

Supervision of private laboratories

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- REGULATION (EU) 2017/625 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2017 on official controls and other official activities
- Official controls and other official activities (Art. 2)
- Designation of official laboratories (Art. 37)
 - has the expertise, equipment and infrastructure
 - has a sufficient number of qualified staff
 - impartially and free from any conflict of interest
 - deliver in a timely manner the results
 - in accordance with the standard EN ISO/IEC 17025

Supervision of official laboratories

- Inter-laboratory comparative tests (Art. 38, 101)
- Audits (Art. 39)
- Batch control (validate reagents) (Art. 101)

Obligations of NRL's (Art. 101)

- Coordinate the activities of official laboratories
- Disseminate information from EURL to official labs
- Conduct training courses for staff of official laboratories

Dutch regulation

- Regulation recognition and designation veterinary laboratories
 - Government regulation, since 2006
 - Applies to tests carried out for official programs, including export certification
 - Recognition of national reference laboratories
 - Allows regional labs to carry out certain tests for certain animal diseases
 - Includes 36 diseases by now
 - Requirements for test kits and laboratories

Requirements for test kit

- Manufacturer intends to sell kit on the market
 - Notifies WBVR, handing over information package
 - General review for admission
- Manufacturer wants to sell specific batch
 - Each batch has to be tested at WBVR before allowed on the market (specific test panel)
 - Criteria for sensitivity, specificity, reproducibility that have to be met

Requirements for regional labs

- Lab located in Dutch territory
- Accreditation for the test (ISO 17025)
- Official request for recognition
 - Food and Consumer Product Safety Authority
- Supervision tools
 - Audit
 - Ring trials (proficiency tests)
 - Confirmation of non-negative test results
 - Confirmation of sample of negative test results
 - Evaluation of control charts

Thank you for your attention

