UPOV

International Union for the Protection of New Varieties of Plants

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

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SURVEY ON CONFIDENTIALITY AND OWNERSHIP OF MOLECULAR INFORMATION

Document prepared by Crop Life International (CLI), Euroseeds, International Community of Breeders of Asexually Reproduced Horticultural Plants (CIOPORA), International Seed Federation (ISF) and Seed Association of the Americas (SAA)

The annex to this document contains a copy of a presentation to be made at the nineteenth session of the BMT on "Survey on Confidentiality and Ownership of Molecular Information", prepared by representatives from Crop Life International (CLI), Euroseeds, International Community of Breeders of Asexually Reproduced Horticultural Plants (CIOPORA), International Seed Federation (ISF) and Seed Association of the Americas (SAA).

[Annex follows]

Survey on Confidentiality and Ownership of Molecular Information

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CropLife INTERNATIONAL

ISF International Seed Federation

Euroseeds Embracing Nature

SAA Seed Association of the Americas

Background

- Molecular information provided or generated in the course of applications for plant breeders' rights
- Growing pressure from certain countries to make molecular data, publicly available, or in general not to protect such data with a similar confidentiality safeguards as afforded to the physical plant material.

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Background - 2

BMT/18/21

"Proposals for confidentiality and access to data

The discussion group on vegetables agreed to propose inviting breeders, observer organizations and other participants to make presentations on ownership matters during the breeders' day at the nineteenth session of the BMT.

….

To develop an agreement template with breeders for the use of molecular data. The template should include a requirement for a description of the intended use of the data.

Future program (for next BMT):

11. Confidentiality, ownership and access to molecular data (papers invited)"

Background - 3

- Task Force formed
- Assess the breadth and depth of the problem through survey
- Initial polling => survey smaller no. of member companies (most familiar with providing molecular information & most active regarding BMT matters)
- After broader discussion, 16 companies were chosen
- Covering seed-propagated & vegetatively propagated crops (wide range of species & in aggregate have provided significant portion of global PVP applications)
- Of those 16 surveyed companies, 11 replied.

Molecular Information

The Task Force defined molecular information as follows:

…constitutes 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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Molecular Information - 2

With regards to PVP applications, the use of molecular information is different from the use of phenotypic information

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

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

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Q1: Do you provide molecular information with new PVP applications in certain countries?

- Relatively rare that applicants provide molecular information with the PVP applications
- Limited to a few countries & a few crops.
- Proposal: To get full picture on molecular information requirements: perform broad analysis to assess in which countries molecular information needs to be provided, and whether these submissions are voluntary or mandatory.

Q2: If yes, what kind of information do you provide and in which country?

- Rather limited experience among applicants with providing molecular information.
- Where respondents do provide molecular information, it is in most cases SNP markers.

Q3: Do you provide molecular information in order to overcome problems regarding the grant of PVP applications in certain countries? What does it aim to resolve?

- It is very rare that applicants provide molecular information to overcome problems with their PVP applications.

Q4: What is the preferable information to share (e.g. during an appeal procedure) if another variety is shown to share high similarity to your variety?

- As a default, phenotypic information = preferred information to share in case two varieties are similar.
- In certain cases, also molecular information can be used, but it depends on the situation and authority that is requesting the information.
- For infringement cases, EDV purposes, or if necessary, during the PVP application procedure, applicants are willing to share molecular data

Q5: In case a variety would be declared distinct based on the difference in molecular data only, do you agree that this information needs to be published or at least be made available on request to third parties?

- As a default, the decisions of PVP offices should be transparent.
- If distinctness is based on molecular data only, then it should be thoroughly considered what information is made public.
- As a general rule, a recommended set of standard molecular markers and the method used can be published, but not molecular fingerprinting data, specific genetic sequences nor genetic distances, which should stay confidential within the PVP office.
- To guarantee confidentiality of the molecular information, it should be considered to use a non-disclosure or confidentiality agreement provided to the applicant.

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Q6: Do you have any concerns about the sharing of your molecular information with PVP offices? If so, please specify.

In general: no major concern for sharing specific molecular information, as long as:

- it is based on a standardized method of publicly available markers,

and

- confidentiality can be guaranteed.

In case PVP offices generate molecular information, then the same principles apply.

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Q7: Does it matter if the candidate variety is a hybrid parental line? If so, please specify.

It does not matter whether the candidate is a parent line, as long as confidentiality is guaranteed.

However, only the testing method and approach used should be public, so that the testing is transparent, as parental line information can be considered a trade secret and should not be published.

Q8: Are there possible benefits of sharing molecular information with PVP offices e.g. in comparison to the PVP offices generating these data themselves?

- Pros and cons regarding applicants providing molecular information, compared to PVP offices generating such information themselves
- Where applicants are already generating these data and the PVP office is not equipped to do so => cost & time saving
- On the other hand, the independence of data generated by PVP offices could also be appreciated.
- For better comparison between varieties: important that the approach to get to the data is standardized among applicants and PVP offices.
- To avoid: using different market sets within the same crop.

Q9: Certain PVP offices also generate molecular information themselves in the process of DUS examination. Do you have any concerns about the publication of these data? If yes, please specify.

In general, respondents do not feel comfortable if molecular information about specific varieties that is generated by PVP offices is made public.

For some, such publication can be a reason to avoid making PVP applications in that country.

In contrast to specific variety information, a defined set of molecular information e.g. the market set and the method, could be made public.

Consistency among PVP offices and applicants is crucial.

Q10: Does it matter which kind of molecular data are used/published? Are the concerns only regarding whole genome sequence data?

- Public marker data at a density adequate to differentiate the germplasm diversity of a crop species should be sufficient for the purpose of DUS testing and potential publication
- Important that the protocol has been established with involvement of industry.
- Any other type of molecular information raises concerns as it may reveal part of the breeding strategy or a trade secret trait.
- In general, respondents agree that the applicant in all cases needs to give his approval for any publication of molecular data.

Q11: Do you have any problems with the sharing of molecular data between different PVP offices (UPOV members) if these are not published?

No major problems with sharing molecular information for the purpose of supporting a PVP application, but…

⇒ condition: applicant is asked for consent & is able to keep track where what data is shared and to whom.

PVP offices should keep track and install strict procedures, incl. approval, for who has access to the information and apply mechanisms to continue to guarantee confidentiality.

Sharing such data for the purpose of alignment between PVP-offices could be considered a benefit.

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Q12: Which benefits/concerns do you see regarding the set-up of common databases with molecular information between different UPOV members?

Clear benefits in a common database with molecular information:

- would enhance harmonization among UPOV members,
- increase the speed of processing, and
- lead to better accuracy in the variety examination.

Concerns over potential data leaks and the confidentiality of the data.

Some form of centralization where data are analyzed and stored in one or very few locations could be beneficial.

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Q13: In case there is an EDV dispute, do you believe it should be possible to obtain (anonymized) molecular marker information regarding the other varieties in this species from a PVP office?

- It is not the responsibility of a PVP office to get involved in EDV disputes.
- There is a preference for EDV thresholds set by industry.

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Summary - 1

- It is still rare to provide molecular information with their PVP applications & limited to a few countries and a few crops => assess current uses in UPOV members
- With regards to PVP applications, the use of molecular information is different from the use of phenotypic information, as it may reveal part of the breeding strategy or a trade secret trait => molecular information to be treated differently.
- Phenotypic differences should be used as the basis for DUS examination. In certain specific cases and in addition to phenotypic data, also molecular information might be used.
- Broadly expressed concern over use and sharing of molecular information (supplied or generated) between PVP offices. Fear such information could end up in public domain.
- 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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Summary - 2

- As long as the molecular information is based on a standardized method of publicly available markers, and confidentiality could be guaranteed => no major concern with sharing of specific molecular information between PVP offices. Outside of these parameters, respondents do have concerns over the sharing of molecular fingerprinting data, genetic sequences or distances, let alone made public. All such data, should remain confidential at the PVP office.
- Ensure confidentiality of the molecular information by providing a non-disclosure or confidentiality agreement to the applicant.
- Use of molecular information in EDV disputes: respondents agreed that it is not the responsibility of a PVP office to get involved in resolving EDV disputes.
- The below mentioned associations are jointly proposing to assess among UPOV members for which crops, in which situations and for what intended use molecular information is needed in the PVP application process.
- The below mentioned associations are jointly proposing to continue with an open discussion on this topic incl. the points above, with the aim of arriving at harmonized guidance for UPOV members, incl development of agreement template, specifying intended use of the data.

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Thank you for your attention!

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[End of Annex and of document]