

Implementation of ISO/IEC 17025:2017 at Fera in the UK



Rebecca Weekes



Joint venture, formed on 1 April 2015 between Capita (75% - private sector) and Defra (25% - government) to:

- Delivering better outcomes through expert scientific services for public goods and competitive advantage
- National resilience for food & environmental incidents
- Transforming food production
- Investing ca 10% of revenues in R&D
- UK National Reference Laboratory for food safety across 9 scopes
- Recognized by EFSA; Article 36 as competent organization Food Safety Regulation and Standards
- Lead partner in Crop Health and Protection Centre
- 100 years of Regulatory, Safety & Expert Support to Government



Facilities, Partners and Operations



400 staff
including **300** scientists



94 acres secure site with field plots, Glasshouses, specialist wildlife and a new E-Flows mesocosm



75%/25% ownership by Capita/ Defra



Over **100** procedures covered by the UKAS accreditation to the ISO/IEC 17025 Standard



Fera acts as National Reference Laboratory under Regulation (EU) 2917/625 in **7** areas



The Fera entomology collection contains over **150,000** specimens and is a nationally important reference resource



Containment Level [CL] **3** laboratories



Fapas proficiency testing scheme has more than **4,500** participants in over **120** countries



Fera is a founding member of CHAP, one of the Government's Centres for Agricultural Innovation



Adding value across the agri-food chain

Plant and
bee health

Risk
assessment
and analysis

Novel
Diagnostics
and
surveillance

Food and
feed safety

Proficiency
testing and
reference
materials



Crop
Protection

Sustainable
Agriculture

Chemical
safety &
stewardship

Food quality
and
authenticity

Waste
reduction and
biorenewables

The Plant Protection Programme

The Plant Clinic

R&D

Entomology

Virology

Bacteriology

Mycology

Nematology

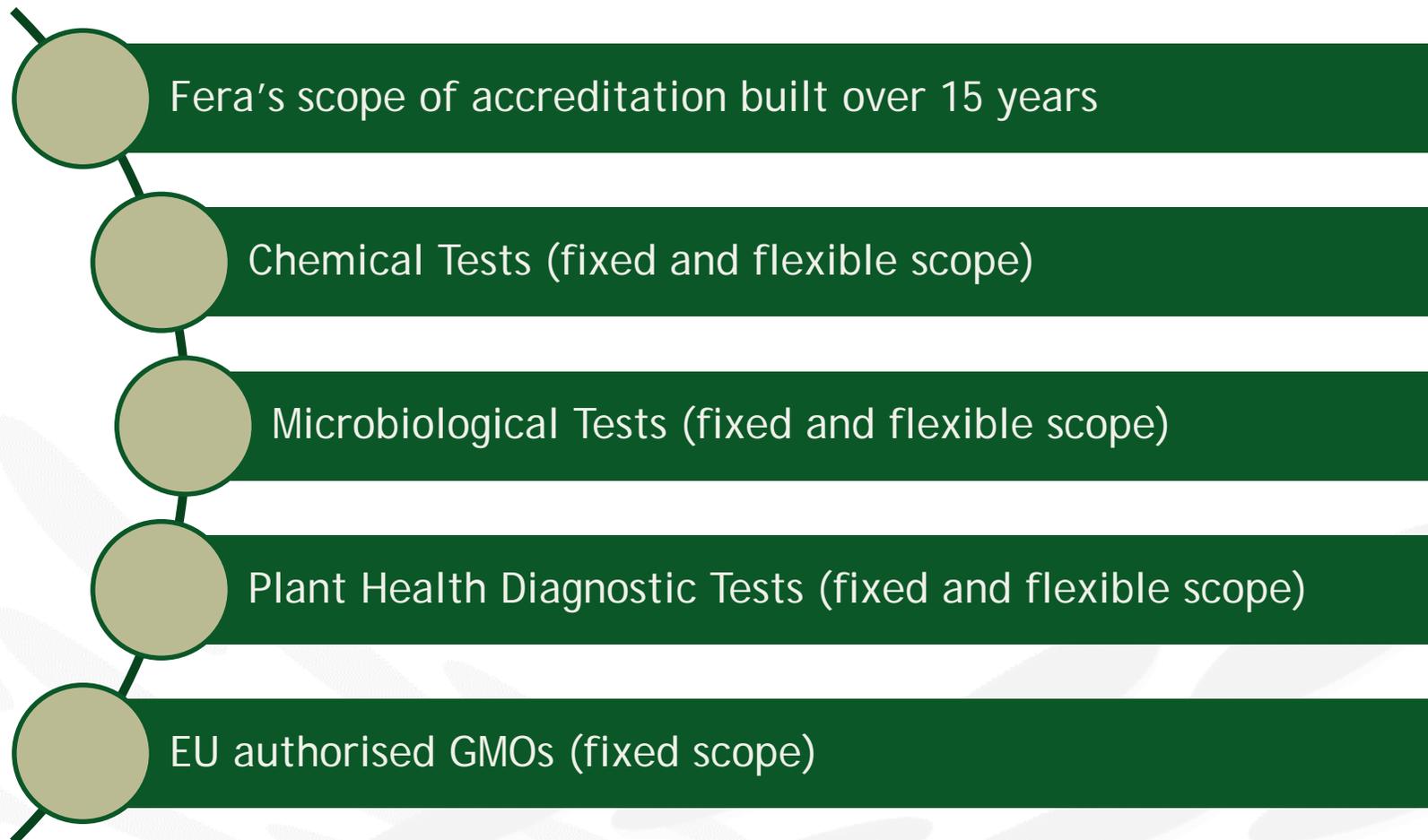
Seeds

Molecular Technology Unit

- National Reference Laboratory
- More than 30,000 samples each year for government and commercial customers worldwide
- Quarantine glasshouse and drainage facilities
- 200+ years of experience across Plant Clinic
- National Collections of plant pests
- Provision of advice and training
- Emergency Response



ISO 17025 at Fera



ISO 17025:2017 transition process



Gap Analysis

- Review of new standard and training (November 2018)
- Identify changes required and impacts
- Completion of transition template (June 2019)



Audit

- UKAS visit (July 2019)
- Clearance of transition findings (October 2019)



Transition

- Next UKAS visit Fera will be audited against the new version of the standard (July 2020)

Transitions findings

- **8 findings** – requirements in the new standard can be addressed by clearance of the mandatory findings.
- **Impartiality** – although this is embedded when people start work in the organisation, we need to actively re-visit and confirm the impartiality responsibilities of staff.
- **Personnel** – documenting competence; although training records are in place we are not consistently documenting ongoing competence and the objective supporting evidence (except in the Plants Programme).
- **Equipment** – insufficient recording of software versions.
- **Reporting results** – need to ensure consistent implementation of the requirements of the new standard.
- **Complaints** – processes are in place but we need to include an independent review prior to the final customer response.

Areas we are improving:

- **Internal proficiency tests** – we have implemented an annual programme of tests. A set of blind samples to test the diagnostician’s ability to correctly perform a particular test. Evidence is recorded in training file and a process has been put in place to deal with failed tests. This process will be shared across the organisation.
- **Impartiality risks and conflicts of interest** – risk logs are being used to identify and analyse risks. High level and project management risk logs are in place to capture issues around impartiality and conflict of interest. We will be rolling out an annual reminder to all staff to review and declare any potential conflicts of interest.
- **Adoption of best practice across a large and diverse organisation** - some areas were already compliant with the new requirements, but implementation was not consistent across the whole organisation. More effective use of internal auditors to focus on particular areas and help implement best practice (e.g. reporting results and internal proficiency tests).



Original thinking... applied

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Original thinking... applied

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