

**Working Group on Biochemical and Molecular Techniques
and DNA-Profiling in Particular****BMT/20/5****Twentieth Session
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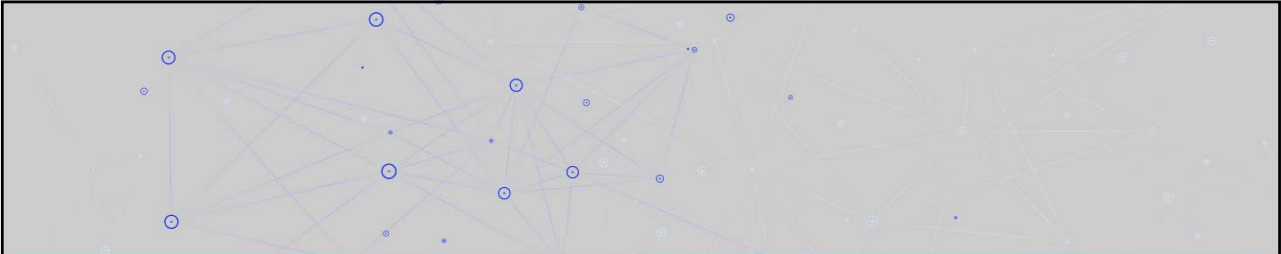
**CONFIDENTIALITY, OWNERSHIP AND ACCESS TO MOLECULAR DATA, INCLUDING MODEL
AGREEMENT TEMPLATE**

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 (CIOPORA), 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 & Ownership 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 (CIOPORA), CropLife International, Euroseeds, the International Seed Federation (ISF) and the Seed Association of the Americas (SAA), at the twentieth session of the Working Group on Biochemical and Molecular Techniques and DNA-Profiling in Particular (BMT).

[Annex follows]



Confidentiality & Ownership of Molecular Information

Next steps



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Background

- Growing concern from applicants on sharing of molecular information beyond their knowledge & control.
- Molecular information provided or generated in the course of applications for plant breeders' rights.
- Mol. Info: Information regarding all provided molecular data, including, but not limited to, sequence information, SNP marker data, genetic distances and comparisons to reference varieties, GAIA distances, and molecular marker profiles.



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Characteristics of PVP material

- Some PVP-ed material will not be available on the market (e.g. parent lines).
- Published information will be available WW, while material on the market is limited to countries of sale.
- In commercial trade, seed often packaged with bag-tag language. Samples for PVP applications often lack bag-tag language => harmonized approach will prevent the need for bag-tag language on PVP samples.



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Different approach

Re. PVP applications: use of molecular information = different from use of phenotypic information

⇒ may reveal part of the breeding strategy or trade secret trait

Purpose of PVP sample is DUS examination.

As a result, molecular information in these situations should be treated differently.



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Survey among applicants

- Task Force formed
- Assess the breadth & depth of problem through survey
- Survey among member companies (familiar with providing molecular information & most active regarding BMT matters)
- Covering seed-propagated & vegetatively propagated crops (wide range of species & in aggregate responsible for significant portion of global PVP applications)
- Survey results shared at last BMT: https://www.upov.int/edocs/mdocs/upov/en/bmt_19/bmt_19_8.pdf



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Survey Summary - 1

- Relat. rare to provide molecular information with PVP applications (limited to few countries & few crops) => no clear overview of current uses in UPOV members.
- Default = Phenotypic differences as the basis for DUS examination. In specific cases & in addition to phenotypic data, also molecular information might be used.
- Broadly expressed concern over use & sharing of molecular information (supplied or generated) between PVP offices. Fear such information could end up in public domain (depending on national policies).
- Where molecular information is used in the PVP application process: crucial that both applicants and DUS examination offices reach agreement beforehand on the molecular method and marker set that is to be used during the PVP application process.



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Survey Summary - 2

- Standardized method of publicly available markers & confidentiality guaranteed => then no major concern with sharing molecular information between PVP offices.
- Outside these parameters: applicants have concerns over sharing (& making public) of molecular fingerprinting data, genetic sequences or distances. Confidential information should remain as such at PVP office.
- Desirable: overview of countries where molecular information is needed in the PVP application process: crops, situations, intended use & policies: distill Best Practices out of this.
- Continue the dialogue.



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Next Steps

Aim: achieve the potential, as specified in TGP/15, of molecular information in supporting PVP applications.

Needed: Clear and customized rules for exchange of molecular information, e.g.:

- by providing option of confidentiality to applicant
- by harmonized approach for all UPOV members.



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Existing Guidance – INF/15

Paragraph 38:

“As stated in Article 12, for the purposes of examination, the authority may require the breeder to furnish all the necessary information, documents or material.

In that regard, **authorities should give consideration to appropriate measures concerning confidentiality**, for example in relation to pedigree information”.



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Existing Guidance – TGP/5

Section 1/3, Article 4

1. The Authorities shall take all necessary steps to safeguard the rights of the applicant.
2. Except with the specific authorization of the Receiving Authority and the applicant, **the Executing Authority shall refrain from passing on to a third person any material, including DNA, or molecular information**, of the varieties for which testing has been requested.

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Raise Comfort level

Several options considered → Most feasible (a.o. lowest admin burden):

- Additional wording to UPOV Model Form => e.g., in the form of question or statement: applicant indicates that sharing of molecular information should be upon his authorization.
- Subsequent uptake in UPOV Test Guidelines.
- Opportunity for further alignment of application forms.
- Raise awareness on importance for applicants



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Option: Model Form

TGP/5 – Section 2/3

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TGP/5: Section 2/3
ORIGINAL: English
DATE: October 21, 2010

INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS
GENEVA

Associated Document
to the
General Introduction to the Examination
of Distinctness, Uniformity and Stability and the
Development of Harmonized Descriptions of New Varieties of Plants (document TG/1/3)

DOCUMENT TGP/5
"EXPERIENCE AND CONCLUSIONS IN DUS TESTING"

Section 2: UPOV Model Form for
the Application for a Plant Breeder's Rights



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Option: Model Form, Q9

Enables exchange between UPOV authorities

9.(a) The technical examination of the variety ☐ has already been completed in _____
UPOV-A1: 9(a)(i)(1) UPOV-A1: 9(a)(i)(2)
 date completed (if known): _____
UPOV-A1: 9(a)(i)(3)

☐ is in progress in _____
UPOV-A1: 9(a)(ii)(1) UPOV-A1: 9(a)(ii)(2)
 date started (if known): _____
UPOV-A1: 9(a)(ii)(3)

☐ has not yet been started
UPOV-A1: 9(a)(iii)

(b) I/We declare that the material provided with the first application is representative of the variety and relevant to this application.
UPOV-A1: 9(b)

(c) Authorization is hereby given to the Authority to exchange with the competent authorities of any UPOV member all necessary information and material related to the variety, provided that the rights of the applicant are safeguarded.
UPOV-A1: 9(c)

What is 'necessary'? → Information necessary for DUS examination



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Model Form

- Possibility = addition of tick box to Q9
- Wording to be decided by UPOV

9.(a) The technical examination of the variety ☐ has already been completed in _____
UPOV-A1: 9(a)(i)(1) UPOV-A1: 9(a)(i)(2)
 date completed (if known): _____
UPOV-A1: 9(a)(i)(3)

☐ is in progress in _____
UPOV-A1: 9(a)(ii)(1) UPOV-A1: 9(a)(ii)(2)
 date started (if known): _____
UPOV-A1: 9(a)(ii)(3)

☐ has not yet been started
UPOV-A1: 9(a)(iii)

(b) I/We declare that the material provided with the first application is representative of the variety and relevant to this application.
UPOV-A1: 9(b)

(c) Authorization is hereby given to the Authority to exchange with the competent authorities of any UPOV member all necessary information and material related to the variety, provided that the rights of the applicant are safeguarded.
UPOV-A1: 9(c)



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Possible wording of tick box to Q9

[x] (d) I/We request that molecular information pertaining to the variety remains confidential and exchange to another UPOV member or examination office is subject to approval by the applicant.

9.(a) The technical examination of the variety	<input type="checkbox"/>	has already been completed in UPOV-A1: 9(a)(i)(1) _____ date completed (if known): UPOV-A1: 9(a)(i)(2) _____ UPOV-A1: 9(a)(i)(3) _____
	<input type="checkbox"/>	is in progress in UPOV-A1: 9(a)(ii)(1) _____ date started (if known): UPOV-A1: 9(a)(ii)(2) _____ UPOV-A1: 9(a)(ii)(3) _____
	<input type="checkbox"/>	has not yet been started UPOV-A1: 9(a)(iii)
(b) I/We declare that the material provided with the first application is representative of the variety and relevant to this application. UPOV-A1: 9(b)		
(c) Authorization is hereby given to the Authority to exchange with the competent authorities of any UPOV member all necessary information and material related to the variety, provided that the rights of the applicant are safeguarded. UPOV-A1: 9(c)		



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Conclusion

- Molecular Information is considered different from phenotypic information.
- Needed: Increased awareness at PVP authorities & raised comfort level by applicants on sharing of Molecular Information.
- Existing UPOV guidance allows for creation of confidentiality safeguards at national level
 - ✓ We call on national authorities to develop policies that adhere to existing UPOV guidance.
- Proposal to elevate to UPOV-wide level via Model Form.



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Thank you for your attention!



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[End of Annex and of document]