



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

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

Specific scope

This guideline specifies the minimum quality standards expected of reference collections receiving, maintaining and providing access to specimens representative of listed quarantine pests^{1,2,3}, invasive plants⁴ or of other organisms that may interfere with their correct identification as a result of shared diagnostic features, close taxonomic relatedness, or occurrence in a similar biological niche such as a particular commodity or shared habitat.

Introduction

In 2001, the Organisation for Economic Cooperation and Development (OECD) Working Party on Biotechnology concluded that there was a need to provide greater quality assurance than was already exercised by culture collections and databases of biological resources⁵. As a result, a series of best practices was published in 2007⁶ to provide guidance for biological resource centres (BRCs) seeking to improve the quality standards of their repositories of living and preserved organisms, their genomes and other information related to their heredity, function, taxonomic classification and diversity. These included specific best practice guidelines on biosecurity for BRCs, for the micro-organism domain and for animal and plant BRCs. Some of the aims of these guidelines were:

- To safeguard biodiversity through repositories for reliable preservation and curation of biological resources.
- To support R&D and diagnostic laboratories by making available biological reference materials of guaranteed identity and quality.
- To underpin accurate taxonomic classification and identification to provide consistent naming of organisms of statutory, agricultural, horticultural, industrial and environmental importance.
- To provide the same level of quality service irrespective of the source of biological materials or information requested.

These guidelines provide basic quality management guidance for culture collections by setting the standard for quality management and biosecurity, building capacity, preservation of biological resources and data management. Although the detailed guidelines were intended to improve quality assurance in current collections and databases, it was recognised that full compliance with the guidelines would be difficult for many collections and that they may remain somewhat aspirational. Indeed, to date, only a few of the larger reference collections containing quarantine organisms have been able to fully comply with the best practices proposed through the OECD guidelines.

The larger reference collections of micro-organisms (including viruses, bacteria and fungi) have probably made most progress in terms of organised quality assurance. The EU demonstration project known as CABRI (Common Access to Biological Resources and Information) was initiated in 1996 and its database (<http://cabri.org>) is now maintained by seven member BRCs, some of which hold plant quarantine organisms, including the Belgian Co-ordinated Collection of Micro-organisms (BCCM), the CABI collections of bacteria and filamentous fungi, Centraalbureau voor Schimmelcultures (CBS) collections of bacteria and filamentous fungi and Deutsche Sammlung von Mikroorganismen und Zellkulturen (DSMZ) collections of bacteria, filamentous fungi and plant viruses. A CABRI accreditation scheme has been developed by reviewing and collating methodologies and quality standards appropriate for each biological resource category for accessioning material into member and other collections. These are then measured and critiqued by comparing methods and results obtained with common representatives from each of the collections and randomly checking customer satisfaction.

Whereas the OECD and CABRI guidelines are intended for use by well-resourced public service collections, the World Federation for Culture Collections (WFCC) has also issued general guidelines (<http://www.wfcc.info/guidelines>), which aim to provide a first step towards the implementation of the OECD Best Practice. These include advice on appropriate operational facilities, staffing levels to allow operation at a high standard and training for staff with research expertise related to the aims of the collection. The guidance

also demands compliance with national legislation, rules and regulations and addresses the capability of collections to meet relevant national and international regulations concerning the control, transportation and health and safety aspects of resource handling and distribution.

For botanical collections of plants, The Herbarium Handbook⁷ (Forman *et al.*, 2000) is a widely-used standard text covering best practice for many relevant activities. Further modern administrative procedures are available through the BRAHMS database management system (<http://herbaria.plants.ox.ac.uk/bol>) for botanical researchers managing collections in herbaria, botanic gardens and seed banks. Developed at Plant Sciences, University of Oxford, it provides wide-ranging and innovative functionality to gather, edit, analyse and publish botanical data, optimizing its use for the widest possible range of curation services and research outputs.

The following aims to summarise opinions amongst researchers who both maintain and use reference collections of listed quarantine organisms harmful to plants regarding the expected minimum quality standards which should be applied to the materials and services they provide.

Terms and definitions

Reference collection: A collection of individuals maintained for the purpose of study and authentication. Reference collections are generally large undertakings maintained by institutions; instead of having a single representative of each species, they will typically have multiples, so as to illustrate variations and, be able to provide samples externally for comparisons and research. Reference collections are an important source of information about variations of populations within a species. They are also the repository of type strains or holotypes used as the official definition of a particular species.

Working collection: Collections, usually of individuals belonging to a single organism or group of related organisms, maintained for the purpose of scientific investigation by experts. Working collections are usually maintained by individual researchers or research groups with recognized knowledge of the organism(s) in question. They do not usually provide samples externally other than to deposit individuals of interest into one or more reference collections for safe keeping and/or protection of intellectual property.

Reference material: Live cultures and other material such as infected plant material, DNA/RNA preparations, and images of a diagnostic quality or mounted specimens including insects, mites, nematodes or fungal spores may be considered. The reference material used should be appropriate for the end-purpose (e.g. test or diagnosis) and it should be ensured that it has the features for which it was selected. These features can include expressing a desired antigen for use in serological diagnosis, or displaying specific physical features (e.g. sporulation) if the reference material is used for morphological diagnosis (adapted from EPPO PM 7-84)⁸.

Certified reference material: this is reference material derived from a source that certifies the authenticity of the material. Preferably material should come from an internationally recognised source such as a national reference collection. It should go together with a unique identification code allowing traceability and the name of the person who certifies its authenticity. Details of how the material was authenticated should also be supplied. If appropriate, information about its activity (e.g. pathogenicity, antigenic properties) under specified conditions should also be supplied along with any related uncertainty at a stated level of confidence (EPPO PM 7-84)⁹.

Quality assurance: part of quality management, focussed on providing confidence that quality requirements will be fulfilled.

Quality management systems

A suitable quality management system is essential for the reliable housing and function of a reference collection. The EPPO standard PM 7/84⁸ describes basic requirements for quality management in plant pest diagnosis and the general management and technical requirements described in this guideline also apply to

the establishment and running of reference collections of plant pests. Basic management requirements include provision of appropriate resources (human, financial and structural) to assure sustained continuation of the collection in a suitable state. A quality manager should be identified and all other staff involved in the collection should have defined tasks and responsibilities and their level of training should be documented and assessed regularly. Suitable systems for documentation and archiving, purchasing appropriate supplies, recording non-compliances and for dealing with complaints are also required.

Technical aspects of the quality management system include the need for all facilities and activities to be documented and archived in a technical quality manual and for individual procedures to be described and controlled in standard operating procedure format. Procedures and specific reagents used should be validated and subject to method comparisons where appropriate. In specific cases, it may also be useful to perform proficiency tests to demonstrate adequate application of procedures. All equipment should be clearly identified and a regular maintenance/calibration schedule kept. The number and size of required laboratory and storage facilities should be determined, any specific environmental conditions should be monitored and recorded and an appropriate programme of cleaning and maintenance applied. Specific biosecurity measures and restrictions to access should be implemented and reviewed by an appointed biosecurity officer and should conform to national and international regulations for control of quarantine plant pests.

Finally, there should be a periodic review of the management system to check that procedures are being properly followed and required quality standards are being met. Many reference collections now follow the ISO 9000 standards (http://www.iso.org/iso/iso_9000) for quality management and are certified to ISO 9001:2008 after audits by an accredited external certification body. An update to these standards ISO 9001:2015 is expected at the end of 2015. Where specific technical procedures are consistently used and are critical to the quality of the running or outputs of the collection, it may strengthen the quality management system to have the procedures independently certified to international standards (e.g. ISO 17025:2005). Furthermore, the international standard ISO Guide 34:2009 sets out the management system requirements in accordance with which reference materials shall be produced and is specifically intended to be used by reference collections as part of the general quality assurance procedures.

As an alternative or addition to compliance with ISO standards, CABRI have developed an accreditation scheme for culture collections by reviewing and collating existing methodologies for depositing material into member and other collections and appropriate quality control standards already in use for each type of biological resource. A CABRI Technical Committee implements and enforces these CABRI standards and regularly audits both the laboratory practices and delivery standards of the 8 CABRI member collections and ensures that information procedures and content are kept current and abreast of latest developments.

Minimum quality standards to be achieved

Whilst the choice of quality management system is probably similar for reference collections of all types of plant quarantine pests, specific quality requirements will vary with the type of organism or reference material in question and according to whether reference materials are maintained and provided as live organisms or as fixed specimens or other material. The following guidelines on minimum quality requirements were agreed through consultation amongst experts associated with reference collections of plant quarantine pests, including viruses, phytoplasmas, bacteria, fungi and oomycetes, nematodes, insects and invasive plants. The information is summarised in the tables provided in Appendix 1.

Information required on accession

A reliable catalogue or inventory of all of the holdings of biological reference material and associated metadata is an essential requirement of every reference collection. Essential data for all categories of plant quarantine pest include the following:

- A unique accession number.
- The date of accession (essential for viable organisms but also recommended for fixed specimens).
- Full scientific name, including any relevant infrasubspecific classification.
- Geographic source of specimen (at least to country of origin).
- The date (or at least year) of original collection/isolation.
- The name and contact details of the depositor.
- The current quarantine status of the specimen.
- The nomenclatural status of the specimen (e.g. type, neotype, holotype etc.).

Where available, it is recommended that accession data also includes the details of the person making the initial collection/isolation, the original specimen numbers allocated by the collector or other collections, the conditions required for preservation, the date it was preserved and the traceable history of all quality control checks performed and the persons involved. Other options for data to be collected on accession to the collections include the traceable history of all persons performing identification of the organism, links or references to nucleic acid or protein sequence data obtained from the accession, literature references to the use of the accession as reference material and, with the exception of phytoplasmas, morphological or morphometric data specific to the accession. Although not usually relevant for collections of viruses, phytoplasmas or bacteria, the option to assign images characteristic to accessions of fungi, nematodes, insects, mites or invasive plants may also be considered.

Recommended additional information specific for collections of viable organisms includes date and results of the last viability and purity tests (although not applicable for phytoplasmas), and for bacteria and fungi, the date, details and result of the last pathogenicity test. Other possible options for collections of viable organisms include collection and storage of references to accession numbers in any duplicates held in other collections, the history from sampling/original isolation to deposit in the collection, and expected reactions when used as reference material in specific diagnostic tests.

Data storage and maintenance

Ideally, the catalogue of each reference collection should be maintained in an electronic format in a format which allows (a) traceability of any changes made over time and the persons responsible and (b) also facilitates sharing of publically accessible fields of the data with other collections or networks. All reference collections should document procedures on database maintenance, data back-up and data-sharing. Staff responsible for data storage and maintenance should have adequate training and be able to demonstrate competence in the use of these procedures. Data handling and review should be restricted to such staff.

In addition to data specific to each accession, additional data requiring secure storage will include contact details for all persons responsible for maintaining the collection, contact details for persons donating accessions and contact details for customers to whom accessions are provided or loaned.

Authentication

Whilst the data accompanying a specific organism is the responsibility of the individual collector or the working collection from which it originates, the reference collection has an obligation to authenticate this data prior to its accession. For traceability of the chain of accession, records should be made of the movement of any

material or information entering or leaving the collection including the relevant dates and persons accepting/providing the accessions.

Each collection should document its acquisition policy, including the format of data to be supplied with new accessions. A standard procedure for labelling or barcoding new accessions with a unique identification number, which is specific to the collection, should be available for use by competent persons approved to authenticate the incoming material. Where appropriate, the label should also indicate the preparation date of the specific batch. Identity and purity should always be checked and, where appropriate (usually only for bacterial and fungal pathogens), verification of viability and/or pathogenicity should also be considered. All methods used for this should be recorded as standard operating procedures and archived.

In addition to authentication of new accessions, it may be necessary to check batch to batch variation where live cultures have to be reproduced. Further checking may be required to ensure that material does not become mixed, contaminated or deteriorated, e.g. during storage or when returned to the collection after loan.

Identification methods

The number and type of identification methods used to authenticate each accession and to further investigate biodiversity within the collection will depend on the types of organism held. It is recommended that recognised published procedures are followed and any specific methods are archived as standard operating procedures. Staff should be fully trained in their use before being acknowledged as competent to identify the accessions. Where available, nucleic acid-based identification methods involving specific PCR tests, DNA sequencing or barcoding are recommended for all reference collections. Other SOPs or published procedures may indicate sources and correct use of identification keys (for all types of collection other than viruses), classical morphological or morphometric methods (for all collections other than phytoplasmas). Other methods are more specific for certain types of collection, 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 and the use of iso-enzyme analysis for nematodes.

To ensure that accessions are identified according to the most recent taxonomy, a list of the relevant journals and other sources of approved taxa relevant to each type of quarantine organism should be maintained. These currently include the International Committee on Taxonomy of Viruses (www.ictvonline.org), the International Journal of Systematic and Evolutionary Microbiology and the List of Prokaryotic names with standing in nomenclature (www.bacterio.net), the International Mycological Association (www.mycobank.net), Fauna Europaea (www.faunaeur.org), the plant List (www.theplantlist.org) and the Angiosperm Phylogeny Group Classification (APG III).

As part of the biosecurity risk assessment, the current quarantine status of the organism should also be recorded for each accession in a collection according to Council Directive 2000/29/EC and EPPO listings.

Storage and conservation

Methods for preservation and maintenance of accessions will vary with the type of organism collected. All procedures should be accurately documented to ensure that they are reproducible and that key parameters are recorded and monitored. A maintenance plan should be developed for each type of material to be held and should include specific storage conditions and locations. The type and location of all storage facilities and all containment and biosecurity measures for quarantine organisms should be detailed to the satisfaction of the licencing Biosecurity Officer.

Standard operating procedures should be developed to cover specific preservation methods and approaches used to determine the long term stability of accessions during storage. The regularity of quality checks

required during storage and the expected timing of batch regeneration (for viable cultures) should also be documented. In addition, standard operating procedures should describe methods to determine short-term stability of accessions, e.g. during transport or loan periods. As an added security measure, especially for safeguarding live cultures against failure of storage conditions or other disaster, the duplication of collections at more than one site is usually required.

Production of reference materials

For collections supplying specific reference materials, the methods used to produce the materials should be documented to ensure reproducibility. Methods should be available to allow assessment and guarantee of the uniformity of the reference material. Where specific traits are required by the end user, e.g. specific antigens for use as controls in serological tests or morphological characteristics indicative of a particular taxon, documented evidence should be available that the trait is present in the material supplied. Especially for bacteria and fungi where specific quantity or quality requirements (e.g. different concentrations, populations, matrices, mixtures, viability or levels of purity) may be required, then methods should be available to allow determination of confidence limits for supply with the materials. Where a specific taxon is required, then the chain of accession of the organism should be made available as proof of authenticity. All reference material should be supplied with pre-determined instructions for the end-user.

Access to reference materials

Document archives should contain templates of a new recipient form to allow authentication of customer details, a form for order placement and a material transfer agreement to inform the user of all rights and duties with respect to the material being supplied (e.g. quarantine requirements, intellectual property rights, expected acknowledgements for result reporting/publication and correct accession number format). Customer details should be confidentially archived with password protection. Ideally, a version of the collection database, showing the non-confidential fields, should be made publically accessible via the internet together with access to the other essential documentation required for user registration and ordering. Access to the full database should be password protected and limited only to those persons competent to manage the data.

Procedures for ordering or loan of material, or other means of access to the material, should be clearly mapped and documented and managed only by trained staff that have demonstrated competence in their application and are identified as contact persons to the users. The procedures should ensure that no material is supplied before the correct documentation has been received.

Procedures for packing and shipment should also be clearly documented and should conform to any relevant national and international shipping and quarantine regulations, in consultation with the official biosecurity officer. EPPO Standard PM 3/64¹⁰ offers guidance on import of organisms that are plant pests or potential plant pests, including appropriate risk assessment and containment.

Standard operating procedures should also cover customer communications, 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 should also be archived and followed by all staff connected to the collection.

References and links

1. http://ec.europa.eu/food/plant/plant_health_biosecurity/legislation/index_en.htm
2. <http://www.eppo.int/QUARANTINE/listA1.htm>; <http://www.eppo.int/QUARANTINE/listA2.htm>;
3. http://www.eppo.int/QUARANTINE/Alert_List/alert_list.htm
4. http://www.eppo.int/INVASIVE_PLANTS/ias_lists.htm
5. OECD (2001). Biological Resource Centres: Underpinning the future of life sciences and biotechnology. OECD Publications, Paris, France. pp 66.
6. OECD (2007). Best Practice Guidelines for Biological Resource Centres (June 2007), http://www.oecd.org/document/36/0,3343,en_2649_34537_38777060_1_1_1_1,00.html
7. Forman L, Bridson D, (eds.) (1989). The herbarium handbook. Royal Botanic Gardens, Kew, London.
8. EPPO/OEPP (2007). PM 7/84 (1): Basic requirements for quality management in plant pest diagnosis laboratories. Bulletin OEPP/EPPO Bulletin 37, 580–588.
9. EPPO/OEPP (2010). PM 7/98 (1): Specific requirements for laboratories preparing accreditation for a plant pest diagnostic activity. Bulletin OEPP/EPPO Bulletin 40, 5–22.
10. EPPO/OEPP (2006) PM 3/64 (1): Intentional import of organisms that are plant pests or potential plant pests. Bulletin OEPP/EPPO Bulletin 36, 191–194.

APPENDIX 1:

Summary of minimum quality standards expected of reference collections of quarantine plant pests and invasive plants.

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	Not applicable	Not applicable	Not applicable
Data storage procedures	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	Optional	Optional	Optional	Optional	Optional
Identification methods	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
	Database maintenance procedures	Required	Required	Required	Required	Required	Required	Required
	Data back-up process procedures	Required	Required	Required	Required	Required	Required	Required
Updating taxonomy	Sharing procedures for selected data (e.g. via website or paper inventory/catalogue)	Required	Required	Required	Required	Required	Required	Required
	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	Recommended	Not applicable	Not applicable	Not applicable
Current quarantine status	DNA/RNA sequencing/barcoding methods (where available)	Recommended	Recommended	Recommended	Recommended	Recommended	Recommended	Recommended
	Other identification methods (examples)	Recommended	Not applicable	Recommended	Recommended	Recommended	Not applicable	Not applicable
	Sources of approved taxa (examples)	Required	Required	Required	Required	Required	Required	Required
	Sources of current lists of quarantine organisms and invasive plants	Recommended	Recommended	Recommended	Recommended	Recommended	Recommended	Recommended
	Contact details for persons responsible for the collection	Required	Required	Required	Required	Required	Required	Required
Contact details	Unique number assignment/barcode labelling	Required	Required	Required	Required	Required	Required	Required
	Containment/isolation measures	Required	Required	Required	Required	Required	Required	Not applicable
	Purity	Required	Not applicable	Required	Required	Required	Required	Required
	Measures to avoid cross-contamination or mixing	Required	Not applicable	Required	Required	Required	Required	Required
	Record keeping for movement of accessions in and out of the collection	Required	Required	Required	Required	Required	Required	Required
Chain of accession	Methods to check batch to batch variation	Required	Required	Required	Required	Optional	Not applicable	Not applicable
	Assessment of quality after storage/exchange	Recommended	Recommended	Recommended	Recommended	Recommended	Recommended	Not applicable
	Viability tests and frequency of assessment	Not applicable	Not applicable	Recommended	Recommended	Optional	Not applicable	Not applicable
	Pathogenicity tests and frequency of assessment	Not applicable	Not applicable	Optional	Optional	Not applicable	Not applicable	Not applicable
	Location and maintenance of stores	Required	Required	Required	Required	Required	Required	Required
Storage facilities	Duplication of collections	Optional	Optional	Recommended	Recommended	Optional	Optional	Optional
	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
	Biosecurity for live quarantine organisms	Required	Required	Required	Required	Required	Required	Not applicable
Containment	Production methods	Required	Required	Required	Required	Required	Required	Required
	Analysis of uniformity	Required	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	Not applicable
	Instructions for end users	Required	Required	Required	Required	Required	Required	Required
	Ordering procedures	Required	Required	Required	Required	Required	Required	Required
Preparation of reference materials	Packing and transportation procedures	Required	Required	Required	Required	Required	Required	Required
	Customer communications and feedback	Recommended	Recommended	Recommended	Recommended	Recommended	Recommended	Recommended
	Customer data	Required	Required	Required	Required	Required	Required	Required
	Non-conformance procedures	Required	Required	Required	Required	Required	Required	Required
	Adherence to local plant health licensing requirements	Required	Required	Required	Required	Required	Required	Required
Public access to specimens	Adherence to international quarantine regulations	Required	Required	Required	Required	Required	Required	Required
Legal aspects								