

Technical Committee**TC/58/7****Fifty-Seventh Session
Geneva, October 24 and 25, 2022****Original:** English
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MOLECULAR TECHNIQUES*Document prepared by the Office of the Union**Disclaimer: this document does not represent UPOV policies or guidance***EXECUTIVE SUMMARY**

1. The purpose of this document is to report on developments concerning molecular techniques and to invite the TC to consider proposals concerning: (1) cooperation between international organizations; (2) sessions to facilitate cooperation in relation to the use of molecular techniques cooperation; and (3) confidentiality, ownership and access to molecular data.

2. The TC is invited to:

(a) note the results of the surveys on the use of molecular marker techniques by members, per crop, as set out in the Annex to this document;

(b) note the draft joint document explaining the principal features of the systems of OECD, UPOV and ISTA;

(c) note the topics proposed by the TC for a future joint UPOV/OECD/ISTA workshop, as set out in paragraph 17 of this document; and

(d) note the information from OECD and ISTA that there were no significant developments to discuss at this time and that it might be better to plan a joint workshop in 2023, at the earliest.

(e) consider whether to invite the TWPs to form discussion groups to allow participants to exchange information on their work and explore areas for cooperation on the use of biochemical and molecular techniques in DUS examination;

(f) note discussions held at the TWPs, at their sessions in 2022, on “Confidentiality & Ownership of Molecular Information”;

(g) note the concerns expressed by breeders’ organizations at the TWM that molecular information provided for the examination of a variety should not be provided to others outside the authority that received the application without the permission of the breeder;

(h) consider whether to invite members to provide information on the type and purpose of molecular information used and/or shared; and

(i) consider whether to invite members and observers to report existing policies on confidentiality of molecular information at the TWPs, at their sessions in 2023.

3. The following abbreviations are used in this document:

BMT:	Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular
ISTA:	International Seed Testing Association
OECD:	Organization for Economic Co-operation and Development
TC:	Technical Committee
TWA:	Technical Working Party for Agricultural Crops

TWF:	Technical Working Party on Fruit Crops
TWM:	Technical Working Party on Testing Methods and Techniques
TWO:	Technical Working Party on Ornamental Plants and Forest Trees
TWPs:	Technical Working Parties
TWV:	Technical Working Party for Vegetables

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ANNEX SURVEY ON THE USE OF MOLECULAR MARKER TECHNIQUES BY CROP

COOPERATION BETWEEN INTERNATIONAL ORGANIZATIONS

Background

5. The background to this matter is provided in documents TC/57/8 “Molecular Techniques” and TC/57/8 Add.. “Addendum to Molecular Techniques”.

6. The TC, at its fifty-fourth session¹, agreed that UPOV and OECD should make progress on the matters previously agreed by the TC, namely (see document TC/54/31 “Report”, paragraphs 267 to 271):

(a) to develop a joint document explaining the principal features of the systems of the OECD, UPOV and ISTA;

(b) to develop an inventory on the use of molecular marker techniques, by crop, with a view to developing a joint OECD/UPOV/ISTA document containing that information, in a similar format to UPOV document UPOV/INF/16 “Exchangeable Software”, subject to the approval of the Council and in coordination with OECD and ISTA; and

(c) the BMT to develop lists of possible joint initiatives with OECD and ISTA in relation to molecular techniques for consideration by the TC.

7. The TC, at its fifty-fourth session, agreed to invite ISTA to join the initiatives when in position to do so.

¹ held in Geneva, on October 29 and 30, 2018

8. At their sessions in 2022, the TWV², TWA³, TWO⁴, TWF⁵ and TWM⁶ considered document TWP/6/7 “Molecular Techniques” (see documents TWV/56/22 “Report”, paragraphs 51 to 59; TWA/51/11 “Report”, paragraphs 71 to 75; TWO/54/6 “Report”, paragraphs 66 to 70; TWF/53/14 “Report”, paragraphs 80 to 84; and TWM/1/26 “Report”, paragraphs 70 to 80).

Inventory on the use of molecular marker techniques, by crop

9. The TC, at its fifty-seventh session⁷, requested the Office of Union to inform OECD of the result of the survey, which were presented in document TC/57/8 “Molecular Techniques”, and to report on the developments at the TC, at its fifty-eighth session (see document TC/57/25 “Report”, paragraph 48). On December 13, 2021, the Office of the Union informed the results of the survey to OECD.

10. The TC agreed, at its fifty-seventh session, to continue the survey on the use of molecular markers to obtain information from a greater number of members and to investigate the reasons for members not responding to the first survey.

11. On February 1, 2022, the Office of the Union issued Circular E-22/009 inviting members of the Union to indicate whether they use molecular marker techniques and continue the survey on their use.

12. In response to the Circular E-22/009, 28 members of the Union replied, 15 of which were new responses and 8 provided further information on the use of molecular marker techniques. The summary of responses to the surveys in 2020 and 2022 are as follows:

Member	Use of Molecular marker technique (YES/NO)	Member	Use of Molecular marker technique (YES/NO)
Argentina	YES	Lithuania	NO
Australia	NO	Mexico	NO
Austria	YES	Moldova	NO
Belgium	NO	Netherlands	YES
Bolivia	NO	New Zealand	NO
Brazil	YES	Norway	NO
Canada	YES	Panama	NO
China	YES	Peru	NO
Czech Republic	YES	Poland	NO
European Union	YES	Romania	NO
Estonia	YES	Russian Federation	NO
France	YES	Slovakia	YES
Germany	YES	Spain	YES
Hungary	YES	Ukraine	YES
Ireland	YES	United Kingdom	YES
Israel	NO	United States of America	NO
Italy	YES	Zimbabwe	NO
Japan	YES	YES	20
Jordan	YES	NO	18
Kenya	NO	TOTAL	38
Latvia	NO		

13. The detailed results of the survey are presented in Annex to this document.

² at its fifty-sixth session, held via electronic means, from April 18 to 22, 2022

³ at its fifty-first session, hosted by the United Kingdom and held via electronic means, from May 23 to 27, 2022

⁴ at its fifty-fourth session, , hosted by Germany held via electronic means, from June 13 to 17, 2022

⁵ at its fifty-third session, held via electronic means, from July 11 to 15, 2022

⁶ at its first session, held via electronic means, from September 19 to 23, 2022

⁷ Held via electronic means on October 26 and 27, 2021

Joint document explaining the principal features of the systems of OECD, UPOV and ISTA

Background

14. The TC, at its fifty-fifth session, agreed with the BMT, at its eighteenth session, that relevant elements from the World Seed Partnership and the FAQ on the use of molecular techniques in the examination of DUS, would be a suitable basis for the Office of the Union to develop a draft of a joint document explaining the principal features of the systems of OECD, UPOV and ISTA, in consultation with OECD (see document TC/55/25 "Report", paragraph 182).

Draft joint document

15. The TC, at its fifty-seventh session, noted that it had approved by correspondence the draft joint document explaining the principal features of the systems of OECD, UPOV and ISTA. The TC requested the Office of the Union to inform OECD and ISTA accordingly (see document TC/57/25 "Report", paragraph 52).

16. On December 13, 2021, the Office of the Union transmitted the draft joint document to OECD and ISTA. Responses from OECD and ISTA, when available, will be reported to the Technical Committee.

Lists of possible joint initiatives with OECD and ISTA in relation to molecular techniques

17. The TC, at its fifty-seventh session, agreed to propose the following topics for a future joint UPOV/OECD/ISTA workshop:

- (i) providing information on the use of molecular techniques in each organization;
- (ii) procedure for approval of biochemical and molecular methods in each organization; and
- (iii) possibilities for harmonizing terms, definitions and methods between UPOV, OECD and ISTA.

18. The TC agreed to request the Office of the Union to contact OECD and ISTA to explore suitable dates for a future joint workshop, such as in conjunction with the first session on the TWM, to be held in September 2022.

19. On December 13, 2021, the Office of the Union communicated an invitation to OECD and ISTA to hold another joint workshop on molecular techniques, in conjunction with the first session of the TWM, to be held on September 21, 2022, via electronic means, to include consideration of the topics (i) to (iii) above.

20. On May 15, 2022, the Office of the Union met with OECD and ISTA at the fringes of the International Seed Federation World Seed Congress and discussed cooperation between OECD, ISTA and UPOV in relation to BMT. UPOV had raised the idea of a joint OECD/ISTA/UPOV workshop in conjunction with the TWM, which would be held in September 2022. It was agreed that there were no significant developments to discuss at this time and that it might be better to plan a joint workshop in 2023 at the earliest.

International Seed Testing Association

21. The TWM received a presentation from Ms. Ana Laura Vicario (ISTA) on "ISTA report on the use of molecular techniques", a copy of which is reproduced in document TWM/1/23.

Organisation for Economic Co-operation and Development

22. The TWM received a presentation from Mr. Christophe Rouillard (OECD) on "Latest developments in the application of BMT under the OECD Seed Schemes", a copy of which is reproduced in document TWM/1/24.

23. The TWM noted that OECD had formed the Advisory Group on BMT to deal with all BMT issues under the Seed Schemes, including matters relating to cooperation with other international organizations.

24. *The TC is invited to:*

- (a) *note the results of the surveys on the use of molecular marker techniques by members, per crop, as set out in the Annex to this document;*

(b) note the draft joint document explaining the principal features of the systems of OECD, UPOV and ISTA;

(c) note the topics proposed by the TC for a future joint UPOV/OECD/ISTA workshop, as set out in paragraph 17 of this document; and

(d) note the information from OECD and ISTA that there were no significant developments to discuss at this time and that it might be better to plan a joint workshop in 2023, at the earliest.

SESSION TO FACILITATE COOPERATION IN RELATION TO THE USE OF MOLECULAR TECHNIQUES

25. The TC, at its fifty-fourth session⁸, agreed that discussion groups should be formed for the main crops at each TWP to allow participants to exchange information on their work and explore areas for cooperation (see document TC/54/31 “Report”, paragraph 281).

Technical Working Parties (TWPs)

26. The TWA, at its fifty-first session⁹, held a discussion session to allow participants to exchange information on their work on biochemical and molecular techniques and explore possible areas for cooperation. The TWA considered whether UPOV could support harmonization and cooperation between members already using molecular markers in DUS examination or making information or BMT services available to other UPOV members.

27. The TWA agreed that the Technical Working Parties were a platform for exchanging information about molecular markers in DUS examination, including projects, collaborations and services eventually provided by members. The TWA agreed that UPOV should continue to encourage presentations on using molecular markers in DUS examination, including technical aspects, confidentiality and access to data.

28. The TWA received a presentation on the “Use of molecular techniques in DUS examination: Report from Argentina” by an expert from Argentina. A copy of the presentation is provided in document TWA/51/4.

29. The TWA received a presentation on “Developing a strategy to apply SNP molecular markers in the framework of winter oilseed rape DUS testing” by an expert from France. A copy of the presentation is provided in document TWA/51/4 Add.

30. The TWF, at its fifty-third session¹⁰, received a presentation on “Application of molecular techniques in DUS testing and PBR enforcement of fruit sector in China” by an expert from China. A copy of the presentation is provided in document TWF/53/12.

31. The TWF noted that molecular markers could be used in China as first instance evidence for enforcement of breeders’ rights, followed by a growing trial in case required.

32. Following the presentation from China, the TWF had an open discussion about the use of molecular markers in DUS examination and variety identification. The following aspects were mentioned by participants:

- Possibilities for cooperation on the constitution of common databases, including for authorities receiving relatively few applications for particular crops
- Origin of plant material for DNA extraction (e.g. material provided for DUS testing)
- Selection of markers for each crop, according to intended use (e.g. for PBR and/or variety identification).

⁸ held in Geneva, on October 29 and 30, 2018

⁹ hosted by the United Kingdom and held via electronic means, from May 23 to 27, 2022

¹⁰ held via electronic means, from July 11 to 15, 2022

- Selecting one or more laboratories capable of providing high-quality molecular profiles (e.g. security back-up);
- High cost for harmonizing methodologies for DNA profiling among different laboratories;
- Difficulties to obtain the same results even for laboratories using harmonized methodologies.

33. The TWO, at its fifty-fourth session¹¹, noted that no reports were made on the use of biochemical and molecular techniques in DUS examination of ornamental plants.

34. The TWM, at its first session¹², held a discussion session to allow participants to exchange information on their work on biochemical and molecular techniques and explore possible areas for cooperation.

35. The TWM agreed that sufficient time should be allocated for discussing the agenda items in the future work plan for the meeting and agreed that it would not be necessary to have an open discussion session.

36. The TC is invited to consider whether to invite the TWPs to form discussion groups to allow participants to exchange information on their work and explore areas for cooperation on the use of biochemical and molecular techniques in DUS examination.

CONFIDENTIALITY & OWNERSHIP OF MOLECULAR INFORMATION

37. The background to this matter is provided in document TC/57/INF/6 "Molecular Techniques".

38. The TWPs and the BMT, at their sessions in 2021, received a presentation on "Confidentiality & Ownership of Molecular Information" by an expert on behalf of 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). The TWPs and the BMT considered the proposal to revise document TGP/5, Section 3: Model Application Form, to include a request for confidentiality of molecular information of candidate varieties as follows:

"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."

39. At their sessions in 2022, the TWV¹³, TWA¹⁴, TWO¹⁵, TWF¹⁶ and TWM¹⁷, noted discussions held at the TWPs and the BMT, at their sessions in 2021, on "Confidentiality & Ownership of Molecular Information".

40. The TWA, at its fifty-first session, noted the report from the joint breeders' organizations that a survey on confidentiality of molecular data was being conducted among plant breeding companies across different organizations. The TWA noted that the outcomes of the survey would be presented to the TWM, at its first session. The TWA agreed to invite the joint breeders' organizations to report developments at its fifty-second session.

41. The TWM, at its first session, received a presentation from Mr. Marcel Bruins (CropLife International) on "Confidentiality and ownership of molecular information", a copy of which is reproduced in document TWM/1/22.

42. The TWM noted the concern expressed by breeders' organizations that molecular information provided for the examination of a variety should not be provided to others outside the authority that received the application without the permission of the breeder. The TWM further noted the concern that breeders were lacking clarity and information about how molecular information was being used, and especially shared.

¹¹ hosted by Germany held via electronic means, from June 13 to 17, 2022

¹² held via electronic means, from September 19 to 23, 2022

¹³ at its fifty-sixth session, held via electronic means, from April 18 to 22, 2022

¹⁴ at its fifty-first session, hosted by the United Kingdom and held via electronic means, from May 23 to 27, 2022

¹⁵ at its fifty-fourth session, , hosted by Germany held via electronic means, from June 13 to 17, 2022

¹⁶ at its fifty-third session, held via electronic means, from July 11 to 15, 2022

¹⁷ at its first session, held via electronic means, from September 19 to 23, 2022

43. The TWM agreed that further clarification was required 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.

44. The TWM agreed to invite members and observers to report existing policies on confidentiality of molecular information at the second session of the TWM.

45. *The TC is invited to:*

(a) note discussions held at the TWPs, at their sessions in 2022, on “Confidentiality & Ownership of Molecular Information”;

(b) note the concerns expressed by breeders’ organizations at the TWM that molecular information provided for the examination of a variety should not be provided to others outside the authority that received the application without the permission of the breeder;

(c) consider whether to invite members to provide information on the type and purpose of molecular information used and/or shared; and

(d) consider whether to invite members and observers to report existing policies on confidentiality of molecular information at the TWPs, at their sessions in 2023.

[Annex follows]

TC/58/7

ANNEX

SURVEY ON THE USE OF MOLECULAR MARKER TECHNIQUES BY CROP

Please see the Excel spreadsheet for all the responses received

[Appendix to Annex follows]

Response from the European Union:

USE OF MOLECULAR MARKER TECHNIQUES FOR DUS TESTING IN THE FRAMEWORK OF CPVR

Elements of context

The Technical Committee (TC) of UPOV, at its fifty-fifth session, held in Geneva, on October 28 and 29, 2019, agreed to invite members of the Union to complete a survey as a basis to develop an inventory on the use of molecular marker techniques, by crop, in coordination with the OECD Seed Schemes (see document TC/55/25 "Report", paragraphs 184 and 185).

The information on molecular marker techniques used by members of the Union will be used to develop a joint UPOV/OECD/ISTA document containing that information, in a similar format to document UPOV/INF/16 "Exchangeable Software", subject to the approval of the Council and in coordination with OECD and ISTA.

The present document constitutes the contribution of the CPVO to this survey and, as such, describes the molecular marker techniques that can be used for DUS testing aiming at the granting of Community Plant Variety Rights (CPVR) in the framework of the CPVO policy.

1. Legal framework on the use of molecular techniques in DUS testing for CPVR

The legal framework for conducting DUS testing for CPVR includes the CPVO Basic Regulation 2100/94 (BR) and its Implementing Rules, the CPVO Technical Protocols (TPs) and the guidance documents adopted by UPOV.

The CPVO does not undertake DUS testing himself but, as stated in Article 56 (BR) "shall arrange for the technical examination [...] to be carried out by the competent office or offices in at least one of the Member States entrusted with responsibility for the technical examination of varieties of the species concerned by the Administrative Council".

When carrying out a technical examination, "[...] the Examination Offices shall, for the purposes of the technical examination, grow the variety or undertake any other investigations" (Article 56-BR). Molecular techniques may thus be used to support DUS testing by the entrusted EOs provided that the technical examination is conducted in accordance with the test guidelines issued by the CPVO Administrative Council.

As the same guidelines are used both for variety protection and for registration in the EU, the Directives on the Common Catalogues (Council Directives 2002/53/EC and 2002/55/EC) are also to be taken into account. According to them, the acceptance of varieties shall be based on the results of official examinations, particularly growing trials, covering a sufficient number of characteristics for the variety to be described. Therefore, molecular techniques may be used only as complementary tools in addition to the growing trials.

As a UPOV member, the CPVO respects the agreed framework on the use of molecular techniques in DUS testing as laid down in documents UPOV/INF/18 (adopted by the Council of UPOV in 2011) and UPOV/TGP/15/3 (adopted by the Council of UPOV in 2020). More specifically, the CPVO supports the application by the network of its entrusted EOs of molecular tools according to the models positively assessed as regards their conformity with the UPOV convention.

2. Models supported by the CPVO and examples of application

2.1. Characteristic-specific markers

Molecular markers can be used as an alternative to the phenotypic observation, as predictors of traditional characteristics that are difficult or cumbersome to assess, if a clear link exists. They can be either fully or partly correlated to the phenotype. These methods are included in technical protocols of CPVO on the basis of an evaluation/validation and suggestion of the CPVO crop-expert groups.

2.1.1. Markers 100% correlated to a given state of expression of the characteristic

In that case, the marker may replace the phenotypic observation.

Examples of characteristics concerned:

- Resistances to mono- or oligogenic diseases resistances (e.g. diseases in vegetables, resistance to nematode *Heterodera schachtii* in sugarbeet)
- CMS (cytoplasmic male sterility) in cabbages
- Herbicides (e.g. sunflower, rapeseed)

So far, none of these markers have been included in CPVO TPs.

2.1.2. Markers providing incomplete information on the state of expression of the characteristic

In that case, the marker is only partially linked to the characteristic and give an incomplete information on the level of expression of the trait. Its use has to be described in an assessment scheme that precise the situations where it can be used and when it needs to be completed by a phenotypical observation.

Examples of characteristics concerned: quantitative diseases resistances in vegetables, such as

- Tomato mosaic virus (ToMV)
- Tomato spotted wilt virus (TSWV)

The two sets of co-dominant markers developed for these two tomato viruses have been included in the CPVO TPs for tomato (4.4-2) and tomato rootstocks (1.4) as a potential alternative to the biotests in specific cases.

2.2. Management of variety collections

2.2.1. Combining molecular and phenotypic thresholds to exclude super-distinct varieties from the second growing trial

In this model, two independent thresholds are set for the selection of similar varieties to be included into the growing trial. The first threshold is based on the information of morphological characteristics and the second relies on a genetic distance calculated using a set of markers distributed throughout the genome. Except for morphologically very similar varieties, reference varieties exceeding the two thresholds do not need to be included into the growing trial (they are considered as "super-distinct").

This model is routinely applied by certain entrusted EOs for species like maize, lettuce, wheat and barley, and is currently being tested for oilseed rape through R&D projects co-financed by CPVO.

2.2.2. Genetic selection of similar varieties for the first growing trial

The candidate variety is genotyped using a defined set of markers, and its profile is compared to the varieties from the reference collection. All reference varieties with a genetic similarity to the candidate higher than a certain percentage (e.g. 80%) are to be included in the first growing cycle, all the others being excluded.

During the first cycle, the candidate variety is assessed on uniformity and described morphologically according to the technical protocol. Its morphological description is then compared *in silico* to the descriptions of all the reference varieties.

Remark: the morphological descriptions of the reference varieties used for the in silico comparison shall be based on observations made by the EO (in-house variety descriptions). If the variety descriptions used are not made in-house, they can be used only if notation scales have been harmonized between the examination offices producing and using them (through ring tests for example).

The reference varieties identified to be morphologically similar to the candidate will be included for comparison into a second growing trial. If the variety is clearly distinct from the similar varieties in the first growing cycle and no similar varieties are detected based on the variety description after the first growing cycle, a positive decision on distinctness can be taken after one growing cycle.

This model is under application by certain entrusted EOs for species like French bean and potato. It is currently under test for durum wheat and will be explored for tomato and hemp through R&D projects co-financed by CPVO.

The methods are evaluated by CPVO crop expert groups

2.3. Other uses

2.3.1. Identification in support to the maintenance of variety collections

All the molecular markers used in the above examples can be used for identification purposes in support to the maintenance of reference collections.

In addition, other molecular marker sets can be used also for identification purposes by certain entrusted EOs for species like rose, cherry tree, peach, grapevine, citrus... These sets can be harmonized between EOs (e.g. potato, thanks to a project supported by CPVO) or not.

2.3.2. Detection of GMOs (in the sense of Directive 2001/18/EC)

In specific cases, markers are used by EOs to detect varieties produced with the help of transgenesis or targeted mutagenesis techniques for:

- Confirmation of the presence of a declared genetic transformation (classical transgene insertion, or point mutations triggered by gene editing technologies).
- Detection of adventitious presence of GM seeds in the submitted reference lots.

Conclusion

In summary, many molecular methods are presently being used, or under development, by the CPVO network of entrusted EOs in support of DUS testing.

However, only 2 sets of characteristic-specific molecular markers are officially described in CPVP TPs on the basis of evaluation/validation of experts in the CPVO expert groups.. These markers are publically available. Consequently, the CPVO leaves to its entrusted EOs the role of describing the molecular tools they use in respect of the CPVO policy for the methods used in relation to variety reference collections.

[End of Appendix and of document]