

Policy use DUS material

Policy: Ownership and use of DUS samples and of DNA from DUS samples during and after completion of the DUS study.

Introduction

Just as breeding is evolving, so DUS research follows these developments and adapts constantly adapting. New questions and challenges are emerging and new techniques are being applied to ensure and improve the quality of DUS research. It is in the interest of the applicant to be clear about the use made of their material during and after completion of the DUS examination. Naktuinbouw has found that there is currently a lack of clarity about the use of DUS samples and, consequently, on the use of DNA from the DUS samples.

Based on a proposal from Naktuinbouw and after consultation with the industry, the Board for Plant Varieties adopted the following policy. This policy was established after consultation with the applicants. Once adopted, the policy will be announced and published on the Council's website. Subsequent efforts will be made to arrive at an internationally accepted system of agreements (CPVO/ UPOV).

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

UPOV

Within UPOV, hardly any clear rules can be found 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. In the course of the examination, the authority may grow the variety or carry out other necessary tests, cause the growing of the variety or the carrying out of other necessary tests, or

take into account the results of growing tests or other trials which have already been carried out. For the

purposes of examination, the authority may require the breeder to furnish all the necessary information, documents or material".

In the UPOV TGP document, the CPVO policy document mentioned below is given as an example given for dealing with DUS material.

CPVO

The CPVO has laid down more in the CPVO Policy on the status of plant material used for DUS testing purposes:

(http://www.cpvo.europa.eu/documents/announcement/2012/CPVO_Policy_on_the_Status_of_Plant_Material_Used_for_DUS_Testing_Purposes.pdf)

The issues from this Policy will be discussed below.

The Netherlands - Council 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 research, the Netherlands follows the CPVO policy.

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3. The CPVO policy

The use

1. What should an examination station do with plant material if the application is withdrawn or rejected?

1.1 The material will be destroyed or returned to the applicant upon request. Only if there is Common Knowledge, the material may be included in a (living) reference collection.

2. May a research station send material to another CPVO entrusted station?

2.1 Yes, material may be sent to another station that is entrusted for the crop in question. sent.

2.2. If the material is from parental lines, the applicant/breeder should be informed.

2.3. The material may be used by the receiving station only for DUS research.

2.4. May a research station send material to another station that is not CPVO entrusted? This is allowed only with the consent of the applicant/breeder.

3. What may a research station do with plant material if plant variety rights are granted?

3.1. If there is no living reference collection; destroy or after request; return it to the applicant.

3.2. If there is a living reference collection the material will in principle be included in it.

3.3. If the material is held by the entrusted station then on request it may be sent to another entrusted station or to another research station under the same conditions as stated under paragraph 2 (above).

4. What may a research station do with plant material after the plant breeder's right has expired?

4.1 If the material is included in a living reference collection, the material may remain in it.

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

The CPVO policy is applied in the Netherlands to Community applications, but also to National applications for Plant Breeders' Rights and for inclusion in National lists.

Under the same conditions, parts of DUS samples are also provided to the certification authorities of other EU Member States in the context of admission/ marketing.

Upon completion of the study, material that is not included in a living reference collection is destroyed by default, unless the applicant has requested that the material be returned.

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

In all cases where DUS material is provided to third parties (both in the context of Plant Breeders' Rights, admission or control of trading/certification) the applicant/stand holder will in all cases be informed in all cases.

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

When sending to third parties, it will be stated that DUS material may only be used for DUS purposes and

Certification may be used.

5. Use of descriptions and photos taken from the DUS sample

As part of the DUS examination, a breed description will be made and photographs will be taken of (parts of) applications. 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 implemented in such a way that breed descriptions and possibly photos are included

on the website of the Board for Plant Varieties and Naktuinbouw.

An exception to this are the variety descriptions of parental lines if these parental lines as part of hybrid research (e.g. for Maize). In this case the descriptions are not public. Upon publication, any reference to breeding history shall also be removed.

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

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

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

- The research on individual traits (e.g. resistances)
- Organising reference collections based on DNA profiles
- Inclusion in a reference collection (database) (e.g. potato, Phalaenopsis etc.)
- Possible research on stability
- Possibly research into genetic conformity as substantiation of insufficient morphological differences or in case of morphological differences suspected to be non-genetic but origin-based
- For possible future reference

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

The DNA from the DUS samples is subject to the same rules as the DUS samples themselves (including the additions mentioned in paragraph 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, in some crops the genetic characteristics of the DNA from the DUS sample are examined. In contrast to the variety descriptions (as described under paragraph 5) such DNA characteristics, will NOT be made publicly available. The Plant Variety Council considers such information to belong to business and manufacturing data containing trade secrets because DNA profiles can be retrospectively

traceable to specific processes or products. This means that in the event of any requests under the

under the Public Access Act, no DNA-related information will be provided. Raw DNA data or profiles are therefore not public or retrievable. These data/profiles are included in the reference database of Naktuinbouw.

8. DNA use after DUS testing

DNA can not only be used during the DUS investigation, but also proves to be a good aid in the identification of varieties and in the enforcement of plant breeders' rights. Thus, the plant breeders' rights system is strengthened. 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 investigative material used to gather evidence against the offender. Since this is a use outside the use for DUS purposes, it requires prior consent from the rights holder is required. In the case of infringement evidence, this is directly to his advantage. Consent will always be given.

8.2 In anonymised form as a background sample in a DNA comparison test between two samples in the case mentioned under 8.1 and in anonymised form to determine e.g. genetic thresholds within crops in EDV discussions that can be carried out in collaboration with industry be conducted. Industry will be involved in the determination of threshold values. Although strictly speaking this use falls outside the use for DUS purposes, anonymisation is sufficient security against misuse that thereby 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 after prior consent of the owner of the breed concerned.

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 research station stores these data.

The stored data can be used for various purposes. These purposes can be distinguished purposes 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. Use outside DUS research in anonymised form such as threshold EDV determination, use as anonymised background samples in comparison between two samples.

And in uses where prior permission is required from the DNA sample owner such as:

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

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

10. Concluding remarks

As new insights and techniques may play a role in the adopted policy in the future, the policy will be evaluated periodically in consultation with the industry after 2 years and adapted if necessary.
be adjusted.

This policy was adopted by the Plant Variety Council on 27 February 2015 and comes into force on 1 May 2015