



CPVO

Community Plant Variety Office

Entrustment Requirements for CPVO Examination Offices

Note: Any electronic or hard copies of this document are not subject to change service

Entrustment Requirements

Entry into force as from 01/01/2023

Marien Valstar

Marien Valstar, Chair of the CPVO Administrative Council
Angers, 27 April 2022

Contents

1.	Scope	4
2.	Definitions	4
3.	Organisation and management	6
4.	Independence, impartiality and integrity	6
5.	Confidentiality	7
6.	Cooperation	7
6.1.	Variety testing on behalf of CPVO	7
6.2.	Take-over reports	7
6.3.	Other cooperation	7
7.	Personnel	8
8.	Quality system	8
8.1.	Document control	8
8.2.	Records	8
8.3.	Examination reports	9
8.4.	Corrective action procedure	9
8.5.	Internal audits and reviews by management	9
9.	Facilities and equipment	10
9.1.	Crop Management	10
9.2.	Supplies	10
9.3.	IT equipment and software	11
10.	Technical guidelines and procedures	11
10.1.	Technical guidelines	11
10.2.	Trial planning, trial design	11
10.3.	Selection of varieties for the growing trial	11
10.4.	Observation of characteristics	12
10.5.	Additional characteristics	12
10.6.	Distinctness	12
10.7.	Uniformity	12
11.	Handling plant material of candidate varieties	13
12.	Variety collections	13
12.1.	Introduction	13
12.2.	Constitution of variety collections	14
12.2.1	Forms of variety collection	14
12.2.1.1	Variety Descriptions	14
12.2.1.2	Living Plant Material	15
12.2.2	Factors to be considered for inclusion of a variety in a variety collection	15
12.2.2.1	Range of the variety collection	15
12.2.2.2	Making an inventory of varieties of common knowledge for inclusion in the variety collection	16
12.2.2.3	Geographical scope	16



12.2.3. Varieties of common knowledge not included in the variety collection or for which living plant material is not available	16
12.3. Maintenance of variety collections	17
12.3.1. General	17
12.3.2. Variety descriptions	17
12.3.3. Living plant material in variety collections.....	17
12.3.4. Sources of living plant material	18
12.3.5. Maintenance and updating/renewal of living plant material	18
12.4. Cooperation in the maintenance of variety collections	19
12.4.1. Exchange of standard samples with other EOs.....	19
13. Subcontracting	19

Document history:

Created: March 2021	Checked: 23.03.2022	Approved: 27.04.2022	Version 5.0
Entrustment Requirements		Status: Final	printed: 27.04.2022



1. Scope

This document specifies criteria to be applied for the assessment of the competence of EU examination offices (EOs) performing variety testing on behalf of the Community Plant Variety Office (CPVO) under an entrustment arrangement, including take-over of reports produced for National Listing or national plant variety rights. These criteria equally apply to technically qualified bodies within the scope of their contractual arrangements in order to become or remain eligible for subcontracting.

2. Definitions

For the purpose of this document the following definitions apply

Assessment/audit:	process undertaken to review the competence of an EO, based on quality requirements and/or other normative documents and for a defined scope of entrustment.
Correction:	immediate reaction to an observed non-conformity in order to address an issue with a short-term perspective.
Corrective action procedure:	reactive process to address situations of non-conformity, complaints or observations indicating a need for action with the intent to avoid recurrence.
Database:	structured collection of information including effective retrieval according to search criteria by electronic data processing or other means.
Designation Agreement (DA):	contractual agreement between CPVO and an EO.
Document control:	set of procedures and policies for handling both external and internal documents, in order to have adequate, validated and up to date information available at all required locations. Note that control refers to steering and managing rather than to checking, which itself can be an element of any control measures.
DUS testing:	variety testing with the aim to verify if criteria for distinctness, uniformity and stability (DUS) are fulfilled in order to substantiate decisions for the protection of a plant variety.
Entrustment:	attestation by the Administrative Council related to an EO, conveying formal acceptance of its competence to carry out tasks related to variety testing.
Entrustment type:	defined limitation in the scope of the entrustment within a particular botanical taxon. An entrustment type should correspond to the extent possible to a grouping characteristic or criteria which can effectively be used for grouping, in the sense that varieties belonging to a particular entrustment type should, in most of the cases, be considered distinct from varieties not belonging to it. This also means that an entrustment type should be defined in a way which allows a clear attribution of varieties to the relevant entrusted examination office (with a scope of entrustment in compliance) on basis of the information provided in the technical questionnaire. In case the entrustment type is empty, this implies that the EO is entrusted for all (potential) types of varieties belonging to this botanical taxon.
Entrusted examination office:	office entrusted by the Administrative Council to perform variety tests on behalf of the CPVO.

NOTE: Whenever the word "EO" is used in the text, it applies to both the entrusted EOs and those having applied for entrustment, unless otherwise specified.



Examination reports:	documented result of various stages of an examination serving as basis for decisions made in the process of verifying compliance with the DUS requirements (Council Regulation No 2100/94, Articles 7, 8, 9): preliminary report (to confirm the examination request and summarise information available at this stage), interim report (report referring to the completion of an individual growing period where there is more than one of these), and final report (result of the examination).
External experts:	panel of external experts which might be consulted by EOs to assist in the research of reference varieties to be grown alongside the candidate variety (also known as "walking reference collection") and to provide complementary expertise when needed. These experts are bound by the rules adopted by the Administrative Council (Doc-AC/06/03/16). To be distinguished from other external experts consulted on subjects other than DUS technical examinations.
Nonconformity:	failure to comply with applicable requirements. A requirement is a need, expectation, or obligation.
Quality assurance (QA):	part of QM aiming at creating confidence in an organisation's endeavour to meet quality requirements.
Quality management (QM):	systematic approach in order to control an organisation with respect to quality; includes activities under the headings: Q-policy, q-objectives, q-planning, q-control, q-assurance and q-improvement.
Scope of entrustment:	list of genera and/or species for which an EO holds authorisation to carry out variety testing work on behalf of the CPVO. The scope of entrustment is validated by a decision of the AC and it can only be extended by a decision of the AC. It is valid from the date of the notification of the AC decision by the President of the CPVO. It can however be reduced by mutual agreement EO-CPVO. In such case it is valid from date of the change of that agreement. The validated scope of entrustment and additional specifications, e.g. applicable cultivation types, for each EO is published in the public area of the CPVO website.
Take-over report:	examination report for a variety concerning a species within its scope of entrustment at the moment of sending a request for "take-over" produced or in the process of being produced by an EO for prior official purposes and considered suitable by CPVO in accordance with Commission Regulation No 874/2009, Article 27.
Technically qualified body (TQB):	subcontractor that provides services for the purpose of technical examinations /verifications under the authority of an EO and with approval by the CPVO.
Technical guidelines	approved document for individual species/botanical taxa which outlines in detail how the DUS test for candidate varieties of that species/botanical taxon should be carried out. Technical guidelines can take the form of (i) CPVO technical protocols, (ii) UPOV test guidelines, (iii) national protocols, (iv) CPVO simplified standard protocols.
Vademecum	CPVO document collection accessible to TLOs which outlines working procedures between the CPVO and its entrusted examination offices
Variety collection:	varieties of common knowledge which are relevant for the examination of distinctness of candidate varieties. Descriptive information about these varieties must be available in the collection and in addition for some species, living material.
Variety testing:	examination on a representative sample of plant material requested officially to verify compliance with the distinctness, uniformity and stability criteria. Depending on the focus of a given examination it may take the



form of a technical examination or of a technical verification, i.e. the verification if the continuing existence of the variety is unaltered.

3. Organisation and management

The EO shall have an organisation that enables it to maintain the capability to perform its technical and administrative functions satisfactorily.

The EO shall define and document the responsibilities and reporting structure of the organisation.

The EO shall provide effective supervision by persons familiar with the variety testing methods and procedures, the objectives of the variety test and the evaluation of the examination results.

The EO shall have named and qualified persons (and replacements) who will deputise in the absence of any manager and examiner, however named, responsible for examination services.

Each post affecting the quality of the variety testing services shall be described. These job descriptions shall include the requirements for education, training, technical knowledge, language skills and experience.

4. Independence, impartiality and integrity

The EO or the organisation, of which it forms a part, shall be legally identifiable.

An EO that is part of an organisation involved in functions other than examinations in the context of variety tests shall be identifiable within that organization.

The EO shall have documentation describing the scope of operations for which it claims competence: scope of entrustment. It shall describe its other functions in sufficient detail to make a distinction between operations to which the entrustment requirements apply and to which they do not (e.g. seed certification).

The EO and its staff shall not engage in any activities that may conflict with their independence of judgement and integrity in relation to their examination activities. In particular the EO DUS-testing staff shall not become directly involved in the breeding, marketing or commercial propagation of the species examined. Where the organisation of which it forms a part is involved in such activities, the EO shall provide evidence of effective separation of responsibilities and independence of the DUS testing team within the organisation, demonstrating that there is no influence from the hierarchy of the organisation. The provisions of the Designation Agreement (DA) in relation to conflict of interests are applicable. This applies also to TQBs as listed in the DA.

Involvement of external experts in DUS activities by an EO shall be under suitable arrangements for safeguarding independence, impartiality and integrity of decisions. In case of use of external experts in the sense of this document, decisions issued by the Administrative Council and in the Vademecum shall be followed. There shall be a documented procedure specifying the roles and responsibilities of experts involved and defining how appointments are made. Appropriate records shall be held, including an updated list of experts. The use and details of external experts shall be notified to the CPVO as stipulated in the AC Decision of 15/11/2006 (<https://cpvo.europa.eu/en/applications-and-examinations/technical-examinations/external-experts>).



5. Confidentiality

The EO shall ensure confidentiality of information obtained in the course of its examination activities. Proprietary rights shall be protected by coding plant material of candidate varieties and comparison inbred lines used in variety testing and by any other suitable measures such as access control to test sites and keeping confidential materials under lock.

6. Cooperation

6.1. Variety testing on behalf of CPVO

The EO shall ensure timely and effective communication with the CPVO as stipulated in the DA, particularly with respect to

- a) Non-delivery of plant material;
- b) submitted plant material that does not fulfil the requirements;
- c) problems in relation to Distinctness, Uniformity or Stability during the technical examination;
- d) any deviation from the technical protocol;
- e) visits of the trial by respective applicants;
- f) deadlines for reporting as specified in the contractual arrangements.

The EO shall afford the necessary cooperation with the CPVO in monitoring and evaluation exercises.

6.2. Take-over reports

For variety testing work initiated for other purposes than Community plant variety rights, provisions of in the pertinent section of the DA apply once the CPVO has made a request to take-over a report. Note: Take-over reports require that the species is included in the EO's scope of entrustment and that other relevant requirements of this document are applicable since the inception of the examination work.

6.3. Other cooperation

The EO shall participate actively in pertinent crop sector working groups for the species or group of species relevant to its activities and organised by CPVO. If EOs cannot participate in a meeting, they have to justify this to the CPVO in advance. Active participation involves commenting on working documents and attending each of the pertinent CPVO crop sector meetings .

An EO should participate in the UPOV technical working party for the species in which they are entrusted. In case they are not able to do so, an EO should be able to demonstrate that they have commented on any working documents related to those species.

Whenever possible, the EO should participate in ring tests and research and development (R&D) projects involving species within its scope of work arranged by the CPVO or other providers of such tests.



7. Personnel

Personnel performing duties affecting the quality of examination work shall be competent on the basis of appropriate education, training, skills and experience. The EO has to ensure that suitable language skills are available at each DUS trial location to enable effective communication in English with CPVO and applicants.

The EO shall implement effective measures to qualify personnel for relevant species or groups of species. Such measures may comprise but are not limited to formal training, on the job training, in-house training, advanced training, workshops, and working party sessions.

Training measures shall be planned in advance and a training plan shall be established to ensure that the training of personnel, in the technical and administrative aspects of the work in which they are involved, is kept up to date. Staff should have followed the UPOV-DL205 distance-learning course or any equivalent training. In addition, DUS examiners should have followed the specialised UPOV-DL305 distance-learning course or an equivalent training covering the same content.

The EO shall have documented procedures establishing internal coordination and harmonisation of the work of examiners.

The EO shall appoint a Technical Liaison Officer (TLO) who acts as technical manager, or supervises technical managers, qualified and experienced in the operation of the EO and having overall responsibility that the variety test activities are carried out in accordance with this document. TLOs shall be permanent employees and shall be responsible for disseminating information in relation to latest developments, as for example discussed in UPOV and CPVO meetings.

8. Quality system

8.1. Document control

Internal and external documents necessary for the operation of the EO shall be controlled. Document control procedures with respect to

- a) approving;
- b) uniquely identifying;
- c) reviewing and updating;
- d) distributing and withdrawing and;
- e) retaining;

relevant documents shall be established. The EO shall prevent the unintended use of obsolete documents.

8.2. Records

Records shall be kept to provide evidence of adherence to established procedures and to keep track of activities performed within the quality management system. Records shall remain legible, readily identifiable and retrievable. Corrections to records shall be validated with date and signature by an authorised person. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.



Retention of records and primary observations in variety test activities shall be not less than the period of the validity of the title or, in case of rejection, the period for filing and processing an appeal. Primary observations are those either in original form in a field book or transcribed in into electronic format.

8.3. Examination reports

Reports to the CPVO shall be submitted timely and in the format defined in the contractual arrangement. Reports and variety descriptions shall include an unambiguous reference to the protocol used. Primary observations and additional records shall be kept and supplied upon request.

Retention of final reports and associated variety descriptions shall be not less than the period of the validity of the title or, in case of rejection, the period for filing and processing an appeal.

8.4. Corrective action procedure

The EO shall implement a documented procedure for dealing with nonconformities encountered. Corrective actions shall be appropriate to the effects of the nonconformities and prevent recurrence. The procedure shall have provisions in order to:

- a) review nonconformities (including customer complaints);
- b) determine the causes of nonconformities;
- c) evaluate the need for action to ensure that nonconformities do not recur;
- d) determine and implement action needed;
- e) record the results of action taken; and
- f) review corrective action taken.

8.5. Internal audits and reviews by management

The EO shall carry out a system of planned and documented internal quality audits to verify compliance with the criteria of this document and the effectiveness of the quality system. All areas of work within the scope of entrustment shall be assessed at least annually.

The management of the examination body shall review the quality system at least once a year to ensure its continuing suitability and effectiveness. The results of such reviews shall be recorded and include:

- a) results of audits;
- b) feedback from interested parties;
- c) trends in nonconformities;
- d) status of corrective actions;
- e) follow-up actions from earlier management reviews;
- f) fulfilment of objectives;
- g) changes that could affect the management system;



h) analysis of appeals and complaints .

9. Facilities and equipment

The EO shall have available to it suitable and adequate facilities and equipment to permit all activities associated with the variety tests. Equipment and facilities may comprise but are not limited to:

- Field facilities
- Glasshouses
- Laboratories
- Machines
- Information technology (IT) equipment and software

Facilities and equipment shall comprise all elements necessary in order to provide for the conditions and assessments specified in the technical protocols.

The EO shall have clear rules for the access to and the use of specified facilities and equipment.

The EO shall ensure the continued suitability of the facilities and the equipment mentioned above for their intended use.

The EO shall ensure that all such equipment is properly maintained, in accordance with documented procedures and instructions.

Where relevant, equipment shall be subjected to in-service checks between regular recalibrations. The EO shall have documented procedures for dealing with defective equipment.

Defective equipment shall be removed from service by segregation, prominent labelling or marking. The EO shall examine the effect of defects on previous variety tests.

Relevant information on the equipment shall be recorded. This will normally include identification, calibration and maintenance.

9.1. Crop Management

The technical examinations should be carried out under conditions ensuring normal growth and cultivation conducted under 'good practice'. The EO should therefore keep records of all cultivation measures including soil preparation, and monitor growing conditions (like temperature, irrigation, rainfall and fertilization) and crop treatments.

The EO shall retain sufficient records in order to provide evidence that the incident of growth conditions that would jeopardize a sound conduct of the examination are noticed.

The EO shall ensure that DUS trials are adequately protected against adverse climatic events in order to avoid the loss of an entire growing season. The EO shall provide appropriate facilities such as irrigation, frost protection, protection against pest and diseases attack, etc, such measures being similar to those adopted by the industry in the vicinity of the EO or operating under comparable environmental conditions for the entrusted species. The EO shall have a documented procedure establishing the criteria used for setting up the protection measures.

9.2. Supplies

Where relevant to the quality of variety testing work, e.g. for chemicals, reference materials, measurement instruments, growing media, the EO shall have procedures for:



- a) selection of qualified suppliers;
- b) issuing appropriate purchasing documents;
- c) inspection of received materials;
- d) ensuring appropriate storage facilities.

Where applicable the condition of stored items shall be assessed at appropriate intervals to detect deterioration.

9.3. IT equipment and software

For computers and automated equipment used in connection with variety tests, the EO shall ensure that:

- a) computer software is tested in order to confirm that it is adequate for use; this shall materialise in the absence of systematic errors in reporting to the Office due to IT shortcomings.
- b) procedures are established and implemented for protecting the integrity of data;
- c) computer and automated equipment is maintained in order to ensure proper functioning; and
- d) procedures are established and implemented for maintenance of security of data.

10. Technical guidelines and procedures

10.1. Technical guidelines

In case of the existence of a CPVO Technical Protocol (TP) such protocol shall be used.

If no CPVO protocol is in force for the genus or species concerned, the UPOV Test Guideline for the genus or species concerned shall be applied. Deviations from the UPOV test guideline must be notified in good time to the CPVO. If no UPOV test guideline has been adopted, a national technical guideline shall be used. The Examination Office shall send to the CPVO for prior approval, national protocols and any subsequent amendments, to be used when testing varieties on behalf of the CPVO. For species where no national protocol exists the CPVO simplified standard protocol shall be used and sent as well to the CPVO for approval. The CPVO shall publish these national protocols.

10.2. Trial planning, trial design

The trial design must be according to the CPVO technical protocol or UPOV test guideline or approved national protocol.

10.3. Selection of varieties for the growing trial

The selection of varieties of common knowledge, to be included in the growing trial represents a key step in assessing distinctness and is done according to the principles in UPOV TGP/9 (see chapter 13 on variety collections).



There has to be a documented procedure for the selection of varieties for the growing trial, defining in detail:

- a) the criteria to exclude a variety from the growing trial, including biomolecular data, if any;
- b) the tools used in the process.

In case the EO wishes to use characteristics not mentioned in the relevant technical guideline or CPVO technical questionnaire to select the varieties for the growing trial, the CPVO shall be informed accordingly.

10.4. Observation of characteristics

Observation of all the characteristics shall be obligatory (except non-asterisked disease resistance characteristics, which shall be optional if so indicated in the technical guideline), providing that observation of a characteristic is not rendered impossible by the expression of any other characteristic, or the expression of a characteristic is prevented by the environmental conditions under which the test is conducted. In the latter case, the CPVO should be informed. In addition, the existence of some other regulation e.g. plant health, may make the observation of the characteristic impossible.

Reasons in case of non-observation of characteristics shall be recorded.

The method of observation for each characteristic of the relevant technical guideline has to be followed as indicated and the procedure how the final value/note is established shall be documented. Notwithstanding, in specific situations a different method of observation may be used as well. Deviating methods shall be documented and communicated to the CPVO.

10.5. Additional characteristics

The agreed procedure in respect of additional characteristics as indicated in the CPVO Vademecum has to be followed.

10.6. Distinctness

Observations shall be analysed taking into account the standards as mentioned in the applicable technical guideline and in accordance with the UPOV document TGP/9 Examination of Distinctness and any relevant Vademecum procedures.

In the case that differences of the candidate variety to similar varieties as indicated in section 16 of the variety description are within the same state of expression, relevant data for describing the difference shall be provided to the CPVO together with the final report.

In case the variety is not distinct, the relevant data of the comparison between the candidate and the variety from which it is not distinguishable shall be provided to the CPVO together with the final report.

10.7. Uniformity

Observations shall be analysed taking into account the standards as mentioned in the applicable technical guideline and in accordance with the UPOV document TGP/10 Examination of Uniformity and any relevant Vademecum procedures. In case the variety is not sufficiently uniform, the relevant data from the characteristics concerned shall be provided to the CPVO together with the final report.



10.8. Stability

Observations shall be analysed taking into account the applicable technical guideline and in accordance with the UPOV document TGP/11 Examination of Stability and any relevant Vademecum procedures.

In case the variety is not sufficiently stable, the relevant data shall be provided to the CPVO together with the final report.

11. Handling plant material of candidate varieties

The EO shall ensure that samples to be examined are uniquely identified and marked to provide for traceability of observations and findings.

Any apparent abnormalities of the plant material received with respect to the plant material request and instructions noticed shall be recorded (e.g. by taking a picture) without delay. Where there is any doubt as to the material's suitability for the examination, or where the plant material as submitted does not conform to the description provided, the EO shall consult with the CPVO before proceeding.

The EO shall be able to demonstrate that it only accepts material for variety testing complying with the plant material request of the special issue of the Official Gazette of the CPVO (S2/S3 Publication) and related instructions.

The EO shall have documented procedures and appropriate facilities to control deterioration of plant material while under its responsibility.

12. Variety collections

12.1. Introduction

Article 55 (1) of the Basic Regulation establishes that:

"Where the Office has not discovered any impediment to the grant of a Community plant variety right on the basis of the examination pursuant to Articles 53 and 54, it shall arrange for the technical examination relating to compliance with the conditions laid down in Articles 7, 8 and 9 to be carried out by the competent office or offices in at least one of the Member States entrusted with responsibility for the technical examination of varieties of the species concerned by the Administrative Council, hereafter referred to as the 'Examination Office or Offices'".

The prescribed procedure is thus to assess distinctness, uniformity and stability in a growing trial carried out by an entrusted EO.

Furthermore Article 7 (1) specifies that:

"A variety shall be deemed to be distinct if it is clearly distinguishable by reference to the expression of the characteristics that results from a particular genotype or combination of genotypes, from any other variety whose existence is a matter of common knowledge on the date of application determined pursuant to Article 51".

Details for varieties to be considered a matter of common knowledge are addressed in the section 12.2.2.2 of this document.

Given that the list of varieties of common knowledge for a given species can be very large, the EO shall follow the UPOV recommended process (see UPOV TGP/4 Constitution and Maintenance of Variety Collections). That process can be summarized in the following steps:



Step 1: Making an inventory of the varieties of common knowledge

Step 2: Establishing a collection ("variety collection") of varieties of common knowledge which are relevant for the examination of distinctness of candidate varieties

Step 3: Selecting the varieties from the variety collection which need to be included in the growing trial or other tests for the examination of distinctness of a particular candidate variety.

The identification of varieties of common knowledge which need to be included in the variety collection and the establishment of a variety collection (Step 2) are addressed below. The use of the variety collection to select varieties to be included in the growing trial or other tests (Step 3), is addressed in chapter 10.3.

The constitution and the maintenance of a variety collection depend on the way the species in question is propagated (seed/vegetatively). In particular, variety collections of seed propagated varieties may follow different requirements than vegetatively propagated varieties.

Exceptions or specifications to the above mentioned distinction are addressed specifically on species level, where necessary.

Furthermore the number of applications per species can have an impact on the requirements. Where this is the case, it will be indicated.

12.2. Constitution of variety collections

12.2.1. Forms of variety collection

With regard to agricultural, vegetable and specified fruit species (see annex 1), a variety collection of a given species shall comprise variety descriptions and living plant material. Exceptions to this principle where a collection of variety descriptions is required but not a living reference collection are vegetatively propagated agricultural and vegetable species/varieties as well as fruit species not included in the aforesaid list.

With regard to the ornamental species, a variety collection of a given species shall comprise variety descriptions and may comprise living plant material.

12.2.1.1. Variety Descriptions

The following forms of variety description shall be included in the variety collection for agricultural, vegetable and fruit species as specified. It also shall apply to the ornamental species where there is a CPVO technical protocol.

- a) Variety descriptions produced by the EO establishing the variety collection. These descriptions should enable the EO to identify effectively reference varieties to be compared to candidate varieties in the growing trial.
- b) Variety descriptions not established by the EO in case of special cooperation between EOs and the CPVO (e.g. species specific database projects) or special cooperation between EOs only. In such a case a detailed documentation on cooperation should be available.
- c) In addition, for ornamental species with a CPVO TP and for those fruit species where indicated in the technical protocols: images (e.g. photographs, illustrations or digitalized images) of representative parts of the plants of each variety, produced by the respective EO.



The descriptive and pictorial information produced by the EO shall be held and maintained in the form of a searchable database.

For other species the following forms of variety descriptions are considered sufficient:

- a variety description according to the UPOV Test Guidelines which has not been produced by the EO establishing the variety collection;
- a variety description produced by another party where the variety is registered;
- images (e.g. photographs, illustrations or digitalized images) of representative parts of the plants;
- relevant descriptive information from, for example, scientific publications, commercial catalogues, databases, etc.

12.2.1.2. Living Plant Material

The prescribed procedure of examining distinctness is to conduct a growing trial or other test containing the candidate variety and the relevant varieties of common knowledge. This requires that living plant material is available.

For species with a living variety collection, the EO shall collect and maintain living plant material of varieties of the species concerned in the variety collection.

The inclusion of samples of parent lines of common knowledge into the variety collection of an EO shall be on a needs basis according to the similarity of candidate varieties in any given DUS trial.

For the ornamental species and for fruit species not included in the annex 1, as well as vegetatively propagated agricultural and vegetable species/varieties, the EO may only obtain living plant material of reference varieties as and when those varieties need to be included in growing trials or other tests.

12.2.2. Factors to be considered for inclusion of a variety in a variety collection

When establishing a variety collection it is necessary to decide first on the range of the collection and then to identify the varieties of common knowledge which are covered by that range. It is important to note that a variety collection cannot be established definitively. The variety collection needs to be continuously updated taking into account the evolution of lists of varieties of common knowledge, the development of new types of varieties and the introduction of new plant genetic material, and needs to be reviewed in relation to each new candidate variety. Candidate varieties shall also be considered for inclusion in a variety collection.

12.2.2.1. Range of the variety collection

A variety collection may encompass a whole species or more than one species if there are interspecific hybrids or may be limited to a subspecies or to types of varieties or groups of varieties within a species or subspecies. Consequently, the variety collection shall encompass all varieties of a given type within the identified range. "Type of variety" means that varieties of that type have a common trait, or traits, often physiological traits (e.g. winter wheat, or garden roses, or indeterminate tomato varieties, or identified apple mutation groups, or "Entrustment types"), by which they are recognized beyond the purposes of the examination of DUS.

For fruit species listed in annex 1 and seed-propagated agricultural and vegetable species/varieties the living variety collection shall cover at least those common knowledge varieties that are suitable to grow in the climatic conditions of a respective EO.

In the case of agricultural species where the testing of hybrid varieties requires the submission of their components (generally parent lines) and where both can also be subject to applications and are as such covered by the relevant technical protocols, the variety collection shall be set up as follows:



For applications of hybrid and parental line varieties where a pre-screening system on the basis of parental lines and the formula is not used, the variety collection shall include all hybrid and parental line varieties which are varieties of common knowledge. Parental lines of common knowledge are at least those which have been registered into an official register (protection and/or national listing).

For applications of hybrid varieties where a pre-screening system on the basis of parental lines and the formula is used, the variety collection shall include all parental lines of all hybrid varieties which are in common knowledge and those hybrid varieties of common knowledge which reveal similarity in the formula of a candidate variety.

12.2.2.2. Making an inventory of varieties of common knowledge for inclusion in the variety collection

The inventory shall take into account the list of protected varieties and the official, or other, registers of varieties, in particular:

For agricultural and vegetable species, the inventory shall include varieties protected under National and Community PBR, varieties registered in the Common Catalogue, the OECD list, the Conservation variety list and varieties in trade or in commercial registers for those species not covered by a National or the Common Catalogue.

For agricultural species with hybrid varieties the requirement of the previous section 12.2.2.1 applies.

For the other crop sectors, the inventory shall include varieties protected under National and Community PBR, varieties of National Catalogues for fruit species (where such catalogues exist) and varieties in trade or in commercial registers e.g. register of varieties commercialized in Dutch auctions (VKC).

The inventory shall take into account the list of varieties which are the subject of an on-going application for protection or official registration (candidate varieties).

In addition to the above, for ornamental and fruit species the inventory shall take into account to the extent appropriate:

- example varieties referred to in the technical protocols;
- any commercial document in which varieties are marketed as propagating or harvested material, especially when there is no official registration system;
- any list including varieties which are publicly available within plant collections (varieties included in genetic resource collections, collection of old varieties, etc.);
- information provided by relevant plant experts.

12.2.2.3. Geographical scope

In addition to the territory of the EU consideration shall also be given to:

- a) territories where plant material of the type and species concerned is traded;
- b) territories with which the country of the EO concerned has a relationship for breeding activities, seed trade or any exchange of plant products and which have similar climatic and growing conditions;
- c) other territories where examination of distinctness is conducted for the type and species concerned.

12.2.3. Varieties of common knowledge not included in the variety collection or for which living plant material is not available



A variety collection cannot be established definitively and may not contain all varieties of common knowledge (see chapter 12.1). In addition, there may be situations where the authority cannot obtain living plant material of a variety included in the variety collection. Furthermore, as a consequence of the deletion of a variety from a register (PBR or National Listing), there may no longer be material available of that particular variety.

The EO shall make reasonable efforts to collect information and/or plant material in order to have a complete variety collection according to the principles mentioned above. The EO shall have a documented policy describing criteria/reasons for deviating from above principles i.e. not including certain varieties of common knowledge into the collection. In the case of parent line varieties of common knowledge, the EO shall be able to demonstrate that it has at least analysed the variety descriptions drawn up by other entrusted EOs for that species.

12.3. Maintenance of variety collections

12.3.1. General

The variety collection needs to be updated every time the EO tests a new candidate variety, taking into account the evolution of lists of varieties of common knowledge, the development of new types of varieties and the introduction of new plant genetic material. It is necessary to establish contacts with the relevant authorities in different territories to obtain information and to be able to obtain descriptions and living plant material as required. It is also important to complete the variety collection on a case-by-case basis considering the information provided by the applicant, particularly concerning the breeding scheme of the candidate variety. The purpose of the following subsections is to clarify the requirements on some specific aspects concerning the maintenance of variety collections in the form of variety descriptions and living plant material.

12.3.2. Variety descriptions

With regard to in-house variety descriptions based on the relevant applicable technical protocols, it is important to note that technical protocols may be revised, possibly leading to the introduction of some new characteristics and the deletion of some others from the table of characteristics. Furthermore, the states of expression of a characteristic may be amended. Therefore, descriptions which have been prepared using different versions of the relevant technical protocols for the same species or type of species may not be fully compatible. In these cases, the descriptions shall be updated on the basis of new growing trials or aligned as far as possible according to a documented procedure.

12.3.3. Living plant material in variety collections

The maintenance of a variety collection of living plant material involves a number of activities, the aim of which is to enable a variety to be used in relation to the growing trial or other tests when examination of distinctness renders it necessary. For the purposes of this document, maintenance of living plant material refers to the way the living plant material is maintained in storage (e.g. seed) or under cultivation (e.g. vegetatively propagated varieties).

Where a variety collection exists as a database of variety descriptions with the necessary living plant material being assembled when required, thus avoiding any need for living plant material to be maintained by the EO on an on-going basis, in such cases, the practice is to request material of the relevant reference varieties from the appropriate source each time it is necessary to conduct a specific examination of distinctness. In this way, varieties selected from the variety collection can be included in the growing trial or other tests to enable direct plant-to-plant comparisons.

When living plant material is procured on a needs basis for the growing trial, it shall be established that it conforms to the variety. If there is no variety description established by the EO available, the variety should be checked against other appropriate descriptions, e.g. plant registers or commercial catalogues.



12.3.4. Sources of living plant material

For varieties entered in an official register:

- breeder / maintainer / applicant / title holder / procedural representative
- or official authorities

For varieties which are not entered in an official register:

- breeder / maintainer
- market
- plant collections

Breeders are an important source of living plant material and cooperation with breeders is encouraged. For protected varieties breeders have an obligation to maintain and provide plant material, since lack of maintenance or supply of a variety may lead to a technical verification test and ultimately to the cancellation of the Community plant variety right (CPVR).

Examination offices shall assure notification to the CPVO in case material of a CPVR protected variety has not been provided, since this can result in the launching of a verification exercise by the CPVO. The plant material of the procured variety shall be of a comparable stage of development as the candidate variety.

12.3.5. Maintenance and updating/renewal of living plant material

The EO shall have a documented procedure for storing, maintaining and monitoring the quality of the plant material.

Seed propagated varieties shall be maintained by keeping seeds in safe conditions which will ensure germination and viability, periodical checks, and renewal as required.

Vegetatively propagated varieties shall be maintained under appropriate growing conditions (e.g. glasshouse, orchard, in vitro), where it shall be ensured that the plants are adequately irrigated, fertilised, pruned and protected, including from harmful pests and diseases

With respect to the living plant material already included in the variety collection, the following situations require the renewal of that material, such as:

- when the material originally provided by the applicant was in the quantity needed for DUS examination only, and more material is needed after the examination for long-term storage in the collection;
- when the material in the collection has been depleted or has deteriorated;
- in variety collections of vegetatively propagated perennial varieties: Observations shall be made on plants at the same physiological stage, although the plants may be of different ages. Nevertheless, at some time, the plants may become over-mature (i.e. too old for observations) and need to be renewed.

Living material in variety collections representing varieties for which a DUS test was carried out at that EO shall be renewed after verification in a side-by-side comparison. In case where no material is available anymore, such verification could be done with any other test that has proven to give similar results between the material in the collection and the new material.

A documented procedure for verifying material before its introduction in the collection, whether of new varieties of common knowledge or renewal of material of varieties already included in the variety collection, shall be established.



12.4. Cooperation in the maintenance of variety collections

For the establishment of variety collections, the availability of information on varieties of common knowledge is a key requirement. Exchange of information between authorities, breeders, botanic gardens, gene banks, and any other possible source of information is very important to define the list of varieties to be included in the collection.

For the purposes of the examination of DUS, the CPVO insists on cooperation between entrusted EOs/authorities including, in particular, the exchange of information and living plant material of varieties of common knowledge for the examination of distinctness.

An EO may choose to limit its cooperation by only:

- Supplying living material of varieties which are listed or protected in the country and for which it had performed the DUS test
- Supplying an amount of plant material that is needed to authenticate a larger sample provided by, for example, the breeder
- Supplying material once for any given EO within the CPVO network of EOs entrusted for that species.

12.4.1. Exchange of standard samples with other EOs.

Where living material is exchanged the dispatching EO shall ensure that:

- The holder of proprietary rights gives consent to any material transfer of candidate varieties to offices that are not entrusted for the respective species
- The holder of proprietary rights is duly informed about material transfer between EOs that are entrusted for the respective species and involving parent lines or disclosing hybrid formulas

Any material not representing parent lines or disclosing hybrid formulas may be supplied to any other authority without restrictions, once the variety is protected by CPVR title or is marketed (CPVO Policy on the Status of Plant Material Used for DUS Testing Purposes: https://cpvo.europa.eu/sites/default/files/documents/announcement/2012/CPVO_Policy_on_the_Status_of_Plant_Material_Used_for_DUS_Testing_Purposes.pdf).

13. Subcontracting

When an EO chooses to avail itself of subcontractors for all or part of the DUS test for the species according to the Designation agreement, Annex 2, for which it is entrusted, by contracting such work to technically qualified bodies, it shall ensure and be able to demonstrate:

- a) that its subcontractor (TQB) is approved by the CPVO for the specific task performed on behalf of the EO via a prior notification based on the Annex to the DA;
- b) that the subcontractor does not use further subcontractors for performing the task, unless agreed between all parties;
- c) that the subcontractor meets the requirements of this document;
- d) that regular assessments of the subcontractor's adherence to the provisions of this document are carried out. Where appropriate these assessments must be carried out by an audit team appointed by the CPVO.

The EO shall notify the CPVO for prior approval if any part of the DUS test is conducted under the responsibility of the breeder, or if an external contractor is utilised for the provision of variety collections.



The responsibility for the technical validity of the work performed under such arrangements rests with the EO itself.

