



EURL-CAMPYLOBACTER TRAINING COURSE

THE ORGANISATION OF

PROFICIENCY TESTS

Introduction and general aspects

Helena Höök, DVM, PhD

9th October 2019



TODAY'S SCHEDULE

08:00–08:40	Introduction and general aspects ISO 22117:2019 & Guidance document	Helena
08.40–09.10	Practical aspects on PT organisation	Therese, Linda
09.15–10.00	Design and performance assessment	Helena
10.00–10.20	Coffee/tea	
10.20–11.20	Group exercise	Helena
11.20–12.00	Reference materials and testing Summary of morning	Sevinc Helena
12.00–13.00	Lunch	
13.00–13.30	Group exercise (continued)	
13.30–14.30	Group presentations and discussion	
14.30–14.45	Closing remarks	Helena
14.45–15.15	Coffee/tea	
15.30	Bus transfer to Stockholm Arlanda Airport	

REGULATION (EU) 2017/625 ON OFFICIAL CONTROLS



Article 101

Responsibilities and tasks of national reference laboratories

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

(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;



TERMINOLOGY

- **Interlaboratory comparison (ILC):** organisation, performance, and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions
- **Proficiency test:** evaluation of participant performance **against pre-established criteria** by means of ILC
- **Accreditation:** formal recognition that an organisation is **competent** to carry out specific tasks

STANDARDS AND OTHER DOCUMENTS

- **ISO/IEC 17043:2010:** Conformity assessment — General requirements for proficiency testing (replaced ISO Guide 43)
- **ISO 13528:2015:** Statistical methods for use in proficiency testing by interlaboratory comparison
- **ISO 22117:2019:** Microbiology of food and animal feeding stuffs — Specific requirements and guidance for proficiency testing by interlaboratory comparison (replaces ISO 22117:2010)
- **Guidance Document** for the organisation of Proficiency Tests by NRLs for national networks, including partial outsourcing
- **ISO Guide 35:2017:** Reference materials — Guidance for characterization and assessment of homogeneity and stability

GENERALITIES (ISO/IEC 17043)



4. Technical requirements

- 1 General
- 2 Personnel
- 3 Equipment, accommodation and environment
- 4 Design of proficiency testing schemes
- 5 Choice of method or procedure
- 6 Operation of proficiency testing schemes
- 7 Data analysis and evaluation of proficiency testing scheme results
- 8 Reports
- 9 Communication with participants
- 10 Confidentiality

5. Management requirements

- 1 Organization
- 2 Management system
- 3 Document control
- 4 Review of requests, tenders and contracts
- 5 Subcontracting services
- 6 Purchasing services and supplies
- 7 Service to the customer
- 8 Complaints and appeals
- 9 Control of nonconforming work
- 10 Improvement
- 11 Corrective actions
- 12 Preventive actions
- 13 Control of records
- 14 Internal audits
- 15 Management reviews

ISO 22117:2019

MICROBIOLOGY OF FOOD AND ANIMAL FEEDING STUFFS — SPECIFIC REQUIREMENTS AND GUIDANCE FOR PROFICIENCY TESTING BY INTERLABORATORY COMPARISON

- Complement to ISO/IEC 17043 and other available documents
 - Specific requirements for work with **microorganisms**, e.g. sample homogeneity and stability
 - Interpretation of **detection** tests (not covered by an existing document)
- Contents
 - 1 Scope
 - 2 Normative references
 - 3 Terms and definitions
 - 4 Scheme design and purpose
 - 5 Technical requirements and guidance for sample design and content
 - 6 Sample verification by the provider
 - 7 Sample handling
 - 8 Performance evaluations
- Current version replaces ISO 22117:2010



GUIDANCE DOCUMENT FOR THE ORGANISATION OF PROFICIENCY TESTS BY NRLS FOR NATIONAL NETWORKS, INCLUDING PARTIAL OUTSOURCING

- Drafted by EURLs *Campylobacter*, Coagulase Positive Staphylococci, *Listeria monocytogenes*, *Salmonella*, *Escherichia coli*
- Version 2 July 2019 (after comment round in NRL networks)
- Guidance for outsourcing
 - criteria to outsource (parts of) PTs organised by NRLs
 - criteria to select PT providers
- Expanded to
 - criteria for NRLs to organise PTs in their respective scope



CHOICE OF METHOD

The NRL should define the method(s) to be used in the NRL PT, according to the rules defined at national level by the CA and either of the alternatives:

- only a **reference method**, in particular defined in EC Regulation 2073/2005,
- a **choice** between the **reference method** and **alternative** (including proprietary) methods, if **validated/certified** according to the relevant part of EN ISO 16140 series;
- **both** the **reference method** and an **alternative method** meeting the **validation/certification** conditions defined in the second indent, when the laboratory has the two methods in use, or
- a method **developed and/or recommended by the EURL/NRL**.

OUTSOURCING: SELECTION OF A PT PROVIDER



- Quality management
 - preferably accredited according to EN ISO 17043
 - if accredited the PT should be conducted under accreditation
- Data to be provided to NRL
 - the results of each participating OL, with its identity
 - the value of individual performance parameters for each participating OL

THANK YOU FOR THE ATTENTION!