



WP 3

Minimum quality guidelines for EU reference collections of quarantine plant pests and invasive plants.

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Q-collect Workshop
Rome, 2015-09-08/09



Objectives of Q-Collect WP3

	<u>Month</u>
3.1. Review current quality control standards in EU collections of quarantine organisms.	12 <input checked="" type="checkbox"/>
3.2. Define and agree minimum quality standards that can be applied within EU collections.	15 <input checked="" type="checkbox"/>
3.3. Produce harmonised guidelines to achieve recommended quality standards during: <ul style="list-style-type: none">– preparation– conservation– shipment/access– use of reference materials	19 <input checked="" type="checkbox"/>
3.4. Facilitate consultation with other collections and end-users in EU and EPPO countries to harmonise and increase awareness of quality.	24

Why do we need quality standards in reference collections?

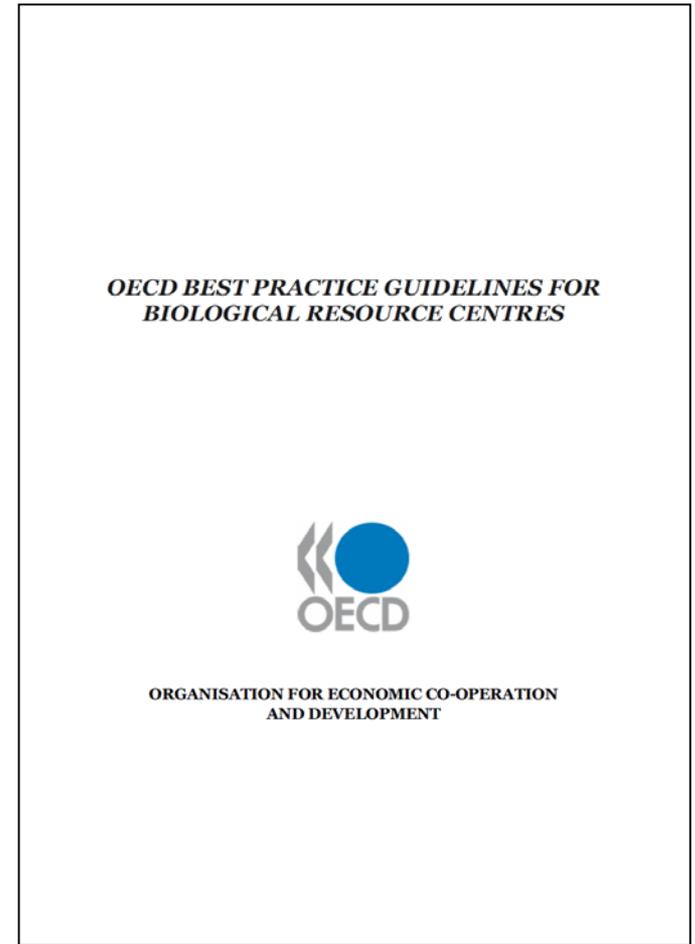
- To further safeguard biodiversity.
- To more effectively support R&D and diagnostics.
- To underpin accurate taxonomic classification and identification.
- To ensure consistent service irrespective of the source of reference materials or information.

Existing guidelines

OECD Working Party on Biotechnology (2007)

- Best practice guidelines for biological resource centres (BRCs)
- Basic quality management guidance
 - General
 - Micro-organisms
 - Plants & Animals
- Compliance by only a few larger reference collections – aspirational for most

<http://www.oecd.org/sti/biotech/38777417.pdf>



Existing guidelines



Common Access to Biological Resources and Information (CABRI) database (<http://cabri.org>) - 1996

- Bacteria, fungi and viruses
- 7 member BRCs (including BCCM, CABI, CBS and DSMZ)
- CABRI accreditation scheme
 - Methodologies, Quality Standards, Audits



World Federation for Culture Collections (WFCC) general guidelines (<http://www.wfcc.info/guidelines>) - 2010

- Cultures of microorganisms
- First step towards the implementation of the OECD Best Practice
- 10 members (including BCCM, CBS and DSMZ)



1. Quality management systems

- Essential for reliable housing and function of a reference collection
- Many reference collections follow ISO 9000 standards and are certified to ISO 9001: 2008 after audit by an accredited external certification body.
- Other quality management systems already exist, e.g.
 - CABRI accreditation scheme for culture collections
 - BRAHMS management system for herbaria and seedbanks
- EPPO standard PM 7/84 describes general and technical quality management requirements for diagnostic laboratories.



**EPPO PM 7/84 (1)
Basic requirements
for quality
management in
plant pest diagnosis
laboratories**



- Appropriate resources
- Purchase of supplies
- Definition of tasks & responsibilities
- Recognition & prevention of conflicts of interest
- Documentation & assessment of training
- Verification of subcontract quality
- Complaints procedures
- Confidentiality agreements
- Suitable documentation & archiving
- Procedures to record & correct non-compliances
- Periodic review of the system

- Standard operating procedures (SOPs) & technical manuals
- Training & records
- Proficiency testing
- Containment/Isolation
- Environmental conditions
- Space & no. of labs
- Maintenance & cleaning
- Preparation and disposal
- International/regional standards
- Method comparison & validation
- ID of equipment
- Calibration/maintenance



ISO standards

- ISO/IEC 9001:2008
 - Generic standard for quality management system
- ISO/IEC 17025: 2005
 - Technical standard demonstrating the competence of testing and calibration laboratories (technically assessed by experts)
- ISO Guide 34:2009
 - Confirms identity, characteristics and chain of custody of certified reference material
- ISO/IEC 17043: 2010
 - General requirements for proficiency testing
- ISO/IEC 11133:2014
 - Preparation & performance of culture media for laboratories performing microbiological analyses.

Minimum quality standards

a) Information required on accession

A reliable catalogue/inventory of all holdings of biological reference material and associated metadata are required, including:

- A unique accession number
- The date of accession (essential for viable organisms but also recommended for fixed specimens)
- Full scientific name
- Geographic source (at least to country of origin)
- The date of original collection
- Name and contact details of the depositor
- Current quarantine status
- Nomenclatural status (e.g. type, neotype, holotype)



Minimum quality standards

b) Data storage and maintenance

Ideally, the catalogue should be maintained in an electronic format and allow:

- Traceability of any changes made and persons responsible
- Sharing of publically accessible data fields with other collections/networks.

Also generally required:

- Procedures on database maintenance, data back-up and data-sharing.
- Staff training in data storage and maintenance
- Data handling and review restricted to competent staff
- Secure storage of contact details (donors, curators & customers)



Minimum quality standards

c) Authentication

A reference collection has an obligation to authenticate data on a particular specimen prior to its accession.

- Documented acquisition policy
- Archived standard procedures, where appropriate, for
 - labelling/barcoding new accessions
 - Identity and purity checks (including batch to batch variation, mixing, deterioration or contamination)
 - verification of viability and/or pathogenicity (usually only for bacterial or fungal pathogens)
- Records of movement of material/data in or out of the collection



Minimum quality standards

e) Storage and conservation

Methods for preservation and maintenance of accessions will vary with the type of organism collected.

Documented procedures should include:

- A maintenance plan for each type of material
- The type, location and specific conditions of all storage facilities
- Containment and biosecurity measures for live quarantine organisms
- Specific preservation methods
- Regularity of quality checks during storage
- Approaches to determine stability of accessions during storage or after loan periods
- Methods and timing of batch regeneration (for viable cultures)
- Requirements for duplication of collections for safe-keeping



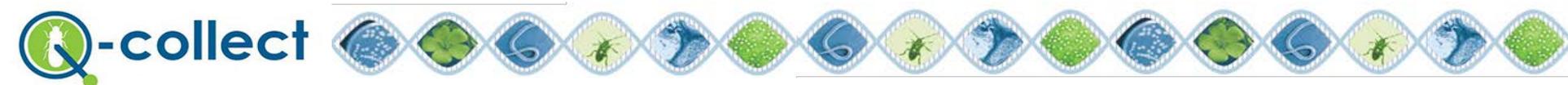
Minimum quality standards

f) Production of reference materials

Collections supplying specific reference materials should be able to ensure their authenticity and reproducibility.

Archived documents should include:

- Standard methods used to produce the materials
- Methods to assess and guarantee uniformity of reference material
- Documented evidence that a required trait is present in the material, e.g.
 - specific antigens for use as controls in serological tests
 - morphological characteristics indicative of a particular taxon
 - different concentrations, populations, matrices, mixtures, viability or levels of purity
- The chain of accession of specific taxa, as proof of authenticity.
- End-user instructions to accompany reference material



Minimum quality standards

g) Access to reference materials

Ideally, a collection database, showing the non-confidential fields, should be made publically accessible. Document archives should contain:

- New recipient form to authenticate customer registration details
- A template order form
- A material transfer agreement to inform the user of all rights and duties with respect to the material being supplied
- Procedures for ordering or loan of material, or other means of access
- Procedures for packing and shipment conforming to relevant national and international shipping and quarantine regulations.
- Customer communication procedures, including archiving and follow-up of feedback and complaints
- Procedures for dealing with non-conformance with the quality management system and other feedback from internal and external audits.



3. Minimum quality standards Appendix

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Issues	Information to be held / Standard operating procedures and competences required	Viruses/viroids	Phytoplasmas	Bacteria	Fungi/oomycetes	Nematodes	Insects/mites	Invasive Plants
Data to be stored on each accession	Specimen full scientific name	Required	Required	Required	Required	Required	Required	Required
	Geographic source of specimen (at least to country of origin)	Required	Required	Required	Required	Required	Required	Required
	Host plant or other source/substrate from which it was collected	Required	Required	Required	Required	Recommended	Recommended	Recommended
	Date (at least year) of sampling (where available)	Required	Required	Required	Required	Required	Required	Required
	Sampler/collector	Recommended	Recommended	Recommended	Recommended	Recommended	Recommended	Recommended
	Original specimen number or name given by collector (where available)	Recommended	Recommended	Recommended	Recommended	Recommended	Recommended	Recommended
	Unique accession number in the collection	Required	Required	Required	Required	Required	Required	Required
	Date of deposit in collection	Required	Required	Required	Required	Required	Required	Required
	Preservation conditions and date preserved	Recommended	Recommended	Recommended	Recommended	Recommended	Recommended	Recommended
	Reference to accession numbers for duplicates in other collections (where available)	Optional	Optional	Optional	Optional	Optional	Optional	Optional
	History from sampling to deposit in collection (if available)	Optional	Optional	Optional	Optional	Not applicable	Not applicable	Not applicable
	Traceable history of persons making identification	Optional	Optional	Optional	Optional	Optional	Optional	Optional
	Depositor (where known)	Required	Required	Required	Required	Required	Required	Required
	Current quarantine status in EU	Required	Required	Required	Required	Required	Required	Required
	Species Type (reference strain) strain (yes or no)	Required	Required	Required	Required	Required	Required	Required
	Authorities of scientific name	Not applicable	Not applicable	Recommended	Recommended	Recommended	Recommended	Recommended
	Links or references to sequence data from the accession	Optional	Optional	Optional	Optional	Optional	Optional	Optional
	Date of last viability test	Recommended	Not applicable	Recommended	Recommended	Recommended	Not applicable	Not applicable
	Date of last authenticity check/purity test	Recommended	Recommended	Recommended	Recommended	Not applicable	Not applicable	Not applicable
	Date of last pathogenicity test	Not applicable	Not applicable	Optional	Optional	Optional	Optional	Optional
Traceable history of all quality control checks and persons involved	Recommended	Recommended	Recommended	Recommended	Recommended	Recommended	Recommended	
Images of the accession	Not required	Not required	Not required	Optional	Optional	Optional	Optional	
Literature references to use of the accession as reference material	Optional	Optional	Optional	Optional	Optional	Optional	Optional	
Morphological/morphometric data	Optional	Not applicable	Optional	Optional	Optional	Optional	Optional	
Expected reactions when used as reference material in specific diagnostic tests	Recommended	Recommended	Recommended	Recommended	Recommended	Not applicable	Not applicable	
Data storage procedures	Database maintenance procedures	Required	Required	Required	Required	Required	Required	Required
	Data back-up process procedures	Required	Required	Required	Required	Required	Required	Required
	Sharing procedures for selected data (e.g. via website or paper inventory/catalogue)	Required	Required	Required	Required	Required	Required	Required
Identification methods	Sources and use of identification keys (where used)	Not applicable	Recommended	Recommended	Recommended	Recommended	Recommended	Recommended
	Classical morphological descriptions (where used)	Recommended	Not applicable	Recommended	Recommended	Recommended	Recommended	Recommended
	Morphometric analysis of specimens (where used)	Recommended	Not applicable	Recommended	Recommended	Recommended	Recommended	Recommended
	Other phenotyping methods (examples)	Recommended	Not applicable	Recommended	Not applicable	Not applicable	Not applicable	Not applicable
	DNA/RNA sequencing/barcoding methods (where available)	Recommended	Recommended	Recommended	Recommended	Recommended	Recommended	Recommended
	Other identification methods (examples)	Recommended	Not applicable	Recommended	Not applicable	Recommended	Not applicable	Not applicable
Updating taxonomy	Sources of approved taxa (examples)	Required	Required	Required	Required	Required	Required	
Current quarantine status	Sources of current lists of quarantine organisms and invasive plants	Recommended	Recommended	Recommended	Recommended	Recommended	Recommended	
Contact details	Contact details for persons responsible for the collection	Required	Required	Required	Required	Required	Required	
Labelling	Unique number assignment/barcode labelling	Required	Required	Required	Required	Required	Required	
Storage facilities	Containment/isolation measures	Required	Required	Required	Required	Required	Required	
Purity	Measures to avoid cross-contamination or mixing	Required	Not applicable	Required	Required	Required	Required	
Chain of accession	Record keeping for movement of accessions in and out of the collection	Required	Required	Required	Required	Required	Required	
Comparison with original accession	Methods to check batch to batch variation	Required	Required	Required	Required	Optional	Not applicable	
Viability	Assessment of quality after storage/exchange	Recommended	Recommended	Recommended	Recommended	Recommended	Recommended	
Pathogenicity	Viability tests and frequency of assessment	Not applicable	Not applicable	Recommended	Recommended	Optional	Not applicable	
Storage facilities	Pathogenicity tests and frequency of assessment	Not applicable	Not applicable	Optional	Optional	Not applicable	Not applicable	
Protection from loss	Location and maintenance of stores	Required	Required	Required	Required	Required	Required	
Conservation	Duplication of collections	Optional	Optional	Recommended	Recommended	Optional	Optional	
Containment	Validated conservation methods	Required	Required	Required	Required	Required	Required	
	Determination of long term stability	Required	Required	Required	Required	Required	Required	
	Determination of short term stability (e.g. for transport)	Required	Required	Required	Required	Required	Required	
Preparation of reference materials	Biosecurity for live quarantine organisms	Required	Required	Required	Required	Required	Required	
	Production methods	Required	Required	Required	Required	Required	Required	
	Analysis of uniformity	Required	Required	Required	Required	Required	Required	
	Determination of confidence limits for supply of reference materials with specific quality or quantity requirements	Not applicable	Not applicable	Required	Required	Not applicable	Not applicable	
Public access to specimens	Instructions for end users	Required	Required	Required	Required	Required	Required	
	Ordering procedures	Required	Required	Required	Required	Required	Required	
	Packing and transportation procedures	Required	Required	Required	Required	Required	Required	
	Customer communications and feedback	Recommended	Recommended	Recommended	Recommended	Recommended	Recommended	
	Customer data	Required	Required	Required	Required	Required	Required	
Legal aspects	Non-conformance procedures	Required	Required	Required	Required	Required	Required	
	Adherence to local plant health licensing requirements	Required	Required	Required	Required	Required	Required	
	Adherence to international quarantine regulations	Required	Required	Required	Required	Required	Required	

