

**DOCUMENT ON FLEXIBLE SCOPE
DEVELOPED BY THE EPPO PANEL ON
DIAGNOSTICS AND QUALITY
ASSURANCE**

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Background

- EPPO Workshop on Accreditation for plant pest diagnostic laboratories (York, GB, 2014-02-18/20)



- Discussions on flexible scope in the region
- Lack of harmonisation among accreditation bodies
- Special requirements in plant health



Background

Conclusion of the Workshop:

- EPPO should raise the issue of flexible scope with the European cooperation for Accreditation (EA)



Follow up

- EPPO subsequently attended a meeting organized by EA.
 - EA experts suggested that EPPO should prepare guidelines on the needs for a flexible scope in plant health and provide these to the EA as a discussion basis.
- An EWG composed of French, Dutch, Danish, British and Belgian experts met on 2014-09-11/12
 - A discussion paper was drafted on the approach to flexible scope in plant health



Discussion paper on the approach to flexible scope in plant health

- Content

- Description of specific challenges in plant health
- Suggestions for possible solutions for flexible scope approaches in the region.



Review process

- The Panel on Diagnostics and Quality Assurance (2014-11-25/26) reviewed the discussion paper
 - The document was considered too long and shortened
 - Only the most essential parts were kept describing the specific situation for plant health and possible solutions.
 - All comparisons to food safety, animal health or microbiology were removed.
 - A final version was prepared.



Main points in the final document presented to EA

- **Current context for laboratories performing official plant pest diagnostic activities**
 - ISO/IEC Standard 17025 accreditation
 - PM 7/098 *Specific requirements for laboratories preparing accreditation for a plant pest diagnostic activity* provides specific guidance to harmonize the implementation of ISO 17025
 - Control regulation EC no 882/2004 (current proposal under revision and includes phytosanitary area – requirement that all laboratories performing official analysis have to be accredited and the scope of the accreditation shall include ‘all methods used’)



Main points in the final document presented to EA

- **Specific challenges of accreditation for plant pest diagnostics**
 - Diversity of pests and pest/host matrices and possible combinations, and consequences for validation.
 - Low number of samples for specific tests
 - Differences between detection and diagnosis
 - Lack of reference material (including regulated pests and their 'look-alikes')
 - Proficiency tests



Main points in the final document presented to EA

- **Potential solutions**

- Proficiency testing on method level rather than pest/method/matrix
- Level of validation modified
- Confirmation of a diagnosis or diagnosis of unknowns reviewed



Where we are now....

- **Feedback from EA Accreditation bodies (AB) (discussed at the meeting for food and feed)**
 - 1st there are ABs without no experience in the accreditation of pest diagnostic laboratories.
 - 2nd, there are ABs that don't see any provision for phytosanitary testing is needed, because most issues discussed in the EPPO document are already well covered by existing EA rules (e.g. EA 2-15)..and
 - 3rd there are ABs that welcome this potential use of this document.
- **EA General points**
 - On distinction between testing for diagnostic purposes and the diagnosis itself.
 - "real" diagnosis (diagnosis of unknowns), much more complex and which is based on expertise. For us, this type of diagnosis can not be treated by flexible scopes and is outside the scope of ISO/CEI 17025.



What next....

- Outputs from the EA LC meeting 9-10 September in Belgrade
- Feedback from this group? Any other issues that need to be considered?
- Thank you for your attention.

