

#### WP3

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

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# Objectives of Q-Collect WP3

		<u>Month</u>
3.1.	Review current quality control standards in EU collections of quarantine organisms.	12 🗹
3.2.	Define and agree minimum quality standards that can be applied within EU collections.	15 🗹
3.3.	Produce harmonised guidelines to achieve recommended quality standards during:	19 🗹
	<ul><li>preparation</li></ul>	
	<ul><li>conservation</li></ul>	
	<ul><li>shipment/access</li></ul>	
	<ul> <li>use of reference materials</li> </ul>	
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.

## Scope

#### Minimum quality standards for <u>reference collections</u> of:

- EU or EPPO listed quarantine pests
- EPPO listed invasive plants
- Other organisms that may interfere with their correct identification ("lookalikes")
  - Shared diagnostic features
  - Close taxonomic relatedness
  - Occur in a similar biological niche (e.g. particular commodity or shared habitat)

#### Reference collections

- Collections of individuals maintained for the purpose of study and authentication.
- Large undertakings maintained by institutions;
- Typically have multiple representatives of many species,
- Able to provide samples externally for comparisons and research.
- Important sources of information about variations of populations within species.
- Repositories of type strains or holotypes used as the official definition of a particular species.



- Specific quality requirements vary according to:
  - Type of organism or reference material
  - Whether maintained as live organisms, fixed specimens or other material.
- Minimum quality standards agreed through consultation amongst experts associated with reference collections of quarantine organisms

viruses, phytoplasmas, bacteria, fungi and oomycetes, nematodes, insects and invasive plants.

- Minimum quality standards for:
  - Information required on accession
  - Data storage and maintenance
  - Authentication
  - Identification methods
  - Storage and conservation
  - Production of reference materials
  - Access to reference materials































## 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

OECD BEST PRACTICE GUIDELINES FOR BIOLOGICAL RESOURCE CENTRES



ORGANISATION FOR ECONOMIC CO-OPERATION
AND DEVELOPMENT



## 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)



## Existing guidelines



The Herbarium Handbook (Forman et al., 2000)

Standard explaining most plant/seed collection related activities



- BRAHMS database management system http://herbaria.plants.ox.ac.uk/bol
- Supports collection management in herbaria, botanical gardens and seed banks.

## 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.



























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

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

Quality General Management Technical 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.



# 2. Specific competencies, documentation & procedures

- Catalogue of specimens
- Key accession data for internal and external information
- SOPs + data on identification and authentication methods
- SOPs + data on preservation and storage methods
- Data storage and retrieval methods
- Customer communication procedures (order forms, MTA, website etc.)
- Procedures for specimen distribution/sharing



























### 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)



### 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)



## c) Authentication

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

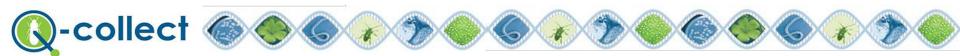
- Documented acquisition policy
- Archived standard procedures, where appropriate, for
  - labelling/barcoding new accessions
  - Identity and purity checks (including batch to batch variation, mixing, deterioration or contamination)
  - verification of viability and/or pathogenicity (usually only for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



#### d) Identification methods

The number and type of identification methods used will depend on the types of organism held. It is generally recommended that:

- Recognised published procedures are followed
- Where available, nucleic acid-based identification methods (e.g. specific PCR tests, DNA sequencing or barcoding) should be used for reference collections
- Specific ID methods should be archived as standard operating procedures, e.g.
  - inoculation of differential hosts or use of specific antisera for viruses
  - use of nutritional profiling, fatty-acid profiling, Maldi-TOF or DNA fingerprinting for bacteria
  - the use of iso-enzyme analysis for nematodes
  - sources and correct use of identification keys (for collections other than viruses)
  - classical morphological or morphometric methods (for all collections other than phytoplasmas)
- Staff should be fully trained and competent in their use
- Sources of approved taxa relevant to each type of organism should be available
- Lists of current quarantine status (Council Directive 2000/29/EC and EPPO listings) of each type of organism should be available

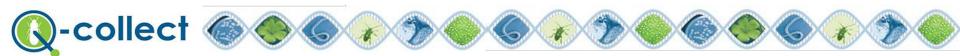


## e) Storage and conservation

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

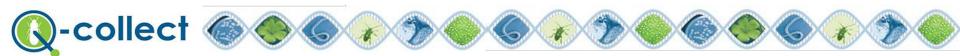


#### f) Production of reference materials

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

#### Archived documents should include:

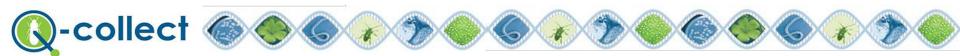
- Standard methods used to produce the materials
- Methods to assess and guarantee uniformity of reference material
- Documented evidence that a required trait is present in the material, e.g.
  - specific antigens for use as controls in serological tests
  - morphological characteristics indicative 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



## 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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sues	Information to be held / Standard operating procedures and competences required	Viruses/viroids	Phytoplasmas	Bacteria	Fungi/oomycetes	Nematodes	Insects/mites	Invasive Plants
ita to be stored on each	Specimen full scientific name	Required	Required	Required	Required	Required	Required	Required
cession	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	Recommende
	Date (at least year) of sampling (where available)	Required	Required	Required	Required	Required	Required	Required
	Sampler/collector	Reccommended	Recommended	Recommended	Recommended		Recommended	Recommende
	Original specimen number or name given by collector (where available)	Reccommended	Recommended	Recommended	Recommended		Recommended	Recommende
	Unique accession number in the collection	Required	Required	Required	Required	Required	Required	Required
	Date of deposit in collection  Preservation conditions and date preserved	Required Recommended	Required Recommended	Required Recommended	Required Recommended	Required	Required Recommended	Required Recommende
	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
	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			Recommende
	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		Not applicable	Not applicable
	Date of last authenticity check/purity test	Recommended	Recommended	Recommended	Recommended		Not applicable	Not applicable
	Date of last pathogenicity test	Not applicable	Not applicable	Optional	Optional		Not applicable	Not applicable
	Traceable history of all quality control checks and persons involved	Recommended	Recommended	Recommended	Recommended		Recommended	Recommende
	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
ata 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
lentification methods	Sources and use of identification keys (where used)	Not applicable	Recommended	Recommended	Recommended	Recommended	Recommended	Recommende
	Classical morphological descriptions (where used)	Recommended	Not applicable	Recommended	Recommended	Recommended	Recommended	Recommende
	Morphometric analysis of specimens (where used)	Recommended	Not applicable	Recommended	Recommended	Recommended	Recommended	Recommende
	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	Recommende
	Other identification methods (examples)	Recommended	Not applicable	Recommended	Not applicable	Reccomended	Not applicable	Not applicable
pdating taxonomy	Sources of approved taxa (examples)	Required	Required	Required	Required	Required	Required	Required
urrent quarantine status	Sources of current lists of quarantine organisms and invasive plants	Recommended	Recommended	Recommended	Recommended	Recommended	Recommended	Recommende
ontact details	Contact details for persons responsible for the collection	Required	Required	Required	required	Required	Required	Required
abelling	Unique number assignment/barcode labelling	Required	Required	Required	Required	Required	Required	Required
orage facilities	Containment/isolation measures	Required	Required	Required	Required	Required	Required	Not applicable
urity	Measures to avoid cross-contamination or mixing	Required	Not applicable	Required	Required	Required	Required	Required
hain of accession	Record keeping for movement of accessions in and out of the collection	Required	Required	Required	Required	Required	Required	Required
omparison with original	Methods to check batch to batch variation	Required	Required	Required	Required	Optional	Not applicable	Not applicable
ccession	Assessment of quality after storage/exchange	Recommended	Recommended	Recommended	Recommended			Not applicable
iability	Viability tests and frequency of assesment	Not applicable	Not applicable	Recommended	Recommended	Optional	Not applicable	Not applicable
athogenicity	Pathogenicity tests and frequency of assessment	Not applicable	Not applicable	Optional	Optional		Not applicable	Not applicable
orage facilities	Location and maintenance of stores	Required	Required	Required	Required	Required	Required	Required
rotection from loss	Duplication of collections	Optional	Optional	Recommended	Recommended	Optional	Optional	Optional
onservation	Validated conservation methods	Required	Required	Required	Required	Required	Required	Not applicable
	Determination of long term stability	Required	Required	Required	Required	Required	Required	Not applicable
	Determination of short term stability (e.g. for transport)	Required	Required	Required	Required	Required	Required	Not applicable
ontainment	Biosecurity for live quarantine organisms	Required	Required	Required	Required	Required	Required	Not applicable
eparation of reference	Production methods	Required	Required	Required	Required	Required	Required	Required
aterials	Analysis of uniformity  Determination of confidence limits for supply of reference materials with specific	Required Not applicable	Required Not applicable	Required Required	Required Required	Required Not applicable	Required Not applicable	Required Not applicable
	quality or quantity requirements	Doguirod	Doguirod	Dogwirod	Doguirod	Doguirod	Doguirod	Doguirod
ublic access to specimens	Instructions for end users	Required Required	Required	Required	Required Required	Required Required	Required	Required Required
ibile access to specimens	Ordering procedures	Required Required	Required Required	Required Required	Required Required	Required Required	Required Required	Required
	Packing and transportation procedures  Customer communications and feedback	Recommended	Recommended	Recommended	Recommended	Recommended		Recommende
	Customer data	Required	Required	Required	Required	Required	Required	Required
	Non-conformance procedures	Required	Required	Required	Required	Required	Required	Required
egal aspects	Adherence to local plant health licensing requirements	Required	Required	Required	Required	Required	Required	Required
gai aspects								
	Adherence to international quarantine regulations	Required	Required	Required	Required	Required	Required	Required

































