

DUS Material Use Policy: Ownership and Use of DUS Samples and DNA from DUS Samples During and After DUS Research as of January 1, 2025

1. Introduction

Just as breeding is evolving, DUS research is following these developments and adapting continuously. New questions and challenges arise and new techniques are applied to ensure and improve the quality of DUS research. It is in the applicant's interest to be clear about the use of their materials during and after the DUS research.

Based on a proposal from Naktuinbouw and after consultation with the plant breeding industry, the following policy was adopted by the Board for Plant Varieties (the Board). This policy was established after consultation with the applicants. Once adopted, the policy will be announced and published on the website and in the Gazette of the Board.

2. Current status of policies on ownership and use of DUS materials at national and international levels

UPOV

Within UPOV there are hardly any clear rules on ownership and use of DUS samples. Art. 12 of the UPOV '91 convention reports only:

Examination of the application. "Any decision to grant a breeder's right shall require an examination for compliance with the conditions under Article 5 to Article 9. During the examination, the authority may grow the variety or conduct other necessary tests, cause the growing of the variety or the conducting of other necessary tests, or consider the results of growing tests or other trials which have already been conducted. For the purposes of examination, the authority may require the breeder to furnish all the necessary information, documents or material."

The UPOV TGP document cites the CPVO policy document mentioned below as an example for handling DUS material.

CPVO

CPVO has laid out more in the CPVO Policy on the status of plant material used for DUS testing purposes: CPVO Policy on the Status of Plant Material submitted for DUS testing purposes | CPVO

Further on in this document, the topics in the CPVO policy are discussed.

The Netherlands – Board for Plant Varieties.

In the Netherlands, the status is as follows:

For ownership of the DUS sample applies:

- The applicant/breeder is and remains the owner of the DUS sample during and after the DUS examination.
- The Board for Plant Varieties will have the DUS sample at its disposal in order to perform the DUS test or have it performed, and
- Naktuinbouw manages the DUS sample.

Regarding the use of the DUS sample in the context of the DUS examination, the Netherlands follows the CPVO policy.

3. The CPVO policy.

In this policy document, “material” includes a DNA sample of the material taken by a examination office for DUS purposes. Examination office means an entrusted examination office (designated as such by the A.C. of CPVO).

CPVO's DUS material use policy.

1.1 What should a examination office do with plant material if the application is withdrawn or rejected?

1.1. The examination office must destroy the material or return it to the applicant.

1.2. If the variety is widely known, the examination office may keep the material in its reference collection.

2. May a examination office send the material to:

2.1 To another examination office?

2.1.1 Yes, upon request, a examination office will forward material to another examination office.

2.1.2 If the material consists of parent lines or would reveal information about hybrid formulas, the examination station should inform the rights holder that the material has been sent to another examination station.

2.1.3 The examination office may not use the material received from another examination office for any purpose other than for DUS examination or R&D projects between examination offices aimed exclusively at improving DUS examination.

If R&D projects to improve DUS research involve a non-entrusted research agency or a third party, permission from the title holder is required. The provisions on confidentiality and conflict of interest in the consortium agreement between the CPVO and the examination office shall apply and be included in the consortium agreement signed by the partners of the R&D projects.

2.1.4 If the material is used for purposes other than those mentioned in 2.1.1 - 2.1.3, permission from the right holder is required. Also in this case, the provisions on confidentiality and conflict of interest in the consortium agreement between the CPVO and the examination office apply.

2.2 May a examination office send the material to a non-entrusted examination office or a certifying authority or any other entity?

2.2.1 The examination office may send material to another non-entrusted examination office upon request only if the permission of the right holder has been obtained and such permission has been communicated to such non-entrusted examination office.

2.2.2 The examination office may transmit material to a certification body on request only if the consent of the right holder has been obtained and this consent has been communicated to the certification body.

2.2.3 The examination office may further provide material to any other entity only if the consent of the right holder has been obtained and communicated to such other entity.

3. What may the examination office do with the material after the variety has been granted a Community plant variety right?

3.1 If the examination office does not maintain a living reference collection, the material will be destroyed or returned to the applicant.

3.2 If the examination office maintains a living reference collection (including DNA samples), the material must be retained by the examination office.

3.3 If the material is retained, the examination office may transfer material to another examination office or to a non-entrusted examination office upon request under the same conditions as shown above in section 2.

4. After expiration of the validity of the community plant variety

4.1. Material retained in a reference collection must be retained after expiration of a community plant variety right.

4. Current use of DUS sample (plant material) in the Netherlands.

The CPVO policy is applied in the Netherlands to community applications as well as national applications for plant variety rights and for inclusion in national lists. Upon completion of the examination, material that is not included in a living reference collection is destroyed by default, unless the applicant has requested that the material be returned. Under the same conditions, DUS samples are also provided to the certification authorities of other EU member states in the context of national authorization.

In addition to these rules, the following is stipulated for national applications:

(a) In all cases where DUS material is provided to third parties (whether in the context of plant breeders' rights, admission or control of marketing/certification) the applicant/holder will be informed.

b) Where reference is made to "use for DUS research" this should be understood to mean all actions relating to the granting of Plant Breeders' Rights or admission. This excludes use for enforcement of plant breeders' rights (infringement research) and other uses.

c) When sending to third parties it will be stated that DUS material may only be used for DUS purposes and/or certification.

5. Use of descriptions and photographs made on the basis of the DUS sample created

As part of the DUS examination a variety description is made and photographs are taken of (parts of) DUS examination plots containing registered varieties. These variety descriptions and photos are stored in Naktuinbouw databases and are consulted when searching and selecting reference varieties as comparators in DUS research. Such variety descriptions and photos - unlike DUS reports - are public. This publicity is accomplished in such a way that variety descriptions and possibly photos are included in the NRR on the website of the Plant Variety Council. An exception to this are the variety descriptions of parental lines if these parental lines have been examined as part of hybrid research (e.g. in maize). In this case the descriptions are not public. When published, any reference to breeding history is also removed.

6. Current use of DNA in DUS research in the Netherlands

During the DUS research in certain crops DNA is isolated from each DUS sample or (leaf) material is stored, from which DNA can later be isolated. The DNA is stored by Naktuinbouw.

DNA from DUS samples can be used to support DUS research:

- The research on individual traits (e.g. resistances),
- Organizing reference collections based on DNA profiles,
- Inclusion in a reference collection (database) (e.g. potato, Phalaenopsis etc.),
- Possible research on stability,

- Possibly examination for genetic conformity as substantiation of insufficient morphological differences or in case of morphological differences suspected not to be genetic but provenance-based,
- For possible future reference.

7. Use of DNA and DNA profiles created from the DUS sample. created

The DNA from the DUS samples is subject to the same rules as for the DUS samples themselves (including the additions mentioned in Section 4). The background to this is that anyone who has the DUS sample available can also extract the DNA from it themselves. Analogous to the morphological characteristics of the plant material, the genetic characteristics of the DNA from the DUS sample are examined for some crops. Unlike variety descriptions (as described under paragraph 5), such DNA characteristics will NOT be made public. The Plant Variety Council regards such information as belonging to business and manufacturing records that contain trade secrets, because DNA profiles are subsequently traceable to specific processes or products. This means that any requests under the Open Government Act will not provide DNA-related information. Raw DNA data or profiles are therefore not public or retrievable. These data/profiles will be included in Naktuinbouw's reference database.

8. DNA use after DUS testing

DNA can not only be used during the DUS examination, but also proves to be a good aid in the identification of varieties and in the enforcement of plant breeders' rights. This strengthens the plant variety rights system. There are three different options in this use:

8.1 As a named identified standard representing the variety (the DUS sample). This establishes the indisputable link between the object of protection and the research material used to gather evidence against the infringer. Since this is a use outside the use for DUS purposes, it requires the prior consent of the rights holder. In the case of infringement evidence - where the rights holder himself submits a sample to see if it is the same as the standard identified under his name - this is directly to his advantage. Consent will always be given.

8.2 In anonymized form as a background sample in a DNA comparison test between two samples. Here a third party will submit a sample with the request to check/check whether this sample (already) appears in the database. Otherwise, this use runs parallel to the use mentioned under 8.1. In addition, use in anonymized form to determine e.g. genetic thresholds within crops in EDV discussions that can be carried out in cooperation with industry. Industry will be involved in the determination of threshold values. Although strictly speaking this use is outside the use for DUS purposes, the anonymization is sufficient security against misuse that with it the consent of the DNA sample owner is not considered necessary.

8.3 If, for any reason, a third party wishes to have a supplied sample compared to a standard identified by name in the database, this can only be done with the prior consent of the owner of the breed in question (if the DNA sample is included in the database from this).

9. Use of DNA data

In general, results from the use of DNA for e.g. resistance testing and databases are stored in the form of data (fingerprints etc.) for possible future use. The examination office stores these data.

The stored data can be used for various purposes. These purposes can be distinguished into those that do not require the consent of the DNA owner:

9.1 Use within DUS research such as use in managing reference collections, comparison in the context of stability questions, identity check on replacement samples in living reference collections. Uses outside DUS research in anonymized form such as threshold EDV determination, use as anonymized background samples when comparing two samples.

And in uses requiring prior permission from the DNA sample owner such as:

9.2 comparison of samples in the context of possible mix-ups, possible infringement, providing to examination offices not trusted by CPVO, etc.

It should be noted that by order of a court, the Council and Naktuinbouw will have to cooperate in confiscating material and data.

10. Concluding remarks

Because new insights and techniques may play a role in the established policy in the future, the policy will be evaluated periodically in consultation with the industry after 2 years and adjusted if necessary. This policy was adopted by the Plant Variety Board on October 10, 2024 and, upon publication, will take effect on January 1, 2025.