

International Union for the Protection of New Varieties of Plants

Technical Working Party on Testing Methods and Techniques TWM/1/22

First Session Original: English

Virtual meeting, September 19 to 23, 2022 Date: September 7, 2022

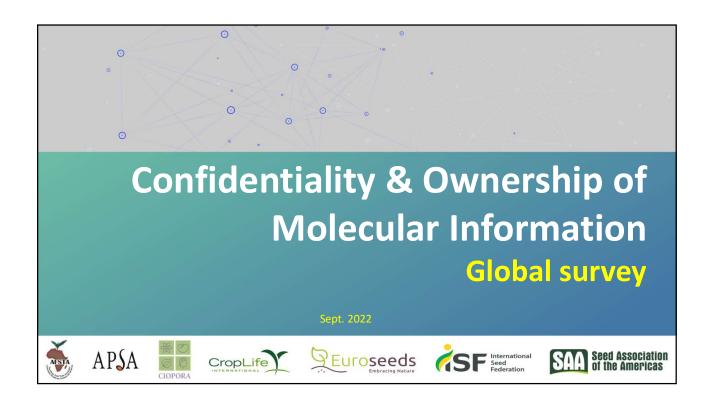
CONFIDENTIALITY AND OWNERSHIP OF MOLECULAR INFORMATION

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 (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 on "Confidentiality and ownership of molecular information", 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), to be made at the first session of the TWM. The country related information contained in this document has been provided by companies responding to the survey and relevant countries have not verified the accuracy or completeness of the information.

[Annex follows]



Background

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















Developments 2020

- 2020: global plant breeders Task Force formed (see logos)
- Preliminary survey in 2020, to assess depth of problem
- 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 BMT: https://www.upov.int/edocs/mdocs/upov/en/bmt 19/bmt 19 8.pdf















Developments 2021

- 2021: Proposal developed by Task Force
- Addition of Tick box in UPOV Model Form
- "[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."
- Presentations in all TWP's and BMT: https://www.upov.int/edocs/mdocs/upov/en/bmt 20/bmt 20 5.pdf















Conclusions from UPOV TWP's & BMT in 2021

<u>TWA</u>: "....noted the importance of confidentiality of molecular information for breeders and agreed that **further discussion** would be required on the topic"

<u>TWV</u>: ".... a <u>further discussion</u> with breeders will be needed to find a pragmatic solution to address the concerns of the breeders but to prevent unnecessary administrative burden for authorities."

TWO: "....that <u>further discussion</u> would be needed to find a suitable solution to address the concerns of the breeders while preventing unnecessary administrative burden for authorities.

TWF: ".... agreed that further discussion was required"

<u>BMT:</u> "...<u>invite presentations</u> on current practices on confidentiality and access to molecular data to be made at the first session of the TWM. & ".... <u>current practices</u> in UPOV members and observers could <u>provide a suitable basis</u> for further discussions on the topic"















Developments 2022: Global survey

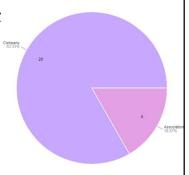
 24 entities (comp & assoc) replied, providing info on the following:

<u>Countries:</u> AR, BR, CN, CPVO, DE, ES, FR, ID, IN, LV, MX, NL, NZ, PH, PK RU, SE, TH, UK, US, VN, ZA

<u>Crops:</u> Brassica, Clover, Corn, Cotton, Forage crops, Grasses, Lettuce, Melon, Pea, Phalaenopsis, Pepper, Potato, Rapeseed, Rice, Ryegrass, Soybean, Sunflower, Tomato, Watermelon, Wheat

Companies knowledgeable & active in PVP field

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Q2: Is molecular information used, generated or acquired by the PVP office in any of the countries where you have filed for PVP?

- YES, in most countries of country list in previous slide
- In addition, applicants can submit Mol Info to support application
- Some countries request applicants to submit Mol. Info
- UPOV model 1 & 2 approaches are regularly applied
- Mol. Info is generated, also outside of PVP applications (projects)
- Applicants <u>assume</u> that Mol. Info is kept confidential (<u>without agreement</u>)
- Some PVP offices consider that <u>no consent is needed</u> from applicants for sharing of Mol. Info: viewed as unacceptable by respondents















Q3: Are you as applicant informed in case the PVP office generates molecular information from your candidate varieties?

- In most cases applicants are not informed & not aware of the policy
- i
- Only a few countries inform applicants (e.g., Arg.)
- Also, some conflicting statements by country, which indicates lack of clarity to applicants















Q4: Does the PVP office have a published policy about how it handles molecular information?

- Some countries yes (e.g., Arg., CPVO), some are working on it, but most countries have no policy, or not known
- Lack of information among applicants (& conflicting answers)



Recommendation to PVP offices: Inform applicants about their national/regional policy on Mol. Info & sharing















Q5: Can molecular information in the PVP application be designated as confidential?

- In most countries there is no such possibility
- Based on replies: possible in AR, RU, VN, ZA
- Several 'don't knows'
- Lack of information among applicants





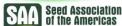












Q6: Do you know if the PVP office, where you applied for PVP, shared the molecular information of your variety with third parties, with or without your consent?

- Many 'No' and 'I don't knows' => lack of clarity
- Indications that sometimes Mol Info is shared without consent
- Outside of DUS: with consent and anonymized for tomato SNP database
- Some companies agreed to share material with INVITE project



Q8: What is the molecular information used for?

- Multiple crop examples given
 - UPOV Model 1 & 2
 - Isozymes for distinctness
 - Creation of crop database
 - Distinction between morphologically similar varieties
 - Verification of hybridity, variety identity, purity or GE
 - Enforcement: Stop infringement















Seed Association of the Americas



Q9: Is the molecular technique used by the PVP office on routine or occasional basis?

- Many examples of routine work
- Some occasional work, e.g., specific projects
- In a few countries no use of Mol. Info















Q12: Did the national authority apply any confidentiality agreement with the applicant on molecular information?





- CPVO: policy for use within scope of DUS examination
- NL: Consent for specific use in projects
- In most other countries: no confidentiality agreement available, or no awareness of such an agreement















Conclusions - 1

- Diverging policies
- Lack of information on side of applicants
- Breeders need much more clarity on how Mol information is managed & used

















How can UPOV and its members help?

Can UPOV

- recommend that national PVP offices have (& publish) a Policy on Confidentiality of Mol info?
- help national offices to establish such a policy and promote harmonization of such policies?
- propose a standard text for Confidentiality of Mol info?
- work with 'other examination offices' on this topic, when needed?















Potential solutions how to overcome this concern / ideas from the survey



- A <u>separate authorization form</u> where the applicant can indicate whether it is OK to share molecular information of a specific variety with other PVP offices in other countries: 42%
- Possibility for the applicant to indicate on the PVP application form whether it is OK to share molecular information with other PVP offices in other countries: 37%
- An authorization form that applies to all future varieties of the applicant: 11%
- Other solutions: e.g. <u>share per country</u> 10%















Conclusions - 2

Concern: how will this be checked and monitored?

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

Recommendation to PVP offices: Inform applicants about their national/regional policy on Mol. Info & sharing

<u>Final Aim</u>: Global alignment of Mol. Info policies => legal security















Thank you for your attention!















[End of Annex and of document]