

**Working Group on Biochemical and Molecular Techniques  
and DNA-Profiling in Particular**

**BMT/19/5**

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**ACCESS TO REFERENCE MATERIAL AND MOLECULAR DATA FROM CPVO EXAMINATION OFFICES**

*Document prepared by an expert from the European Union*

*Disclaimer: this document does not represent UPOV policies or guidance*

The annex to this document contains a copy of a presentation on “Access to reference material and molecular data from CPVO examination offices”, prepared by an expert from the European Union, to be made at the nineteenth session of the BMT.

[Annex follows]



**CPVO**  
Community Plant Variety Office

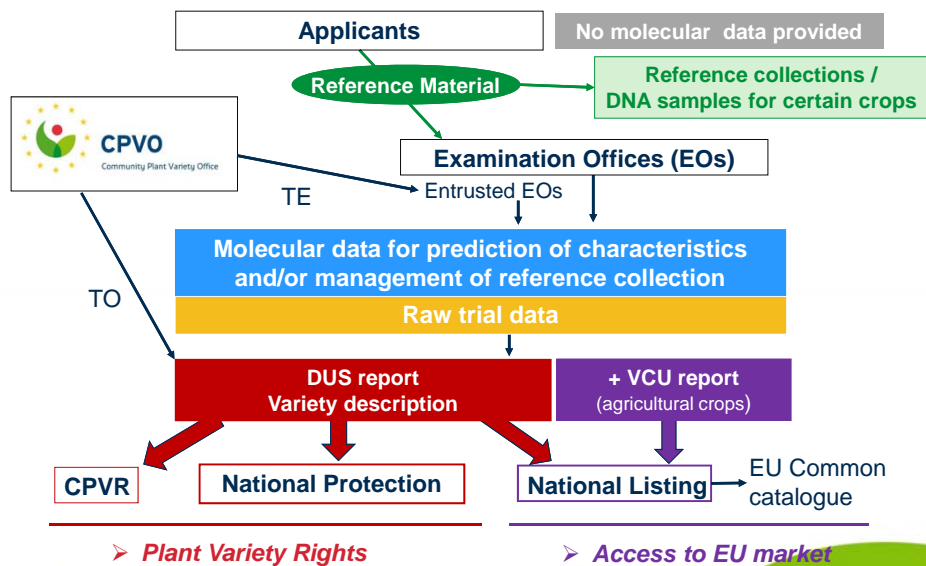
UPOV BMT19 - Agenda Item 11:  
Confidentiality, ownership and access to  
molecular data

## Access to reference material and molecular data from CPVO examination offices

Cécile COLLONNIER

CPVO (Angers, France)  
[www.cpvo.europa.eu](http://www.cpvo.europa.eu)

### MATERIAL and DATA for listing and PVR in the EU



## ACCESS TO DATA in the EU

Balanced application of 3 fundamental rights :



### PROPERTY

Regulation (EU) 608/2013 - customs enforcement of **intellectual property rights**

### PERSONAL DATA PROTECTION

Regulation (EC) 2017/0002 - processing of personal data

→ emphasis added to **intellectual property**.

### CITIZEN'S RIGHTS TO GOOD ADMINISTRATION AND ACCESS TO DOCUMENTS

Regulation (EC) 1049/2001 - public access to documents

Article 4 : exceptions

- e.g. - protection of institutions' decision-making process, public security, defence and military matters, international relations, financial, monetary or economic policy of the Community or a MS,
- court proceedings and legal advice,
- inspections, investigations and audits,
- **protection of commercial interests** of a natural or legal person, including **intellectual property**.



## ACCESS TO DATA produced for CPVR

- There are **no rules on ownership** of data applicable to the CPVO.
- **All data held by the CPVO (from TE and TO) are covered by the rules on access to documents** (Regulation 1049/2001). This means **transparency as a general principle** and confidentiality only when an exception is available.
- Anybody can place a **public access request** to have access to the whole content of the dossier of a variety at the CPVO.



- *(Documents containing)* Raw data kept by EOs do not directly fall within the rules of access to docs since the data is kept by an EO and not directly by CPVO.

But, since the EOs are part of the CPVO PVP network, **it would be very difficult for the CPVO to defend that *(documents containing)* raw data which have been obtained on behalf of the CPVO can be kept confidential**. This issue has not yet been dealt with in court.



## ACCESS TO DATA produced for CPVR

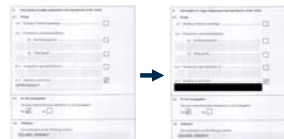
- However, an information can be kept **confidential**, if it is proven that this information constitutes **commercial interests** :



- **Hybrid formulae** (Basic regulation EC-2100/94 on Community plant variety rights, Article 88-3.)

All variety descriptions are publicly available on line but all **references to the parental formula are blackened**.

(Art. 4 of basic regulation 1049-2001).



- **Molecular data** (CPVO Policy as agreed by AC)

**Molecular data held by an EO on a given variety is not accessible to any third party without the consent of the EO and the title holder.**



## ACCESS TO DATA produced by EOs for National Listing/ National Protection in the EU





- EU legislation does not cover this data.
- **If there is a legislation in a MS** saying that the data in question is confidential or owned by the breeder, it **must be followed**.
- **If there is no national legislation, a policy decision is normally taken by the national authority in question.**

In most administrations such a decision is taken after having made a balance of the interests of various stakeholders affected by the decision and the **public interests** at hand.

→ As a consequence, rules may vary between MS depending on the interpretation of relevant governmental authorities and on the national variety testing systems (involvement of third parties in the testing networks, legal obligation to publish the results with or without restricted access, ...)







## ACCESS TO REFERENCE MATERIAL



CPVO Policy on the Status of Plant Material Used for DUS Testing Purposes  
(DOC-AC-2019-1-18- Annex 1)

**Material provided for DUS testing can be made available for this purpose only !**

❖ May an EU Network Office send material...

- ... to another EU Network Office ?  
YES if entrusted for the same species  
If the sample is a parent line, and for **DNA samples** → **information of the title holder**
- ... to an other Examination Office outside the EU network ?  
YES if consent from the title holder  
If the variety is sold on the market, consent not required  
**For DNA samples consent should be obtained from the title holders in any case.**  
**but only for DUS purposes !**





## ACCESS TO REFERENCE MATERIAL

CPVO Policy on the Status of Plant Material Used for DUS Testing Purposes  
(DOC-AC-2019-1-18- Annex 1)



❖ What after the variety has been granted a CPVR ?

- If no living reference collection, material shall be destroyed or sent back to the applicant.  
For species where **DNA samples** are taken from the plant material :  
→ specific rules on a species by species basis.
- If living reference collection, material should be kept by the EU Network Office.

❖ What after the CPVR expires ?  
Material kept in a reference collection should be kept beyond expiry of a CPVR.

❖ What if the application is withdrawn or rejected?

- The EU Network Office should either destroy or send back the material to the applicant.
- If the variety is of common knowledge, the EU Network Office may keep the material in its reference collection.





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## DNA sampling for enforcement purposes

### Service to breeders

#### A. Sampling by the EO

- Example roses:
  - ❖ Established in September 2016
  - ❖ DNA sample from the official sample submitted for DUS  
Sample taken at the end of growing trial (to ensure no off-types are collected)
  - ❖ DNA stored without analysis by a lab working for the EO  
→ comparative analysis in suspected infringement cases.
  - ❖ Initial storing for 5 years: cost 50 EUR/sample
  - ❖ ~ 30% of the applicants use the service
    - Strict confidentiality
    - DNA samples and data from analysis belong to the title holder.
- Extension to other crops under discussion (interest from the breeders of the fruit sector)...



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## DNA sampling for enforcement purposes

#### B. Sampling by the breeder

- Specific procedure for authorized sample taking
- Material: official sample taken during the DUS test or from living ref collection
- By the title holder only → third parties only with written consent
- DNA extraction/analysis by laboratory chosen by the title holder
- Applied especially for grapevine, blueberry, strawberry and certain Prunus species (but the system is opened to all species)

→ De facto, full confidentiality.



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## ACCESS TO MOLECULAR DATA AND MATERIAL FOR DBs SHARED BETWEEN EOs ONLY

### □ DBs involving only CPVO Network Offices for DUS purposes

Access and sharing between partner EOs of **DNA samples and molecular data allowed → information of the title holder** (consent not needed)

Agreement between partner EOs (e.g. CPVO Potato DB project) :

- Data treated as confidential
- Ownership of the produced data shared by partner EOs

### □ DBs involving only CPVO Network Offices for other purposes than DUS , or involving also Examination Offices outside the EU network

Access and sharing between partner EOs of **DNA samples and molecular data subject to the consent of the title holders**

Agreement between partner EOs (e.g. CPVO SNP Tomato project) :

- Data treated as confidential
- Ownership of the produced data shared by partner EOs



## ACCESS TO MOLECULAR DATA AND MATERIAL FOR R&D PURPOSES INVOLVING THIRD PARTIES (academics, technical institutes...)

- Data can be made available with **Consent from EOs + Consent of breeders**

Specific confidentiality agreements, potentially including :

- Anonymization of varieties (coding)
- Exclusion of candidate varieties, lines...



In certain EU MS: global agreements signed with breeders' associations  
(e.g. Charte in France)

- Reference material (including DNA extracts) can be made accessible to third parties under specific conditions = **MTA with the EOs with consent of the breeders**



## ACCESS TO MOLECULAR DATA AND MATERIAL FOR R&D PURPOSES INVOLVING THIRD PARTIES (academics, technical institutes...)

### Example of INVITE



Consortium of 29 partners (~180 persons) :  
academics, breeders, technical institutes, post-registration offices and **12 EU EOs**.

**Molecular analysis** planned on large sets of varieties listed by 12 EOs for 7 crops.

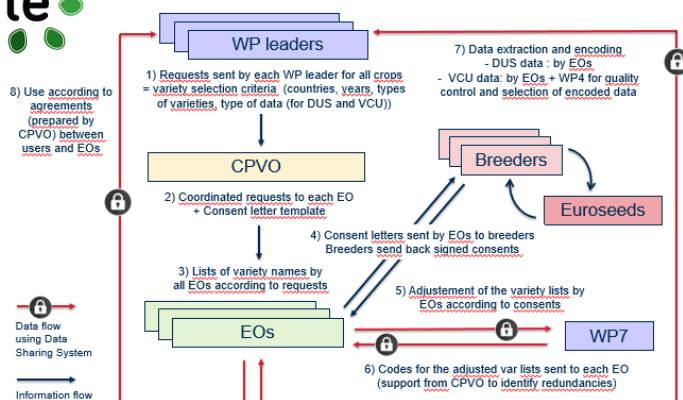
In collaboration with Euroseeds, the WP leaders and the participating EOs, CPVO designed an agreement to frame the access to data and materials by all partners and guaranty **confidentiality** of the produced data.

This agreement describes procedures for:

- 1) getting **consents from the breeders** of all concerned varieties (consent letter)
- 2) **encoding** variety names without redundancies between the 12 EOs
- 3) tracking exchanges of data and reference material (**MTA**).



## ACCESS TO DATA AND MATERIAL FOR R&D PURPOSES INVOLVING THIRD PARTIES (academics, technical institutes...)



Thank you ☺



*Angers, France*

CPVO !

[collonnier@cpvo.europa.eu](mailto:collonnier@cpvo.europa.eu)



[End of Annex and of document]