

QA at Fera - current situation



Fera Science Ltd



Original thinking... applied

'To support and develop a sustainable food chain, a healthy natural environment, and to protect the global community from biological and chemical risks'

- Scientific heritage of over 100 years
- Joint venture between Capita & Defra, since 1st April 2015
- Long-term services agreement with Defra to maintain core capability.
- Helping industry stay ahead of tomorrow's regulation and enhance it's brand values
- Providing expert support and innovative science



Institute for Plant Pathology, 1914

CAPITA



Institute for
Agri-Food Research and Innovation



Fera 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



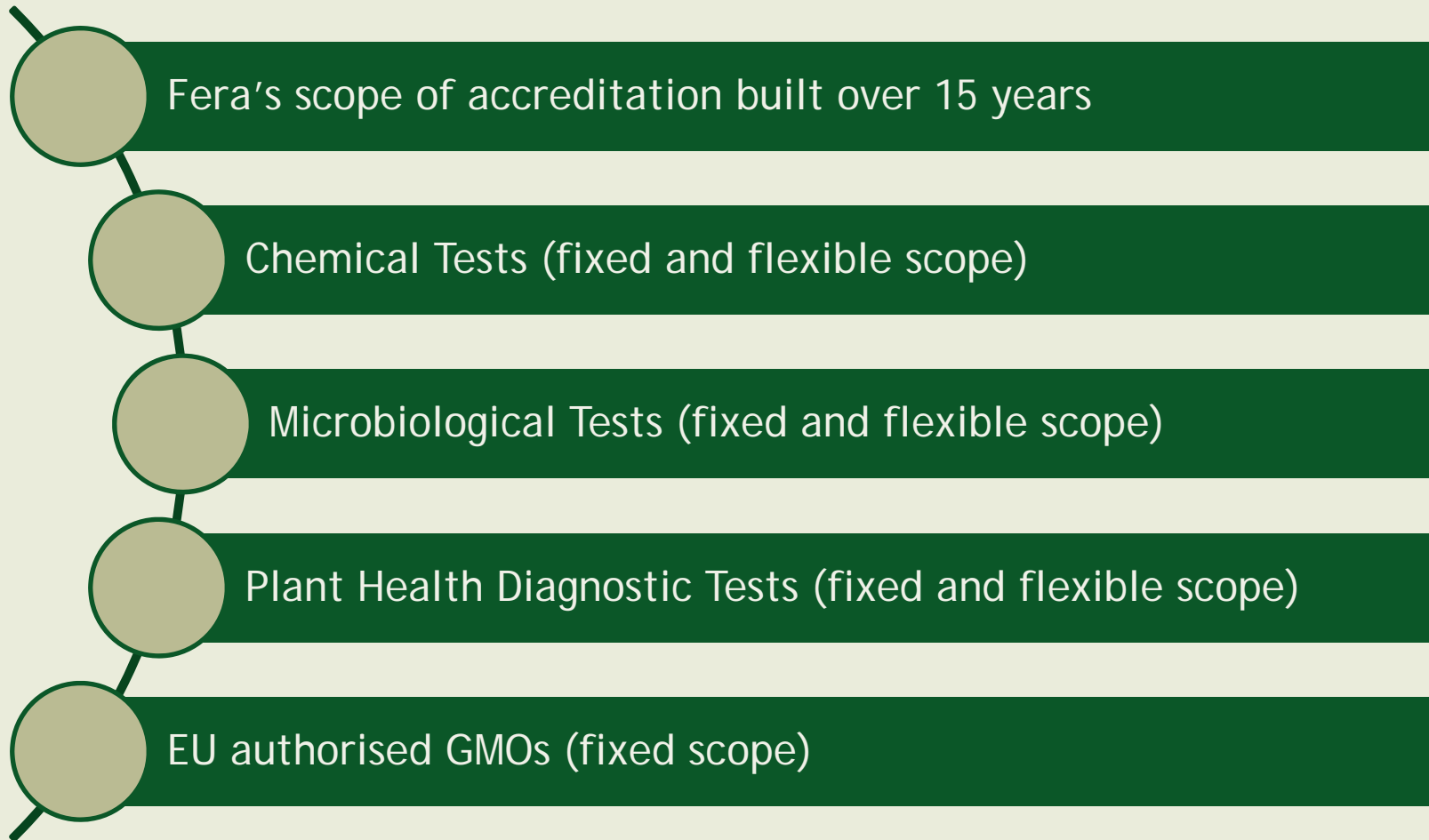
Fera Plant Clinic



ISO17025 at Fera



Original thinking... applied

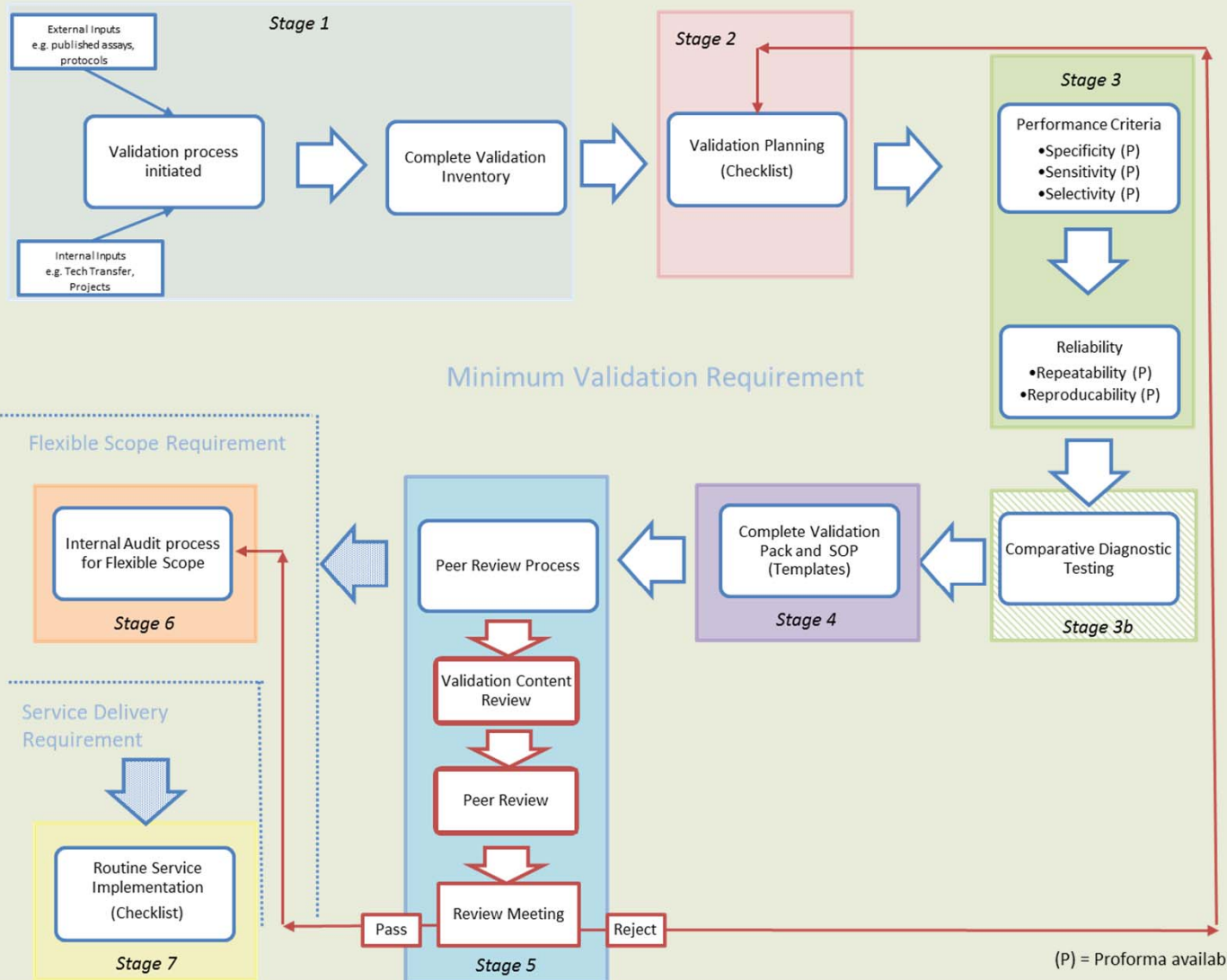


How are we using PM 7/98?



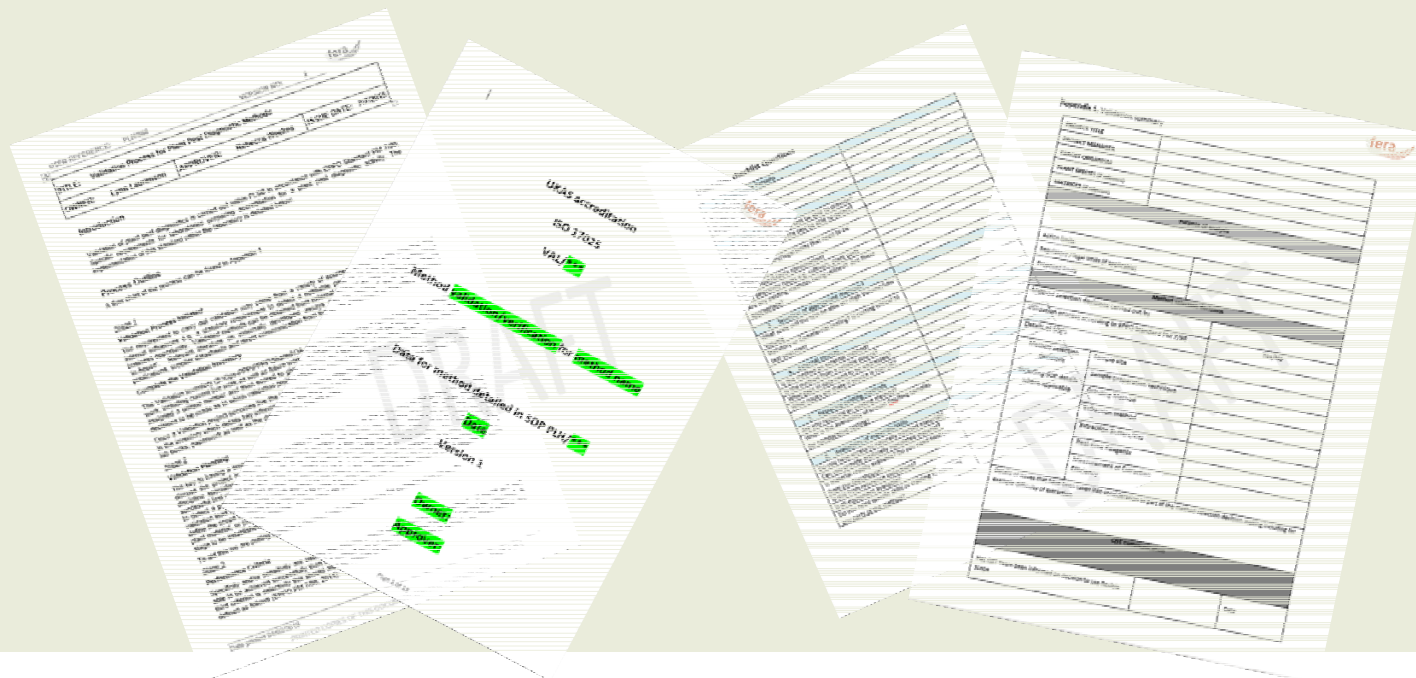
Original thinking... applied

PPP Method Validation Process



Things we've improved:

- Validation groups for discussing and planning
- Mentoring - pairing R&D scientists with diagnosticians to share knowledge
- Better templates with author's notes for SOPs and validation packs
- Aligning the validation summary with the EPPO validation database



Where we sometimes get stuck:

- Matrix issues - when a pest has a huge host range
- End point dilutions and LoD in particular for virology/viroid validations
- Approval of the validation pack
- Adding our data to the EPPO database!!
- Re-visiting evaluation of measurement uncertainty
- Validation of HTS



Validation of HTS



- Can EPPO Standard PM 7/98 be used as a framework for HTS validation?
 - Sensitivity - what depth of sequencing is enough; how many reads is enough?
 - Specificity - range of detection (target and non-target pathogen)
 - Selectivity - influences on assay e.g. cultivar effects
 - Repeatability - at LOD
 - Reproducibility - different operators/equipment
- What question are you trying to answer; 'what is it' or 'is it in there'?
- Needs to be part of a diagnostic work flow
- This needs some lateral thinking

ISO/IEC 17025:2017



Original thinking... applied



Conclusion



- PM7/98 is embedded and is at the core of our validation process
- We still come up against problems, but this is due to the pest not the standard.
- This will be the year that we add our validation data to the EPPO database!
- Validation & accreditation of HTS is our next challenge
- Gap analysis has shown us what we need to do to prepare for 17025:2017
- Measurement uncertainty is uncertain; our approach based on critical points is no longer keeping the auditor happy.



Questions?