Accreditation of official laboratories

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Background

- Article 12 of Regulation (EC) No 882/2004:
  - Competent authorities designate laboratories that carry out analysis of samples taken during official controls
  - To be designated, laboratories have to be accredited in accordance with EN ISO/IEC 17025 on « General requirements for the competence of testing and calibration laboratories »
  - The accreditation « may relate to individual tests or groups of tests »
- Recurrent findings of FVO: lack of accreditation of some official laboratories
- Specific situations (e.g. emerging risks, Trichinella)
- Different understandings of legal or ISO requirements
Consultations of the MS and discussions

- WG on Regulation (EC) No 882/2004 meetings in May and September 2010
- Answers from Regulation (EC) No 882/2004 competent authorities (CAs) to discussion paper on laboratory accreditation sent in January 2011
- Meeting of WG on Regulation (EC) No 882/2004 in May 2011
- Discussion at Animal Health (AH) WG (01.06.2011) and answers from AH WG members to discussion paper on laboratory accreditation sent 16.06.2011
- Plant Health WG and Chief Officers for Plant Health (COPHs) meetings in 2011 (in particular discussions of Task Force 5 on the inclusion of plant health in Regulation (EC) No 882/2004)
Consultation of the Animal Health Working Group

**Objective** of the consultation: to have additional comments:

- on **animal health specific issues** within the framework of official controls
- on issues raised by the **application of the mandatory accreditation to laboratories analysing samples taken during activities other than official controls** (epidemiological surveillance, etc.)

- Issue: **Article 12.3** of Regulation (EC) No 882/2004 according to which the accreditation of laboratories in accordance with ISO 17025 “may relate to individual tests or groups of tests”

- Comments from MS: sentence needs to be clarified

**Clarification of Article 12 of Regulation (EC) No 882/2004:** unless otherwise specified, scope of accreditation shall include all methods used by the laboratory as official laboratory
Issue 2: use of a method recently required in legislation

• Issue: use of a method is a recent/new requirement in Union legislation and requires validation of the new method and (in general) a new accreditation or an extension of accreditation of the laboratory

• Comments from MS: time needed for validation of the method and accreditation of the laboratory, use of a validated but « not (yet) accredited » method by an already ISO 17025 accredited laboratory should be possible

Possibility for the CA of temporary designation with alternative guarantees: laboratory already accredited ISO 17025 (quality assurance system in place) to ensure sound and reliable results, analysis/diagnosis under supervision of CA or national reference laboratory (NRL), temporary designation not exceeding 1 year renewable once – Modification of Article 12 of Regulation (EC) N° 882/2004
Issue 3: changes of a method already in use

- Issue: changes of a method already in use require a new accreditation or an extension of the accreditation already obtained by the laboratory.

- Comments from MS: same as for issue 2

- Possibility for the CA of temporary designation with alternative guarantees (same as for issue 2) - Modification of Article 12 of Regulation (EC) No 882/2004
Issue 4: emergency situations and emerging risks

- Issue: emergency situations or cases of emerging risks where a sudden increase of analytical needs requires the use by official laboratories of a non standardised or non validated method or a standardised method which is not included in their scope of accreditation.

- Comment from MS: swift and efficient management of the situation/risk is the priority, use of a validated but « not (yet) accredited » method by an already ISO 17025 accredited laboratory should be possible.

- Possibility for the CA of temporary designation with alternative guarantees (same as for issues 2 and 3)—Modification of Article 12 of Regulation (EC) No 882/2004
Issue 5: small sized *Trichinella* laboratories

- Issue: important difficulties for small sized *Trichinella* laboratories attached to slaughterhouses or game handling establishments to be accredited ISO 17025

Empowerment for Commission to grant permanent derogations for small sized laboratories attached to food business operators’ (FBOs) premises – Modification of Article 12 of Regulation (EC) No 882/2004

Possible conditions: the laboratory
- performs only specific tests prescribed in Union legislation
  - on a limited number of samples pertaining to the FBOs’ process
  - using standardised/validation methods
- has a quality assurance system in place
- operates under the supervision of an accredited laboratory or of the competent authority
Issue 6: accreditation of animal health laboratories

- Comments from MS: accreditation may be difficult:
  - for methods used in diagnosis of viral diseases because of important resources needed for documentation and validation
  - for methods used in diagnosis of parasitic diseases because of multitude of parasitic diseases and broad spectrum of diagnostic tests

 penyModification of Article 12 of Regulation (EC) No 882/2004: empowerment for the definition of exemptions to Article 12.3 taking into account specific characteristics of the AH sector
Issue 7: participation at proficiency tests (PTs) or comparative tests (CTs)

- Issue:
  - ISO 17025 recommends the participation at PTs/CTs
  - In some areas, like residues of veterinary medicines and pesticides, legislation provides for mandatory participation
  - Sometimes lack of participation of laboratories at PTs/CTs, sometimes lack of PTs/CTs organised, different interpretations of ISO 17025, different mandatory minimum frequencies of participation at PTs/CTs
Issue 7: participation at proficiency tests (PTs) or comparative tests (CTs)

• Comments from the MS:
  • **Frequent/regular participation at PTs/CTs** relevant to the scope of accreditation of the laboratory and satisfactory performance at these PTs/CTs are **absolutely necessary/mandatory**
  
  • To ensure higher participation at PTs/CTs: participation at EURL PTs to be made possible for routine laboratories, possibility to participate at PTs/CTs from NRLs from other MS, organisation of PTs/CTs in a more « horizontal » manner

 Modification of Article 12 of Regulation (EC) No 882/2004: mandatory participation of official laboratories at PTs/CTs organised in their scope of accreditation by the EURL or the NRL on request by either of them
Issue 8: validation of methods

- Issue: ISO 17025:
  - The laboratory has to use standardised methods or validated methods
  - Which methods are / have equivalent status to «standardised methods»?

- Comments from the MS: methods validated by EURLs/NRLs to be given equivalent status to standardised methods
Issue 8: validation of methods

Modification of Article 11 of Regulation (EC) No 882/2004: methods validated by EURLs/NRLs have equivalent status to standardised methods

- Validated methods by EURLs:
  - all EU ABs to deliver accreditation for the use within intended scope of these methods without requesting supplementary internal validation by the laboratory (only verification by laboratory)

- Validated methods by the NRL in a MS:
  - AB of this MS to deliver accreditation for the use within intended scope of these methods without requesting supplementary internal validation by a laboratory in the MS (only verification by laboratory)
Issue 9: specific mandatory methods in legislation

- Issue: lack of flexibility of the system due to too specific mandatory methods in legislation (e.g. in case of changes of the method, emergency situations)

- Comments from the MS: mandatory method performance criteria should be preferred when establishing legislation (instead of mandatory specific methods) to ease/fasten the introduction and use of the latest and most appropriate method

Concerns specific legislation
Issue 10: flexible scope / fixed scope accreditation

- Issue: very different/diverging requirements in particular for flexible scope accreditation (but also for fixed scope accreditation) from one AB to another

- Comments from MS:
  - EA Guide – 2/15 on accreditation of flexible scopes too general
  - Harmonised interpretation of accreditation of flexible scopes absolutely needed accross the EU (if not, huge differences in levels of difficulty, time needed and costs for laboratories)
  - Accreditation of flexible scope in particular usefull if no specific assessment by AB prior to the addition of the matrix/analyte/method to the scope (e.g. in case of emergency situations and emerging risks)
Issue 10: flexible scope / fixed scope accreditation

Additional EA guidance on pros and cons of flexible and fixed scopes, with examples, on what a flexible scope could cover and corresponding precise requirements, on degrees of flexibility of flexible scopes, on flexible scope accreditation assessments by ABs
Thank you for your attention!