



Albert Marinculić, Krešimir Kralj, Zlatko Krovina

# **Tihineleza - dijagnostika i kontrola danas u Hrvatskoj**

- 
- Each year, more than 167 million pigs in the European Union (EU) are tested for *Trichinella* spp. under the current meat hygiene regulations. This imposes large economic costs on countries, yet the vast majority of these pigs test negative and the public health risk in many countries is therefore considered very low.

# Temeljne značajke NOVIH propisa u Hrvatskoj

- 
- Temeljne značajke propisa u izradi su sljedeće:
  - 
  - 1. Meso namijenjeno osobnoj potrošnji moći će i dalje, osim službenih laboratorija akreditiranih po normi HRN EN ISO 17025 za pregled mesa na Trichinellu, pregledavati i ovlaštene veterinarske organizacije pod uvjetom da:
    - 
    - a) se pregled mesa obavlja po referentnoj metodi u skladu s Pravilnikom o načinu pregleda mesa na Trichinellu, („Narodne novine“ br. 62/08, 74/08 i 102/08),
    - b) jednom godišnje sudjeluju u međulaboratorijskom testiranju s nacionalnim referentnim laboratorijem (Veterinarski fakultet Sveučilišta u Zagrebu).
  - 
  -

- 
- 2. Meso namijenjeno javnoj potrošnji i meso divljači će u prijelaznom razdoblju, do ulaska RH u EU, moći pregledavati osim laboratorija akreditiranih po normi HRN ISO 17025 za pregled mesa na Trichinellu i ovlaštene veterinarske organizacije pod uvjetom da:
    - 
    - a) su akreditirane kao kontrolna tijela u skladu s normom HRN EN ISO 17020 te da u okviru akreditacije imaju i post mortem pregled na Trichinellu,
    - b) su započele postupak akreditacije po normi HRN ISO EN 17025,
    - c) jednom godišnje sudjeluju u međulaboratorijskom testiranju s nacionalnim referentnim laboratorijem (Veterinarski fakultet Sveučilišta u Zagrebu)

# Kontrola trihineloze u novom ruhu, sustav kvalitete

- Requirements for off-site and on-site testing are similar
  - QA system and manual
  - Purpose of laboratory
  - Purpose of testing
  - Appropriate test method (fit for purpose)
- 7
  - Standardized and validated method
  - Trained and competent analysts
  - Suitable facilities
  - Proficiency testing
  - External audits for lab accreditation/certification

# QUALITY ASSURANCE PROGRAM

- • Quality Goals – measurable
- • Defined Test Method - suitable, reliable
- • Samples - suitable, stable
- • Internal Quality Control - CCP
- 8
- • External Quality Procedures - PT, accreditation
- • Record keeping - sample tracking and  
traceback
- • Documented results
- • Procedures (SOP's) and Documentation
- • QA Manual

# QA MANUAL

- Reproducibility and reliability of results
- • Permanent record of sample handling
- • Identification and elimination of errors due to poor performance of media, reagents, equipment, etc.
- 13
- • Permanent record of equipment performance
- • Equipment maintenance and calibration procedures
- • Test procedures and results
- • Analyst training and competence
- • Problem solving and corrective action

# AKREDITACIJA LABORATORIJA

## KORAK PO KORAK

- Submission of application and payment of fees
- Review of application
- Report of required corrective items to candidate
- Completion of corrective items
- Preparation of Quality Manual (QM)
- Review of completed QM
- Report of required corrective actions (QM) to candidate
- Completion of corrective actions
- Preparation of laboratory facilities
- Acquisition of all required test supplies and equipment
- 19
- On-site audit (scheduling required)
- Report of required corrective actions to candidate
- Completion of corrective actions
- Preparation of proficiency samples (scheduling required)
- Training of analysts at CFIA Reference Laboratory (scheduling required)
- Successful proficiency testing on-site (scheduling required)
- Comprehensive on-site audit (scheduling required)
- Report of required corrective actions to candidate
- Completion of corrective actions
- Recommendation of certification
- Certification letter issued by CFIA to candidate
- Candidate arranges with CFIA Vet-in-Charge for export certification

# Priručnik kvalitete

- It is a statement of the laboratory's policies and
- good laboratory management practices
- 20
- • Describes the quality assurance system used in a
- testing laboratory
- • Documents plans to meet management and
- technical goals of the quality assurance system

- Proficiency panels performed 2-4 times per yr
- • Required to ensure competence of analysts and quality system of testing
- 27
- • Prepared from experimentally infected rats
- Forbes, **Rajic**, and Gajadhar. 1998. *Proficiency samples for quality assurance in Trichinella digestion tests. J Food Prot 61, 1396-1399*
- Vallée, Macé, Forbes, Scandrett, Durand, Gajadhar, Boireau. 2007. *Use of Proficiency Samples To Assess Diagnostic Laboratories in France Performing a Trichinella Digestion Assay. J Food Prot 70, 1685-*

- **Proficiency Testing (cont'd)**
- • Encapsulated larvae recovered from semidigested
- infected meat
- • Meat-balls prepared from ground-beef
- 28
- • Three levels of larval loads in panels (L,M,H)
- • Proficiency panels validated prior to
- distribution
- • Proficiency testing conducted according to
- pre-established guidelines

# Odgovornost analitičara

- Evaluation of system and analysts
  - Interpretation according to purpose for testing
  - Positive/negative versus quantitative
  - Goal of  $\geq 75\%$  larval recovery from each
- proficiency sample
  - Food safety goal of  $< 1$  LPG of meat
  - Corrective actions may be required
  - Need for establishing reasonable and achievable guidelines