

Administrative and Legal Committee

CAJ/78/INF/5

**Seventy-Eighth Session
Geneva, October 27, 2021**

Original: English
Date: October 19, 2021

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 developments concerning molecular techniques since the seventy-seventh session of the Administrative and Legal Committee (CAJ).

2. The following abbreviations are used in this document:

- BMT: Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular
- CAJ: Administrative and Legal Committee
- TC: Technical Committee
- TWA: Technical Working Party for Agricultural Crops
- TWC: Technical Working Party on Automation and Computer Programs
- TWF: Technical Working Party for Fruit Crops
- TWO: Technical Working Party for Ornamental Plants and Forest Trees
- TWPs: Technical Working Parties
- TWV: Technical Working Party for Vegetables
- OECD: Organization for Economic Co-operation and Development
- ISTA: International Seed Testing Association

3. The structure of this document is as follows:

EXECUTIVE SUMMARY	1
BACKGROUND	2
REVIEW OF DOCUMENT UPOV/INF/17 “GUIDELINES FOR DNA-PROFILING: MOLECULAR MARKER SELECTION AND DATABASE CONSTRUCTION (‘BMT GUIDELINES’)”	2
COOPERATION BETWEEN INTERNATIONAL ORGANIZATIONS.....	2
Joint document explaining the principal features of the systems of OECD, UPOV and ISTA	2
Inventory on the use of molecular marker techniques, by crop.....	3
Lists of possible joint initiatives with OECD and ISTA in relation to molecular techniques	4
SESSION TO FACILITATE COOPERATION IN RELATION TO THE USE OF MOLECULAR TECHNIQUES	5
Developments at the TWPs and BMT at their sessions in 2021	5
CONFIDENTIALITY & OWNERSHIP OF MOLECULAR INFORMATION	6
ANNEX I ELEMENTS FOR DRAFT JOINT DOCUMENT EXPLAINING THE PRINCIPAL FEATURES OF THE SYSTEMS OF THE OECD, UPOV AND ISTA(ONLY)	
ANNEX II SURVEY ON THE USE OF MOLECULAR MARKER TECHNIQUES BY CROP	

BACKGROUND

4. Developments on matters presented in this document at the TC, at its fifty-seventh session, will be reported to the CAJ in document CAJ/78/2 “Report on developments in the Technical Committee”.

REVIEW OF DOCUMENT UPOV/INF/17 “GUIDELINES FOR DNA-PROFILING: MOLECULAR MARKER SELECTION AND DATABASE CONSTRUCTION (‘BMT GUIDELINES’)”

5. The background to this matter is provided in document CAJ/75/11 “Molecular techniques”, paragraphs 31 to 34.

6. Matters concerning the approval by the CAJ of document UPOV/INF/17/1 “Guidelines for DNA-Profiling: Molecular Marker Selection and Database Construction (“BMT Guidelines”)”, on the basis of the text in document UPOV/INF/17/1 Draft 6, are reported in document CAJ/78/3 Rev. “Development of guidance and information materials” (see paragraph 12 to 13) and document CAJ/78/12 “Outcome of the consideration of documents by correspondence” (see paragraph 14 and 35).

7. The CAJ is invited to note the adoption by the Council, by correspondence on September 21, 2021, of document UPOV/INF/17/1 “Guidelines for DNA-Profiling: Molecular Marker Selection and Database Construction (“BMT Guidelines”)”, on the basis of the text in document UPOV/INF/17/1 Draft 6 (see document C/55/12 “Outcome of the consideration of documents by correspondence”, paragraph 18 and 32).

COOPERATION BETWEEN INTERNATIONAL ORGANIZATIONS

8. The background to this matter is provided in document CAJ/76/INF/3 “Molecular techniques”.

9. The CAJ, at its seventy-fifth session, noted that the TC had agreed that UPOV and OECD make progress on matters previously agreed by the TC, as set out in document CAJ/75/13, Annex, paragraph 46¹, namely:

(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.

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

11. Developments concerning the matters above are provided in the following paragraphs.

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

Background

12. 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).

¹ See document CAJ/75/14 “Report”, paragraph 65.

Draft joint document

13. The TC, at its fifty-sixth session, noted developments on a joint document explaining the principal features of the systems of OECD, UPOV and ISTA with the aim of proposing a draft joint document for consideration by the TC at its fifty-seventh session (see document TC/56/23 "Report", paragraphs 50 and 51).

14. The TC noted that the joint document would provide information on the status of molecular techniques for the purposes of each organization. The elements of a draft joint document are provided in Annex I to this document.

15. A draft joint document explaining the principal features of the systems of OECD, UPOV and ISTA will be presented for consideration by the TC, at its fifty-seventh session, for approval. Subject to approval by the TC of the draft joint document, the TC will be invited to request the Office of the Union to inform OECD and ISTA accordingly.

Inventory on the use of molecular marker techniques, by crop

Background

16. The TC agreed that a circular should be issued to request 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.

The survey results

17. The Office of the Union consulted the OECD Seed Schemes on the organization of the survey and possible next steps.

18. After consultation with the OECD, the Office of the Union issued Circular E-20/189 on October 16, 2020, inviting members of the Union to complete a survey on the use of molecular marker techniques, by December 15, 2020.

19. In response to the Circular E-20/189, the following 23 members of the Union provided information on the use of molecular marker techniques:

Australia	Lithuania
Belgium	Mexico
Brazil	Netherlands
China	Norway
Czech Republic	Panama
Estonia	Romania
European Union	Spain
France	Slovakia
Germany	Ukraine
Israel	United Kingdom
Japan	United States of America
Jordan	

20. The results of the survey are presented in Annex I to document TC/57/8, as reproduced in Annex II to this document.

21. The TC, at its fifty-seventh session, to be held in 2021, will be invited to request the Office of the Union to inform OECD of the result of the survey and report developments to the TC, at its fifty-eighth session.

22. The TC will be invited to note the comments received in response to Circular E-21/122 of August 23, 2021, on document TC/57/8 "Molecular techniques" that have not resulted in a revision of the documents (see document TC/57/14 "Outcome of the consideration of documents by correspondence", paragraph 25).

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

23. The BMT, at its eighteenth session², considered document BMT/18/4 “Cooperation between International Organizations” and the request to develop lists of possible joint initiatives with OECD and ISTA, in relation to molecular techniques. The BMT agreed to propose the repeating of joint workshops with ISTA and OECD in future. The BMT agreed to propose a joint initiative that each organization inform the others about use of molecular markers in their work (see document BMT/18/21 “Report”, paragraph 34).

24. The TC, at its fifty-fifth session³, considered possible joint initiatives with OECD and ISTA in relation to molecular techniques and agreed with the proposal made by the BMT, at its eighteenth session, for joint workshops to be repeated in future (see document TC/55/25 “Report”, paragraphs 189 to 191).

25. The TC agreed with the BMT to propose a joint initiative that each organization inform the others about use of molecular markers in their work.

26. The TC noted there were no definitions on biochemical and molecular techniques in UPOV. The TC agreed that information from the survey on the techniques could help to clarify techniques that were considered to be biochemical or molecular.

27. The following joint UPOV/OECD/ISTA workshops on molecular techniques have been organized:

- (a) hosted by UPOV and held in Seoul, Republic of Korea, on November 12, 2014, in conjunction with fourteenth session of the BMT;
- (b) hosted by OECD and held in Paris, France, on June 8, 2016, prior to the Annual Meeting of the OECD Seed Schemes;
- (c) hosted by ISTA and held in Hyderabad, India, on June 29, 2019, in conjunction with the 2019 ISTA Congress.

Possible topics for a future joint UPOV/OECD/ISTA workshop

28. The TC, at its fifty-sixth session, agreed that another joint OECD, UPOV, ISTA workshop on molecular techniques should be organized in the near future. The TC agreed that a joint OECD, UPOV, ISTA workshop on molecular techniques would be an opportunity to discuss the definitions used in molecular techniques with a view to their harmonization.

29. The BMT, at its twentieth session⁴, noted that a poll had been conducted during its twentieth session to assess the following information from participants:

- What are the areas of common interest between UPOV, OECD and ISTA on the use of BMT?
- What would be suitable topics for a joint UPOV/OECD/ISTA workshop on BMT?

30. The BMT considered the responses to the poll and agreed to propose the possible topics for a future joint UPOV/OECD/ISTA workshop.

31. Based on the proposals by the BMT, at its twentieth session⁵, the TC, at its fifty-seventh session, will be invited to consider the following possible 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 methods between UPOV, OECD and ISTA.

² held in Hangzhou, China, from October 16 to 18, 2019

³ held in Geneva, on October 28 and 29, 2019

⁴ hosted by the United States of America and held via electronic means, from September 22 to 24, 2021

⁵ hosted by the United States of America and held via electronic means, from September 22 to 24, 2021

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

32. The background to this matter is provided in document CAJ/76/INF/3 "Molecular Techniques".

Developments at the TWPs and BMT at their sessions in 2021

Technical Working Parties (TWPs)

33. The TWPs, at their sessions in 2021, noted the information provided by participants at the nineteenth session of the BMT on their work on biochemical and molecular techniques and areas for cooperation, as reproduced in Annex I to document TWP/5/7 see documents TWV/55/16 "Report", paragraphs 48 and 49; TWO/53/10 "Report", paragraph 57; TWA/50/9 "Report", paragraphs 85 and 86; TWF/52/10 "Report", paragraphs 10 and 11; and TWC/39/9 "Report", paragraph 70).

34. The TWV, at its fifty-fifth session, formed a discussion group to allow participants to exchange information on their work on biochemical and molecular techniques and explore areas for cooperation. Tomato, lettuce and pepper were discussed during the discussion group.

35. The TWA, at its fiftieth session, held a discussion session to allow participants to exchange information on their work on biochemical and molecular techniques and explore possible areas for cooperation for Soybeans, Potato, Oilseed Rape, Hemp, Faba Bean and Wheat. The TWA agreed to invite presentations to be made at its fifty-first session, to be held in 2022, on biochemical and molecular techniques in the different crops discussed.

36. The TWF, at its fifty-third session, held a discussion session to allow participants to exchange information on their work on biochemical and molecular techniques and explore areas for cooperation for Apple, Strawberry and Peach. The TWF agreed to invite the experts from the European Union and France to make presentations on the use of molecular techniques in DUS examination of apple varieties, at its fifty-third session.

Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular (BMT)

37. The BMT, at its twentieth session, considered document BMT/20/6 "Session to facilitate cooperation" (see document BMT/20/12 "Report", paragraphs 28 to 35).

38. The BMT recalled the information provided by participants at the nineteenth session of the BMT on their work on biochemical and molecular techniques and areas for cooperation, as reproduced in the Annex to document BMT/20/6.

39. The BMT noted the information on the discussion groups that had been formed at the Technical Working Parties, at their sessions in 2021, to allow participants to exchange information on their work on biochemical and molecular techniques and explore areas for cooperation.

40. The BMT held a discussion session to allow participants to exchange information on their work on biochemical and molecular techniques and explore possible areas for cooperation.

41. The BMT 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.

42. The BMT agreed that information on the use of molecular markers by crop was important to promote cooperation between UPOV members and agreed to propose that the survey on the use of molecular markers was continued to obtain information from a greater number of UPOV members.

43. The BMT agreed that it would be useful to confirm the reasons for not responding to the first survey. The TC, at its fifty-seventh session, will be invited to:

- (a) consider whether to continue the survey on the use of molecular markers to obtain information from a greater number of UPOV members; and
- (b) investigate the reasons for members of the Union not responding to the first survey.

44. The BMT agreed that the possibility to form discussion groups during the sessions should be maintained.

CONFIDENTIALITY & OWNERSHIP OF MOLECULAR INFORMATION

45. 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). A copy of the presentation is provided in document TWV/55/4 (see documents TWV/55/16 “Report”, paragraphs 56 to 61; TWO/53/10 “Report”, paragraphs 62 to 64; TWA/50/9 “Report”, paragraphs 91 to 93; TWF/52/10 “Report”, paragraphs 16 and 17; and BMT/20/12 “Report”, paragraphs 25 to 27).

46. The TWV, TWO and TWA 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:

“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.”

47. The TWV noted that some authorities were creating databases with molecular information and using this information for selecting similar varieties and organizing the growing trial.

48. The TWV agreed to request information on whether the proposal could prevent the authority receiving an application from obtaining molecular information from the candidate variety for DUS purposes and whether the proposal was only aimed at preventing the receiving authority from passing on molecular information of the variety to other authorities without approval by the applicant.

49. The TWV noted that a further discussion with breeders would be needed to find a pragmatic solution to address the concerns of the breeders but to prevent unnecessary administrative burden for authorities.

50. The TWV noted that the same presentation would be scheduled for other TWPs at their sessions in 2021, which would allow further consideration of the proposal.

51. The TWO agreed that further discussion would be needed to find a suitable solution to address the concerns of the breeders while preventing unnecessary administrative burden for authorities.

52. The TWA noted the importance of confidentiality of molecular information for breeders and agreed that further discussion would be required on the topic. The TWA noted that confidentiality of molecular information could be subject to legislation in different UPOV members and agreed to invite presentations at its fifty-first session. The TWA noted the expression of interest from Argentina to make a presentation on the topic at the fifty-first session of the TWA.

53. The TWF noted that the matter of confidentiality and ownership of molecular information had not been considered in any detail in the fruit sector and agreed that further discussion was required. The TWF agreed to invite presentations from members and observers on this topic under the agenda item “Presentation on the use of molecular techniques in DUS examination” at its fifty-third session.

54. The BMT noted that discussions on confidentiality, ownership and access to molecular data had been held at the Technical Working Parties, at their sessions in 2021. The BMT noted that the TWPs had invited further discussions on this topic for their next sessions.

55. The BMT agreed to invite presentations on current practices on confidentiality and access to molecular data to be made at the first session of the TWM. The BMT agreed that current practices in UPOV members and observers could provide a suitable basis for further discussions on the topic.

[Annexes follow]

ANNEX I

ELEMENTS FOR DRAFT JOINT DOCUMENT EXPLAINING THE PRINCIPAL FEATURES OF THE SYSTEMS OF THE OECD, UPOV AND ISTA

The Organisation for Economic Co-operation and Development (OECD)*What are the OECD Seed Schemes?*

The OECD Seed Schemes provide an international framework for the varietal certification of agricultural seed moving in international trade. The Schemes were established in 1958 driven by a combination of factors including a fast-growing seed trade, regulatory harmonisation in Europe, the development of off-season production, the seed breeding and production potential of large exporting countries in America (North and South) and Europe, and the support of private industry. Membership of the Schemes is voluntary and participation varies. There are seven agricultural Seed Schemes.

Participating countries

59 countries from Europe, North and South America, Africa, the Middle-East, Asia and Oceania currently participate in the OECD Seed Schemes:

ALBANIA	(2)	LITHUANIA	(2)
ARGENTINA	(2)	LUXEMBOURG	(1)
AUSTRALIA	(1)	MEXICO	(1)
AUSTRIA	(1)	MOLDOVA	(2)
BELGIUM	(1)	MOROCCO	(2)
BOLIVIA	(2)	NETHERLANDS	(1)
BRAZIL	(2)	NEW ZEALAND	(1)
BULGARIA	(2)	NORWAY	(1)
CANADA	(1)	POLAND	(1)
CHILE	(1)	PORTUGAL	(1)
CROATIA	(2)	ROMANIA	(2)
CYPRUS ¹	(2)	RUSSIAN FEDERATION	(2)
CZECH REPUBLIC	(1)	SENEGAL	(2)
DENMARK	(1)	SERBIA	(2)
EGYPT	(2)	SLOVAKIA	(1)
ESTONIA	(1)	SLOVENIA	(1)
FINLAND	(1)	SOUTH AFRICA	(2)
FRANCE	(1)	SPAIN	(1)
GERMANY	(1)	SWEDEN	(1)

¹ Source OECD "Note by Turkey

The information in this document with reference to 'Cyprus' relates to the southern part of the Island. There is no single authority representing both Turkish and Greek Cypriot people on the Island. Turkey recognises the Turkish Republic of Northern Cyprus (TRNC). Until a lasting and equitable solution is found within the context of the United Nations, Turkey shall preserve its position concerning the 'Cyprus issue'.

Note by all the European Union Member States of the OECD and the European Union

The Republic of Cyprus is recognised by all members of the United Nations with the exception of Turkey. The information in this document relates to the area under the effective control of the Government of the Republic of Cyprus."

GREECE	(1)	SWITZERLAND	(1)
HUNGARY	(1)	TUNISIA	(2)
ICELAND	(1)	TURKEY	(1)
INDIA	(2)	UGANDA	(2)
IRAN	(2)	UKRAINE	(2)
IRELAND	(1)	UNITED KINGDOM	(1)
ISRAEL	(1)	UNITED STATES	(1)
ITALY	(1)	URUGUAY	(2)
JAPAN	(1)	ZIMBABWE	(2)
KENYA	(2)		
KYRGYZSTAN	(2)		
LATVIA	(2)		

(1) OECD Member Country
(2) Non OECD Member Country

Figure 1 Map of Participating Countries in the OECD Seed Schemes (2016)



Objectives

The objectives of the Schemes are to encourage the production and use of “quality-guaranteed” seed in participating countries. The Schemes authorise the use of labels and certificates for seed produced and processed for international trade according to agreed principles ensuring varietal identity and purity.

The Schemes facilitate the import and export of seed, by the removal of technical barriers to trade by assuring identification and origin through internationally recognised labels (“passports”) for trade. They also lay down guidelines for seed multiplication abroad, as well as for the delegation of some control activities to the private sector (“authorisation”). The quantity of seed certified through the OECD Schemes has grown rapidly in recent years and now exceeds 1 million tonnes.

How do the Seed Schemes operate

The success of international certification depends upon close co-operation between maintainers, seed producers, traders and the designated authority (appointed by the government) in each participating country. Frequent meetings allow for a multi-stakeholder dialogue to exchange information, discuss case studies, revise rules and update the Schemes. A wide range of international and non-governmental organisations as well as seed industry networks participate actively in the Schemes.

Benefits of the Schemes

- To facilitate international trade by using harmonised certification procedures, crop inspection techniques and use of control plots. The varietal purity standards for the appropriate species are also agreed and standardised by all member states.
- To provide a framework to develop seed production with other countries or companies.
- To participate in the elaboration of international rules for seed certification.
- To develop collaboration between the public and private sectors.
- To benefit from regular exchanges of information with other national certification agencies and Observer organisations.

Annual List of Varieties

The Annual List of Varieties eligible for OECD certification includes varieties which are officially recognized as distinct, uniform and stable, and possess an acceptable value in one or more participating country. The List contains the seed varieties internationally traded using the OECD seed Schemes. The number of varieties included has grown steadily over the last thirty years. Currently, the number of listed varieties amounts to over 62 000, corresponding to 200 species. The List is available online and updated frequently.

Outlook

As seed “consumers” become more demanding, there are greater needs for uniform seed standards, while at the same time public financial resources for regulation and quality control are limited.

Co-operation among countries and stakeholders in the framework of the Schemes is a response to the concern for a market-responsive regulatory approach. Every country is confronted with a different legal framework, institutional barriers and trade relations whilst the different approaches must remain consistent between countries entering international markets as importers or exporters of seed.

Maintainers and seed companies are responsible for ensuring their varieties remain pure and true to the description and the definitive sample (which is the ‘living description’ of the variety) not only domestically, but also across borders. However, there is a need for minimum criteria to be commonly defined, endorsed and enforced when multiplying seed in large quantities for the trade. The OECD Seed Schemes provide this legal framework at international level.

Status of Biochemical and Molecular Techniques (BMT) in the OECD Seed Schemes

The OECD Seed Schemes do not specifically endorse any laboratory method for determining varietal identity or for determining varietal purity. The traditional OECD methods of using field inspection techniques together with pre- and post- control plots are to be regarded as the required methods of determining varietal identity and varietal purity.

However, the OECD Seed Schemes do recognise that there are occasions where these traditional methods limit the certainty of the varietal determination, and in some cases varieties of some species cannot be identified with certainty using these traditional methods. In these specific circumstances, it might be beneficial to use non-field based techniques such as BMT, which must be seen as supplementing and not replacing the more traditional methods.

For more information on the OECD Seed Schemes see: www.oecd.org/tad/seed

International Union for the Protection of New Varieties of Plants (UPOV)

Type of Organization: Intergovernmental

Membership

[List of UPOV members](#) / [Situation in UPOV](#)

What is UPOV?

The International Union for the Protection of New Varieties of Plants (UPOV) is an intergovernmental organization based in Geneva, Switzerland. UPOV was established in 1961 by the International Convention for the Protection of New Varieties of Plants (the "UPOV Convention").

The mission of UPOV is to provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society.

The UPOV Convention provides the basis for members to encourage plant breeding by granting breeders of new plant varieties an intellectual property right: the breeder's right.

What does UPOV do?

UPOV's mission is to provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society. The main objectives of UPOV are, in accordance with the UPOV Convention, to:

- provide and develop the legal, administrative and technical basis for international cooperation in plant variety protection;
- assist States and organizations in the development of legislation and the implementation of an effective plant variety protection system; and
- enhance public awareness and understanding of the UPOV system of plant variety protection.

What are the benefits of plant variety protection and UPOV membership?

The UPOV Report on the Impact of Plant Variety Protection demonstrated that in order to enjoy the full benefits which plant variety protection is able to generate, both implementation of the UPOV Convention and membership of UPOV are important. The introduction of the UPOV system of plant variety protection and UPOV membership were found to be associated with:

- (a) increased breeding activities,
- (b) greater availability of improved varieties,
- (c) increased number of new varieties,
- (d) diversification of types of breeders (e.g. private breeders, researchers),
- (e) increased number of foreign new varieties,
- (f) encouraging the development of a new industry competitiveness on foreign markets, and
- (g) improved access to foreign plant varieties and enhanced domestic breeding programs.

In order to become a UPOV member the advice of the UPOV Council in respect of the conformity of the law of a future member with the provisions of the UPOV Convention is required. This procedure leads, in itself, to a high degree of harmony in those laws, thus facilitating cooperation between members in the implementation of the system.

Does UPOV allow molecular techniques (DNA profiles) in the examination of Distinctness, Uniformity and Stability ("DUS")?

It is important to note that, in some cases, varieties may have a different DNA profile but be phenotypically identical, whilst, in other cases, varieties which have a large phenotypic difference may have the same DNA profile for a particular set of molecular markers (e.g. some mutations).

In relation to the use of molecular markers that are not related to phenotypic differences, the concern is that it might be possible to use a limitless number of markers to find differences between varieties at the genetic level that are not reflected in phenotypic characteristics.

On the above basis, UPOV has agreed the following uses of molecular markers in relation to DUS examination:

(a) Molecular markers can be used as a method of examining DUS characteristics that satisfy the criteria for characteristics set out in the General Introduction if there is a reliable link between the marker and the characteristic.

(b) A combination of phenotypic differences and molecular distances can be used to improve the selection of varieties to be compared in the growing trial if the molecular distances are sufficiently related to phenotypic differences and the method does not create an increased risk of not selecting a variety in the variety collection which should be compared to candidate varieties in the DUS growing trial.

The situation in UPOV is explained in documents TGP/15 “Guidance on the Use of Biochemical and Molecular Markers in the Examination of Distinctness, Uniformity and Stability (DUS)” and UPOV/INF/18 “Possible use of Molecular Markers in the Examination of Distinctness, Uniformity and Stability (DUS)”.

<https://www.upov.int/about/en/faq.html#QB80>

International Seed Testing Association (ISTA)

ISTA’S VISION: UNIFORMITY IN SEED TESTING

Founded in 1924, with the aim to develop and publish standard procedures in the field of seed testing, ISTA is inextricably linked with the history of seed testing. With member laboratories in over 80 countries/distinct economies worldwide, ISTA membership is truly a global network.

Our association produces internationally agreed rules for seed sampling and testing, accredits laboratories, promotes research, provides international seed analysis certificates and training, and disseminates knowledge in seed science and technology on behalf of our membership and governed by its member countries/distinct economies. This facilitates seed trading nationally and internationally, and therefore contributes to food security.

ISTA’S MEMBERSHIP 2019

With member laboratories in 82 countries/distinct economies worldwide, ISTA membership is a truly global network. Currently, ISTA membership consists of:

- 235 Member Laboratories, out of which 136 are ISTA accredited
- 63 Associate Members
- 39 Personal Members

ISTA’S TECHNICAL WORK

The principle objective of ISTA Technical Committees is to develop, standardise and validate methods for sampling and testing of seed quality, using the best scientific knowledge available. They enhance the **ISTA ‘International Rules for Seed Testing’** and develop ISTA Handbooks on seed methods including sampling and testing. Further they are responsible for the organisation of Symposia, Seminars and Workshops. ISTA Technical Committees regularly hold workshops which provide a platform for training as well as the exchange of information, experience and ideas.

There are 20 Technical Committees in ISTA:

	Technical Committees
1.	Advanced Technologies Committee
2.	Bulking and Sampling Committee
3.	Editorial Board of Seed Science and Technology
4.	Flower Seed Testing Committee
5.	Forest Tree and Shrub Seed Committee
6.	Germination Committee
7.	GMO Committee
8.	Moisture Committee
9.	Nomenclature Committee
10.	Proficiency Test Committee
11.	Purity Committee
12.	Rules Committee

13.	Seed Health Committee
14.	Seed Science Advisory Group
15.	Statistics Committee
16.	Seed Storage Committee
17.	Tetrazolium Committee
18.	Variety Committee
19.	Vigour Committee
20.	Wild Species Working Group

ISTA ACCREDITATION PROGRAMME:

ISTA Accreditation verifies whether a laboratory is technically competent to carry out seed sampling and testing procedures in accordance with the ISTA International Rules for Seed Testing. Accredited laboratories must run a quality assurance system, fulfilling the requirements of the ISTA Accreditation Standard. Accreditation can be granted for:

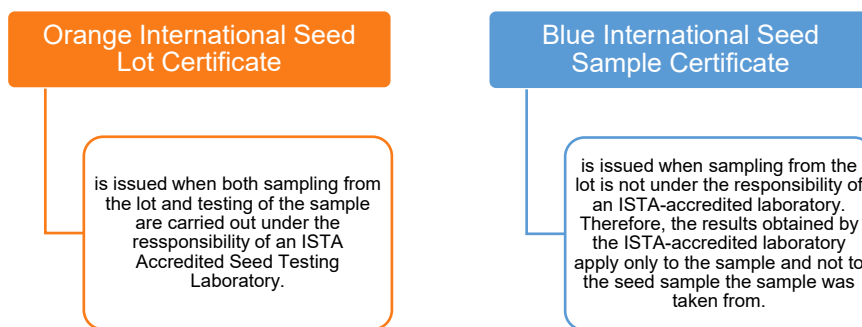
- entities performing sampling only
- laboratories performing testing only
- laboratories performing sampling and testing.

ISTA CERTIFICATES: PASSPORT FOR INTERNATIONAL SEED TRADING

Only ISTA-accredited laboratories are authorised to issue ISTA certificates for seed analysis.

By reporting seed test results on ISTA Certificates, the issuing laboratory assures that the sampling and testing has been carried out in accordance with the ISTA Rules. ISTA Certificates are accepted by most authorities and are mentioned in the seed Acts of several countries.

The ISTA certificates are assuring that the results are reproducible, true and represent the quality of the seed.



More than 200,000 ISTA Orange and Blue Certificates are issued every year, facilitating trading of seed internationally.

THE STATUS OF BIOCHEMICAL AND MOLECULAR TECHNIQUE (BMT) IN ISTA.

The ISTA International Rules for Seed Testing have included BMTs for many years. For example, BMTs are acceptable for GMO testing under a "performance-based approach"; methods that are frequently used include qualitative and quantitative protein detection analyses and various DNA-based methods. BMTs are used as diagnostic and quantitative assessment tools in seed health testing methods. Testing for species and varieties verification also makes use of BMTs by analysing storage protein profiles for sunflower, maize, oat, barley, wheat, rye grass and pea or by DNA fingerprint using molecular markers for maize and wheat. As the versatility of these methods increases and the cost of utilizing them decreases, they may in the future play an even larger role in seed testing.

To learn more about ISTA, visit our website: www.seedtest.org

[Annex II follows]

CAJ/78/INF/5

ANNEX II

SURVEY ON THE USE OF MOLECULAR MARKER TECHNIQUES BY CROP

Please see the Excel spreadsheet for all the responses received

[Appendix to Annex II 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 Annex II and of document]