Conclusion
Intro (1): Importance of the EURL-NRL network

• A network gradually established since late 1970s
• Aim of the network: ensure high quality, uniform testing within the EU, and support Commission's activities in relation to risk management (and risk assessment)
• Important contribution to:
  • The achievement of the objectives pursued by EU legislation
  • The improvement of the food and feed safety in the EU
• International reputation
Intro (2): Major developments in the last decades

- Important increase in the number of EURLs and NRLs
- Successive enlargements of the EU
- Role of the EU as a major food importer and exporter
- Development of international trade resulting in greater risks, emerging/re-emerging diseases
- Evolution of Union policies
- Progress in diagnostic techniques and availability of new and highly sensitive analytical methods
EURLs and NRLs

- 43 EURLs – for each EURL, each MS designates an NRL.
- Each EURL establishes a network with the NRLs, via annual workshops, web-platform, forums for exchanges, trainings and proficiency testing, newsletters, etc.
- Nb of EURLs may vary as COM is regularly reviewing the EURLs' mandate, and e.g. merging existing EURLs, creating new ones.
- EURLs and NRLs must be accredited

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Health and Food Safety
Legal basis

Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Legal basis for EURel (1)

• Art 32.1: responsibility of EURel for food and feed:
  
  (a) providing NRL with details of analytical methods, including reference methods;
  
  (b) coordinating application by NRL of the methods referred to in (a), in particular by organising comparative testing and by ensuring an appropriate follow-up of such comparative testing in accordance with internationally accepted protocols, when available;
  
  (c) coordinating, within their area of competence, practical arrangements needed to apply new analytical methods and informing NRLs of advances in this field;
Legal basis for EURLs (2)

• Art 32.1 (cont'ed)

(d) conducting initial and further training courses for the benefit of staff from NRLs and of experts from developing countries;

(e) providing scientific and technical assistance to the Commission, especially in cases where Member States contest the results of analyses;

(f) collaborating with laboratories responsible for analysing feed and food in third countries.
Legal basis for EURel (3)

- **Art 32.2: Responsibilities of EURel for animal health:**

  (a) **coordinating the methods** employed in the Member States for diagnosing diseases;

  (b) assisting actively in the diagnosis of disease outbreaks in Member States by **receiving pathogen isolates for confirmatory diagnosis, characterisation and epizootic studies**;

  (c) facilitating the initial or further **training of experts** in laboratory diagnosis with a view to the **harmonisation of diagnostic techniques** throughout the Community;

  (d) collaborating, as regards methods of diagnosing animal diseases falling within their competence, with the competent laboratories in **third countries** where those diseases are prevalent:

  (e) conducting initial and further **training** courses for the benefit of staff from **NRLs** and of experts from developing countries;
Legal basis for NRLs (1)

- Art 33.1: MS shall designate one or more NRLs for each EURL (possibly in another MS or EFTA Member)

- Art 33.2: tasks of NRLs:
  
  (a) **collaborate with the EURL**;

  (b) **coordinate**, for their area of competence, **the activities of official laboratories** responsible for the analysis of samples for official controls;

  (c) where appropriate, organise **comparative tests** between the official national laboratories and ensure an appropriate **follow-up** of such comparative testing;
Legal basis for NRLs (2)

• **Art 33.2 (cont'ed):**

(d) ensure the **dissemination** to the competent authority and official national laboratories of **information that the EURL supplies**;

(e) provide **scientific and technical assistance to the competent authority** for the implementation of coordinated control plans;

(f) be responsible for carrying out **other specific duties** if provided for by a Commission legal act, without prejudice to existing additional national duties.
Legal basis for NRLs (3)

• NRLs have to operate in accordance with EN ISO/IEC 17025 and EN ISO/EN 17011

• MS shall communicate the name and address of NRLs to the COM, the EURL and other MS.

• MS that have more than 1 NRL for an EURL must ensure that these labs work closely together, so as to ensure efficient coordination between them, with other NRLs and with the EURL

• Additional responsibilities and tasks for NRLs may be laid down via comitology procedure
Revision of the Official Control (OC) Regulation (1)

- Reg. 882/2004 currently under revision by ordinary legislative procedure
- COM proposal published on 6/5/2013, EP first reading voted on 15/04/2014, "trialogues" currently ongoing
- Indicative timing: adoption in 2017, entry into force in 2018
Revision of the OC Regulation (2): objectives

- **Simplify and clarify** the legal framework applicable to control activities

- **Consolidate** the integrated approach across the food chain in its widest meaning (food and feed, plant health, animal health, animal welfare)

- **Ensure** that MS appropriately resource control authorities through fees charged on operators
Revision of the OC Regulation (3): main changes concerning EURLs/NRLs

Warning: still under discussion at EP and Council and therefore subject to possible further changes

- System of EURLs-NRLs extended to the plant health sector.
- COM to decide in which areas EURLs should be maintained/created

"Where the effectiveness of official controls also depends on the quality, uniformity and reliability of:

- the method of analysis, test or diagnosis employed by the official labs
- the results of the analyses, tests and diagnoses performed by those labs". (wording of COM proposal)

- COM to review regularly the mandate and the designation of EURLs.
- Designations following a public selection process
Revision of the OC Regulation (4): main changes concerning EURLS

- EURLS can include other official labs than NRL in their proficiency testing

- Creation of EU reference centres for animal welfare and for the authenticity and integrity of the agri-food chain

- Some new tasks for EURLS, inter alia:
  - Publication of the list of NRLs designated by the MS
  - Information on Union/national/international research activities
  - If needed: training courses for / coordination of application of methods by official laboratories

- New requirements for EURLS, inter alia:
  - Impartial and free of conflict of interest
  - When relevant, be equipped to comply with biosecurity standards
Revision of the OC Regulation (5): main changes concerning NRLs

- **New requirements for NRLs:**
  - impartial and free of conflict of interest;
  - suitably qualified staff;
  - access to the infrastructure equipment and products needed;
  - staff knowledge of international standards and practices and latest development in research;
  - emergency situations;
  - where relevant, biosecurity standards.

- **Some changes envisaged in the art. on the role of NRLs:**
  - shall participate in training courses and proficiency testing organised by EURLs;
  - where relevant, maintain lists of reference substances and reagents and of manufacturers and suppliers thereof;
  - assist MS in the diagnosis of outbreaks.
Revision of the OC Regulation (6): main changes re. official labs

Methods of sampling, analysis/ diagnosis/testing to be used:

• Applicable to official controls and other official activities in **all sectors**
• **5 years transitional period** for plant health
• Clarified and addition of **methods validated by EURLs or NRLs**
Revision of the OC Regulation (7): main changes re. official labs

- List of requirements applicable to all official laboratories:
  - Has expertise, equipment and infrastructure required
  - Sufficient number of suitably qualified, trained and experienced staff
  - Can deliver the results timely
  - operates and is accredited in accordance with EN ISO/IEC 17025

- Upon request of EURL/NRL, laboratories shall take part in proficiency testing
Revision of the OC Regulation (8): main changes re. official labs

• **Scope of accreditation** ISO/IEC 17025
  - all the methods used when operating as official laboratory
  - one or several methods / fixed or flexible scope

• **Permanent derogations** to mandatory accreditation for laboratories carrying out:
  - Only detection of *Trichinella* in meat
  - only tests within official activities provided that:
    - Only certain methods are used
    - Tests carried out under the supervision of the CA or NRL
    - Regular and successful participation in PT
    - Quality assurance system in place
Revision of the OC Regulation (9): main changes re. official labs

- 5 years transitional period for **plant health labs** to be accredited
- COM empowered to adopt act allowing CA to use **permanent derogations to mandatory accreditation** for all methods used for official controls (if accreditation already for similar/representative methods, used significantly)
- **Temporary derogations to mandatory accreditation** by CA (new methods, changes to a method requiring new accreditation, emergency situations, emerging risks): max 1+1 year
Role of the Commission

• Every year, COM adopts a work programme on the EU financing to EURel for the next financial year
  • required by the Common Financial Framework (Regulation (EU) No 652/2014)

• EURel submit their work programme and budget (now bi-annual) to COM and COM evaluates and approves them.

• COM follows the work of EURel on a regular basis, e.g. approves SOPs, discusses the needs for new analytical methods to support evolution of the legal framework, etc.

• COM usually attends EURel's annual workshops

• COM evaluates the EURel's final report (technical units) and cost claims (financial unit) and proceeds to payments.
In case of underperformance of NRL

Phase 1

• EU RL contacts NRL
• Identification of cause
• Additional training if necessary
• Repetition of comparable test if feasible
• On confidential basis

Phase 2 (continuing underperformance)

• EU RL informs COM
• COM informs CA and requires appropriate action
DG SANTE's goals

• Priority risks/hazards/diseases covered by the network of reference laboratories
• Efficient, well-structured and organised EU network of reference laboratories
• Highly performing reference laboratories
• Optimum use of financial resources
• Continuous improvement of the network of reference labs
• International reputation of the network
Conclusion

- NLRs are responsible for the quality of laboratory analyses in the official controls in Member States
- A network of excellence
- An example looked at by other countries and other sectors
- Contribution to the high performance of the EU food safety and animal health system
- Some evolution of the legal basis in the near future
- In the future, regular review of the mandates (and number) of EURLs (and thus NRLs)
Thank you for your attention