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

Based on a presentation made at the Q-collect Workshop Rome, 2015-09-08/09

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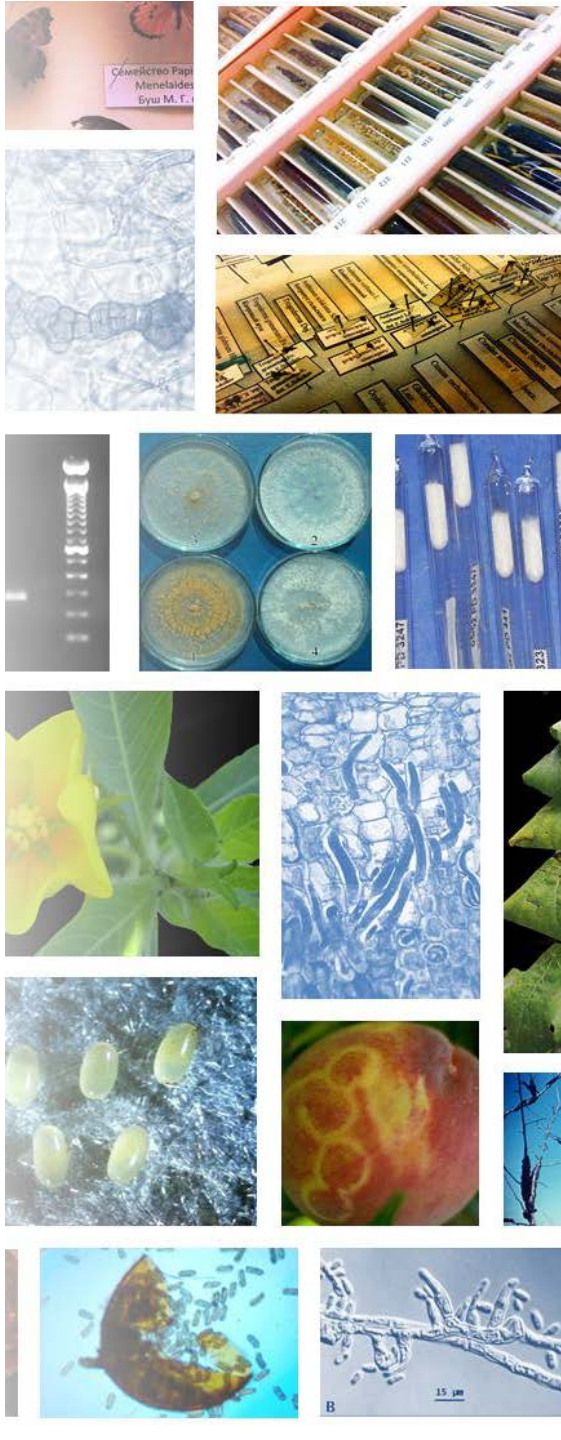


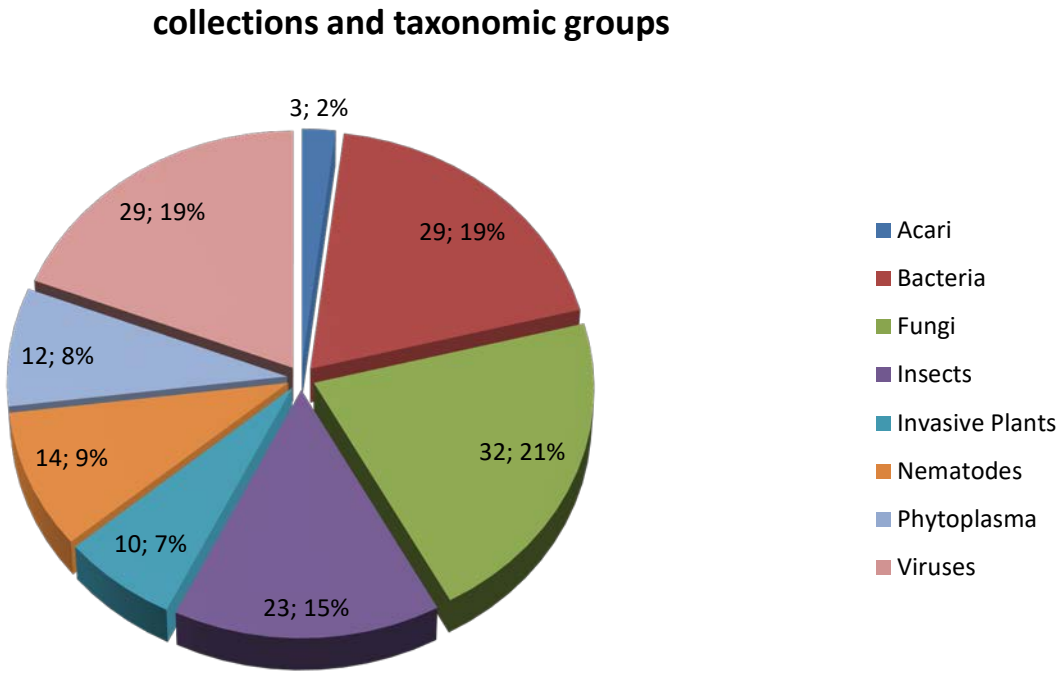
Why a Q-collect project?

- Collections EU dispersed, widespread and of very variable quality. (NPPO's, mandated diagnostic laboratories, Universities, Research Institutes, Natural History Musea, other),
- Own collections related to their specific work and scope,
- Connected to a single specialist,
- Need to improve the infrastructure supporting phytosanitary important collections,

Aims

- Inventory of existing phytosanitary important collections within Europe and their content
- Development guidelines for quality standards
- Development guidelines to improve the accessibility of these collections
- Design and build a network of reference collections
- Development an info-portal on the web
- Dissemination of the results to stakeholders

General information on the institutes / laboratories



Findings

All taxonomic groups are represented.

Inventory of collections for nematodes

Number and location of nematodes collections that took part in the survey

Findings
All relevant plant health collections of nematodes are included apart from one collection from Italy (Bologna)

Quality Standards
Why do we need quality standards in reference collections?

- 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 reference collections of:

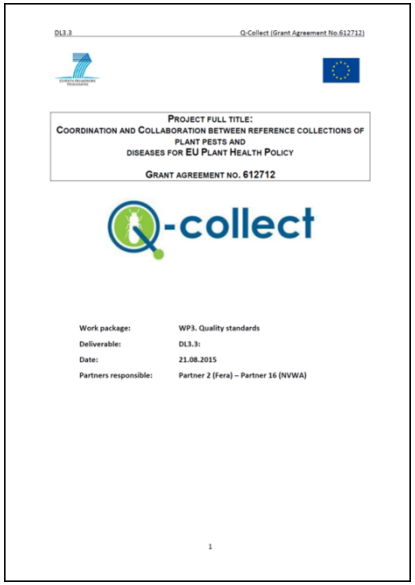
- EU or EPPO listed quarantine pests
- Other organisms that may interfere with their correct identification ("lookalikes")
  - Shared diagnostic features
  - Close taxonomic relatedness
  - Occur in a similar biological niche (e.g. particular commodity or shared habitat)

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.

Minimum quality standards

- 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


DL3.3 Q-Collect (Grant Agreement No.612712)

PROJECT FULL TITLE:
COORDINATION AND COLLABORATION BETWEEN REFERENCE COLLECTIONS OF PLANT PESTS AND DISEASES FOR EU PLANT HEALTH POLICY

GRANT AGREEMENT NO. 612712

Q-collect

Work package: WP3. Quality standards
Deliverable: DL3.3:
Date: 21.08.2015
Partners responsible: Partner 2 (Fera) – Partner 16 (NVWA)

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Different existing guidelines considered

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.
- Other ISO Standard exist

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

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

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

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,
- 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.

Post Q-collect: review by EPPO Panels

Initial objective was to turn the Q-collect recommendations into an EPPO Standard:

Some issues were raised:

- Document on Quality Standards too focussed on large reference collections that are a commercial service.

- According to Q-collect recommendations, working collection should not circulate material

major negative effects on plant pest diagnostic laboratories activities.

Post Q-collect: review by EPPO Panels

Material from working collections is used :

- To run TPS and proficiency tests (PT)
- For test development
- As positive controls
- For training
- For research
- To share material with other laboratories (on the basis of a letter of authority)

Only a small part of the material used in the laboratory is from reference collections, and the working collections are essential to the work above.

Q-collect recommendations can be a long term objectives.

New Approach - focus on quality for the production of Reference Material

Future steps

- Review of the quality criteria proposed in Q-collect by the different specialized Panels
- Development of guidelines for the production of reference material.
- The Workshop has provided input for the preparation of guidelines for nematology.