



The Brucellosis EURL

Assignments and Mandate

Specific activities

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- EURL & NRLs' mandate
 - Only the vet. & food sector
 - Human health reference labs.
 - sometimes not designed
 - out of the EURL's network
- Surveillance of Brucellosis
 - Based almost only on serology
 - *Brucella* strains rarely isolated
 - Biotyping limited to very few labs
- Expertise: not always at the NRL level according to the MS



- Intra-community trade regulations harmonised
- An official NRL in each MS
- Heterogeneous situation of infection
 - Free areas with surveillance programmes 
 - enzootic areas with on-going eradication or vaccination plans
- 👉 **Problems met are different**
- 👉 **Needs are sometimes contradictory**



Ruminants brucellosis in the UE *from EFSA, 2010*



Cattle

+ *B. suis*, *B. ovis* & *B. canis*

Sheep & goats





Tasks & responsibilities of the MS Brucellosis NRLs

Annex C to Council Directive 64/432/EEC

Tasks & responsibilities of the MS Brucellosis NRLs



- Approval of the results of the validation studies demonstrating the reliability of the test method used in the Member State
- Determination of the maximum number of samples to be pooled in ELISA kits used
- Calibration of the standard secondary reference national standard sera (“working standards”) against the primary international standard serum
- Quality checks of all antigens and ELISA kits batches used in the Member State
- Cooperation within the European Union Network of National Reference Laboratories for Brucellosis



In fact, great heterogeneity in applying regulations in the MS:

- Different tests and test methods/protocols
- Different protocols for controlling the reagents (if done)
- No harmonisation of national standards (if they do exist)
- No effective work of the EU network in between meetings, *esp. no follow-up of the proficiency ring-trials (no authority for that)*



A lot of actions of the network in the past but:

- Mainly on a voluntary basis
- Not all MS included in standardisation actions
- Neither co-ordination or monitoring nor complete harmonisation
- No legal chain of responsibilities (EC / MS)
- No specific adequate funding (except for research projects)
- Consensus not always reached

👉 **Decision making** (*Commission level*)

- Difficult or almost impossible
- Critical with an increasing number of MS and tests

👉 **Creation of a EU Reference Laboratory** (2006)

for a more coordinated and integrated approach together with the EC, Task Force, FVO and EFSA.

EURL's general functions



- **Coordinating the methods** employed in the MS for diagnosing diseases
- **Assisting** actively in the **diagnosis** of disease outbreaks in MS by receiving pathogen isolates for **confirmatory diagnosis**, characterisation and epizootic studies
- Facilitating the initial or further **training** of experts in laboratory diagnosis with a view to the harmonisation of diagnostic techniques throughout the Community
- **Collaborating**, as regards diagnostic methods, with the competent laboratories in **third countries** where those diseases are prevalent
- Conducting initial and further **training courses** for the benefit of staff from NRLs and of experts from developing countries



1. Coordinate the diagnostic methods employed in the MS by:

- Typing, storing and supplying strains of *Brucella* sp.
- Preparing, controlling and supplying International Standard sera and other reference reagents to the NRLs (to standardise tests and reagents in the MS)
- Validating reference reagents (antigens and National Standard sera)
- Building up and maintain a sera bank, a collection of *Brucella* sp., and a database of strains isolated across the EU
- Organising periodical comparative tests of diagnostic procedures at EU level and operating laboratory proficiency tests of NRLs



1. Coordinate the diagnostic methods employed in the MS by:

- **Collecting and collating data** and information on the methods of diagnosis used and the results of tests carried out in the EU
- **Characterizing *Brucella sp*** by the most up-to-date methods available to allow greater understanding of the epidemiology of brucellosis
- **Keeping abreast of development** in brucellosis surveillance, epidemiology and prevention throughout the world
- **Acquiring a thorough knowledge** of the preparation and use of the products of vet. immunology used to eradicate and to control brucellosis including the evaluation of vaccines



2. Facilitate **harmonization** of techniques throughout the EU, in particular specifying standard test methodologies
3. Organise **workshops** for the benefit of NRLs, including training of experts from the MS and, as appropriate, from non-member countries, in new analytical methodologies.



4. Provide **technical assistance** to the **Commission**, concerning in particular the standardisation of analytical methods and their implementation
5. Perform **research activities** and whenever possible co-ordinate research activities directed towards improving control and eradication of brucellosis, *specifically by:*
 - Carrying out or collaborating with NRLs in carrying out test validation trials
 - Providing scientific advice to the Commission services and collecting information and reports associated with the activities of the EURL



Brucellosis EURL's work completed

2006-2012



1. Coordinate the diagnostic methods employed in the MS by:

- **Typing, storing and supplying strains of *Brucella* sp. :**
 - Strains received and typed from:
 - Belgium (*B. suis*/*B. abortus*) / Estonia (*B. suis*)
 - Germany (*B. suis*) / Finland (*B. canis*)
 - Italy (*B. melitensis*/*B. suis*) / Poland (*B. suis*)
 - Portugal (*B. suis*) / Romania (*B. suis*)
 - Spain (*B. abortus*, *B. suis*) / Sweden (*B. canis*)
 - UK (*B. ceti*)
 - **Objective: set up a EU strain collection**
- Reference strains supplied to several MS (incl. S99, Rev.1 and S19)



1. Coordinate the diagnostic methods employed in the MS by:

- Preparing, controlling and supplying International Standard sera and other reference reagents to the NRLs (to standardise tests and reagents in the MS)
 - Sheep and goats EU standard sera (2008-2009)
 - Porcine EU standard serum (2012)
 - *B. ovis* EU standard serum (2012)
 - *B. canis* EU standard serum (2012)
 - EU reference brucellin (2011)
 - Anti-A & -M monospecific sera – Anti-R serum
 - Phages Tb, Wb, Iz₁, R/C
 - *B. ovis* CFT antigen produced
- Validating reference reagents (antigens and National Standard sera)
 - National standard sera already evaluated for the CFT
 - Some standards for iELISA (bovine) controlled
 - EU ELISA kits – Italian Brucellin



1. Coordinate the diagnostic methods employed in the MS by:

- Building up and maintain a sera bank, a collection of *Brucella sp.*, and a database of strains isolated across the EU
 - Porcine, bovine, ovine and caprine sera collected from free and infected populations (see tests evaluations)
- Organising periodical comparative tests of diagnostic procedures at EU level and operating laboratory proficiency tests of NRLs
 - Proficiency ring-trials - *Milk indirect ELISA (2) - Blood tests (2)*
 - Based on a simple protocol
 - No statistics Means
 - Standardised reagents
 - Standard procedures (as strict as possible)
 - Help and support for identifying the causes of failure
 - Validation ring-trials (*EU standards - CFT procedure*)
 - Based on a consensus protocol and results validation
 - On a voluntary basis – limited to experienced and « good » labs



1. Coordinate the diagnostic methods employed in the MS by:

- **Collecting and collating data** and information on the methods of diagnosis used and the results of tests carried out in the EU
 - EU NRLs annual reports
 - 2007-2012 report

Objective: improving transparency in parallel with EFSA efforts as regards the zoonoses report to regularly inform the Commission

Content:

Diagnostic tests used and diagnostic strategies

Controls performed on reagents and vaccines

Quality assurance & accreditation at NRL and local labs levels

Epidemiological information as regards Brucella strains in domestic animals and wildlife (human when possible)

- **Acquiring a thorough knowledge** of the preparation and use of the products of vet. immunology used to eradicate and to control brucellosis including the evaluation of vaccines
 - Evaluation of vaccine batches from France, Italy and Spain (S19 & Rev.1)



2. Facilitate **harmonization** of techniques throughout the EU, in particular specifying standard test methodologies

- SOP RBT
- SOP EU CFT
- Guidelines ELISA
- Isolation and identification of Brucella *(to be completed)*
- *Control of RBT, CFT, SAT, MRT antigens (to be validated)*
- *Control of serum and milk ELISA (to be validated)*



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3. Organise **workshops** for the benefit of NRLs, including training of experts from the MS and, as appropriate, from non-member countries, in new analytical methodologies.

- 2007 (Maisons-Alfort) *The new EURL and the NRLs network*
- 2008 (Maisons-Alfort) *False positive serological reactions (FPSR) in Brucellosis*
- 2009 (Lisbon) *Sheep and goats brucellosis*
- 2010 (Brussels) *ring trials*
- 2011 (Malta) *Identification and Typing of Brucella: Bacteriology and Molecular Biology*
- 2012 (Maisons-Alfort) *ring trials*

*Open to candidate countries (Fyrom, Croatia, Turkey),
EES (N, CH, Iceland) & Balkans (BiH, Serb, Ko, Alb, Mo)*

And **training sessions** (CFT and bacteriology)



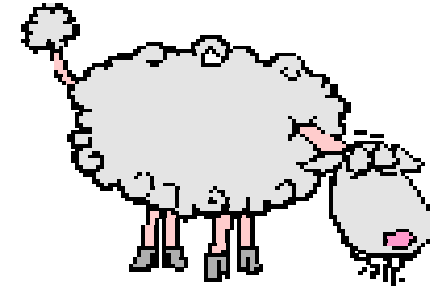
4. Provide **technical assistance** to the **Commission**, concerning in particular the standardisation of analytical methods and their implementation

- Future or revised regulations
- Task Force

5. Perform **research activities** and whenever possible co-ordinate research activities directed towards improving control and eradication of brucellosis

- Assessment of tests for bovine, sheep & goats brucellosis (EFSA report)
- Assessment of tests for porcine brucellosis and *B. ovis* infection
- RT-PCR
- MLVA





Merci de votre attention...
Grazie per l'attenzione!