

Technical Working Party on Testing Methods and Techniques**TWM/2/7****Second Session****Virtual meeting, April 8 to 11, 2024****Original:** English**Date:** March 11, 2024

CONFIDENTIALITY OF MOLECULAR INFORMATION

Document prepared by experts from the African Seed Trade Association (AFSTA), the Asia and Pacific Seed Association (APSA), the International Community of Breeders of Asexually Reproduced Horticultural Plants (CIOFORA), CropLife International, Euroseeds, the International Seed Federation (ISF) and the Seed Association of the Americas (SAA)

Disclaimer: this document does not represent UPOV policies or guidance

The annex to this document contains a copy of a presentation “Confidentiality of Molecular Information”, to be made by experts from the African Seed Trade Association (AFSTA), the Asia and Pacific Seed Association (APSA), the International Community of Breeders of Asexually Reproduced Horticultural Plants (CIOFORA), CropLife International, Euroseeds, the International Seed Federation (ISF) and the Seed Association of the Americas (SAA), at the second session of the Technical Working Party on Testing Methods and Techniques (TWM).

[Annex follows]

Confidentiality of Molecular Information

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Molecular Information of plant varieties

- Concern to breeders
- 2 Surveys done (2020 & 2022)
- Presentations at UPOV TWP's



2020: https://www.upov.int/edocs/mdocs/upov/en/bmt_19/bmt_19_8.pdf

2021: https://www.upov.int/edocs/mdocs/upov/en/bmt_20/bmt_20_5.pdf

2022: https://www.upov.int/edocs/mdocs/upov/en/twm_1/twm_1_22.pdf



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TF-Confidentiality of Molecular Information

- Applicants would appreciate the possibility that proprietary information remains confidential (when needed)
 - with written prior approval from applicant
 - under nondisclosure agreement in sharing to other parties



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TF-Confidentiality of Molecular Information

- Recommendation to PVP offices: Inform applicants about national/regional policy on Molecular Information & sharing
- Final Aim: Global alignment of Molecular Information policies => legal security



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TF-Confidentiality – TWM conclusions

Concerns breeders on:

Sharing molecular information processed for DUS examination to others outside PVP office without permission of breeder.

Lack of clarity and information about how molecular information is being used, and especially shared.

TWM participants requested specification on the type of information and purpose of use of data to be shared (e.g., molecular distances between varieties, genotype sequences) that would require permission before being shared by PVP offices with other PVP offices.

Members and observers are invited to report existing policies on confidentiality of molecular information at the 2nd session of the TWM.



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'PVP office' in subsequent slides

'PVP office' includes all representatives of a UPOV Contracting Party, including DUS examination officers

Special situation for the EU:

Network of Entrusted Examination Offices with clear policy about confidentiality => can share without permission from breeder/applicant within the network



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Propagating Material in subsequent slides

TF defines **Propagating Material**:

‘any material, even if it is itself “harvested”, shall be classified as propagating material, as long as it is capable, whether alone or in combination with other parts or products of that or another plant, of producing another plant with the same characteristics. ‘



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Molecular Information

TF provides definition of **Molecular Information**:

‘Information regarding all provided and/or processed molecular data, including, but not limited to, sequence information, SNP marker data, genetic distances and comparisons to reference varieties, and molecular marker profiles.’



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Proposal: NO permission needed

Use by the PVP office, having received propagating material from the breeder/applicant in the framework of DUS examination, of molecular markers as per UPOV model: *Character specific molecular markers*, for those characteristics, where this alternative method is included in a publicly available technical guideline (*e.g., UPOV Test Guidelines or CPVO technical protocol*) and sharing only results as part of the DUS variety description.



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Proposal: NO permission needed

Setting up an internal database and **using** this database by the PVP office having received propagating material from the breeder/applicant in the framework of DUS examination conform UPOV model: *Combining phenotypic and molecular distinction in the management of variety collections*



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Proposal: NO permission needed

Use by the PVP office **having received** molecular information from the breeder/applicant in the framework of DUS examination and **sharing only results** (*i.e., the relevant notes of the characteristic, e.g., absent/present*) as part of the DUS variety description



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Proposal: Permission needed

Using propagating / reference material or molecular information by the PVP office having received propagating material from the breeder/applicant in the framework of DUS examination **for any other purpose than for the DUS examination.**

Waiving of permission for enforcement issues can be decided at the national or regional level.



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Proposal: Permission needed

Sharing molecular information processed by the PVP office, having received propagating material from the breeder/applicant in the framework of DUS examination of molecular markers as per UPOV model: *Character specific molecular markers*, for those characteristics as an annex to the DUS variety description.



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Proposal: Permission needed

Sharing propagating material or molecular information by the PVP office having received propagating material from the breeder/applicant in the framework of DUS examination conform UPOV model: *Combining phenotypic and molecular distinction in the management of variety collections*, for the purpose of setting up an internal database and using this database at another PVP office.



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Proposal: Permission needed

Sharing molecular information by the PVP office having received molecular information from the breeder/applicant in the framework of DUS examination as an annex to the DUS variety description



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Proposal: Permission needed

Sharing propagating material or molecular information by the PVP office having received propagating material from the breeder/applicant in the framework of DUS examination **for any other purpose than for the DUS examination**, e.g., for enforcement issues whether or not initiated by the applicant/breeder.

Exception: enforcement orders rendered by civil and penal courts and prosecutors. Nevertheless, courts and prosecutor offices take required procedural measures and decisions for the protection of confidentiality of the shared material/molecular information.



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Sharing with third parties

Sharing of molecular information (generated from propagating material submitted for DUS examination purposes) with third parties, such as to certification authorities, requires consent of breeder.



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Conclusions

Robust policies on confidentiality of molecular information: starting point to consider sharing molecular information among PVP offices adhering to these policies

Final Aim: Global alignment of Molecular Information policies

- legal security for breeders
- more efficient use of molecular information for PVP purposes



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