



Application of ISO 17025 flexible scope at Fera

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Current Flexible Scope Position



- Fera currently holds ISO17025 fixed scope accreditation for several exemplar methods
- Every discipline has at least one accredited method
- However, not all ‘families’ of tests are covered
- We also hold flexible scope accreditation for diagnostics in “Real-time PCR for plant pests”
 - Covers all plant health testing by real-time PCR once validation data is produced

Current Position



Potential Flexible Scope 'Families'	Discipline	Flexible?	Current Fixed?
Real-time PCR for plant pests and pathogens	All/MTU	✓	✓
Conventional PCR	All/MTU		
DNA Barcoding / Nucleic acid sequencing	All/MTU		
LAMP for plant pests and pathogens	All/MTU		
ELISA testing	Vir/Myc		✓
Sap Inoculation	Vir		
Agar Test	Seed		
Blotter Test	Seed		
Wash Test	Seed		
Culturing for diagnosis	Myc/Bact		✓
IF Microscopy	Bact		
Fatty Acid Profiling	Bact		✓
Free Living Nematodes	Nem		✓
Cyst Forming Nematodes	Nem		✓
Bait Testing	Myc/Vir		
Bioassay/Host Tests	Bact		✓
Next Generation Sequencing	Vir/MTU		
Horizontal Documentation (e.g.validation)	All		

Strategy Overview



Diagnostic process



*Derogation for propagation material may mean the seeds can pursue broader ISTA accreditation

** For collections used for reference material we may also want to accredit to ISO 34:2009 as well as ISO17025



Approach & prioritisation

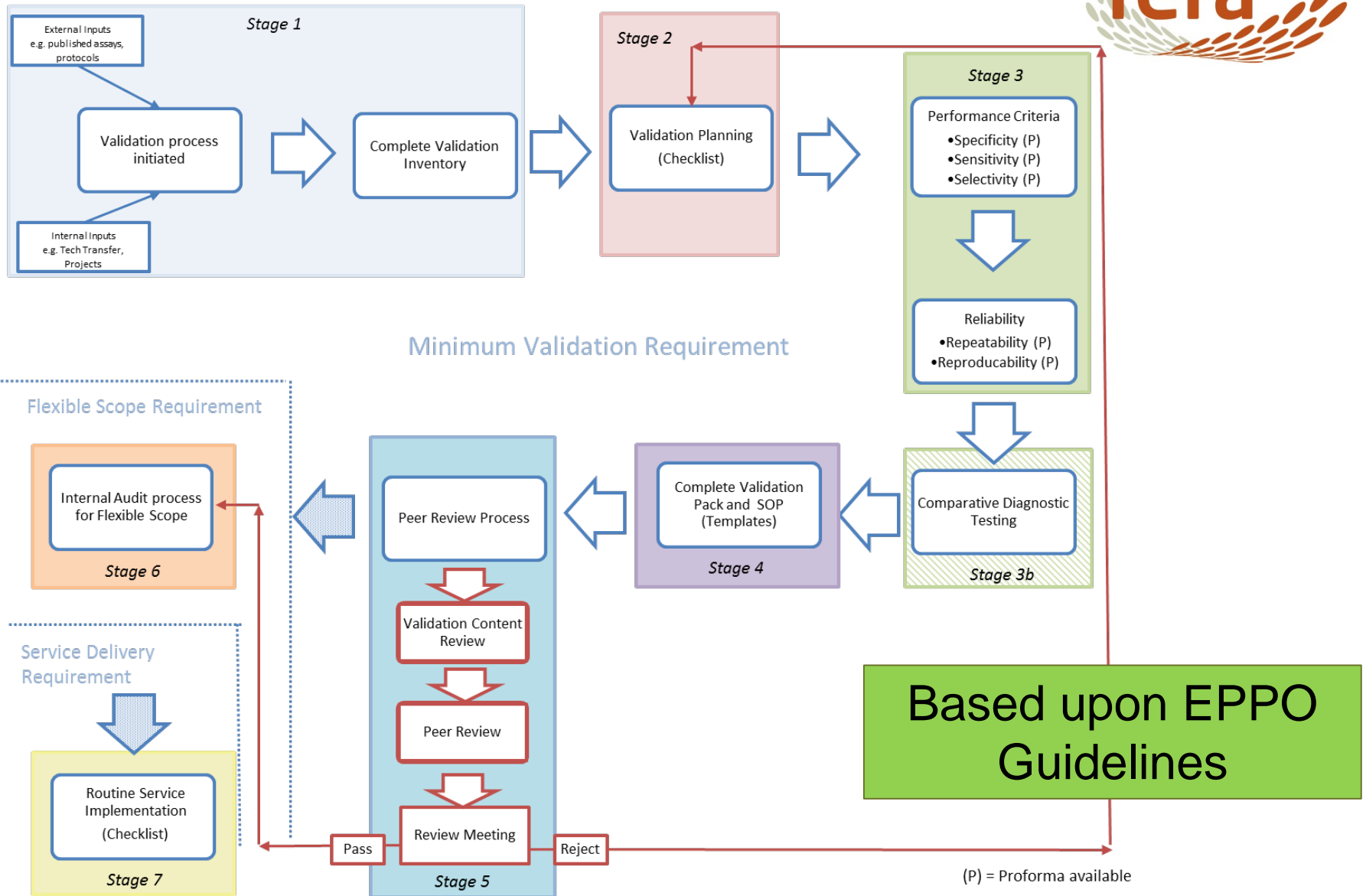
- Fill gaps: fixed scope in all families where it doesn't already exist (convert to flex within 2 years)
- Convert existing fixed to flexible scope
- As propagation material not in the current review, may mean the seeds can pursue broader ISTA accreditation
- For collections used for reference material we may also want to accredit to ISO 34:2009 ('Competence of reference material producers'), as well as ISO17025

Anticipated timing of future accreditation



Potential Flexible Scope 'Families'	Fixed?	Flexible?	Comments
Real-time PCR for plant pests and pathogens	✓	✓	
Conventional PCR	2016	2017	
DNA Barcoding / Nucleic acid sequencing	TBC		Awaiting EPPO document on validation
LAMP for plant pests and pathogens	2016	TBC	
ELISA testing (Virology)	2016	2017	
Sap Inoculation ‡	2017		
Agar Test	2017		
Blotter Test	2017		
Wash Test	2017		
Culturing for diagnosis	✓	2017	
IF Microscopy	2017		
Fatty Acid Profiling	✓	2017	
Free Living Nematodes	✓	TBC	Morphological Identification
Cyst Forming Nematodes	✓	TBC	Morphological Identification
Bait Testing	2017		
Bioassay/Host Tests ‡	✓		
Next Generation Sequencing	2016		Being pursued by Molecular R&D
Entomology Identification	✓	TBC	Morphological Identification
Horizontal Documentation (e.g.validation)	TBC		Approach currently under discussion

PPP Method Validation Process



(P) = Proforma available

Morphological identification

- Still no clear way forward identified but progress is being made
- Ongoing discussions at the regional level with EPPO, about most appropriate approach
- Being lead by EPPO Panel on Entomology
- Fera are engaged (Dom Collins, Fera) and will follow EPPO lead in this area

Alternative ISO standard?

- ISO/CD 13484 : Foodstuffs -- General requirements for molecular biology analysis for detection and identification of destructive organisms in plants and derived products
- New standard being developed - seen as a simpler approach than ISO17025 (currently moving toward the Draft International Standard stage)
- While being pushed by USA, unlikely to be accepted by EU (currently committed to ISO17025)
- Concern about a 'two standard system' (how will it all fit together?)

Flexible scope – challenges

- Still not fully flexible: need to streamline method validation/verification and validation packs.
- Lessons to learn from analytical chemistry – ability to rapidly add new matrix-analyte combinations
- Major challenge: maintaining accreditation when sample numbers are too low
 - UKAS view: there will be challenge over why the method is on the scope if it has not been used since the previous audit