

TC/52/11

ORIGINAL: English **DATE:** February 23, 2016

INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS

Geneva

TECHNICAL COMMITTEE

Fifty-Second Session Geneva, March 14 to 16, 2016

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 in relation to the Technical Working Parties and OECD/UPOV/ISTA Joint Workshop on Molecular Techniques, and to consider a draft question and answer concerning the information on the situation in UPOV with regard to the use of molecular techniques for a wider audience, including the public in general.

The TC is invited to:

- (a) note the report on developments in the TWPs and BMT, as set out in paragraphs 5 to 15 of this document;
- (b) note the plans for the OECD Seed Schemes to organize a Joint OECD/UPOV/ISTA/AOSA Workshop on Biochemical and Molecular Techniques in Paris, France, on June 7 and 8, 2016;
- (c) note that the comments of OECD and ISTA on principal features of the systems of OECD, UPOV and ISTA will be reported to the TC, at its fifty-third session;
- (d) note that the comments of OECD and ISTA on the use of molecular marker techniques, by crop, will be reported to the TC, at its fifty-third session;
- (e) note that the BMT, at its fifteenth session, will be invited to develop a list of possible joint initiatives with OECD and ISTA, to be presented at the TC, at its fifty-third session; and
- (f) consider a draft question and answer concerning the information on the situation in UPOV with regard to the use of molecular techniques for a wider audience, including the public in general, as set out in paragraph 38 of this document.

3. 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

TC-EDC: Enlarged Editorial 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:

1
2
3
4
4
5
5
5
5
6
6
6
7

DEVELOPMENTS IN THE TECHNICAL WORKING PARTIES

- 4. At their sessions in 2015, the TWV, TWC, TWA, TWF and TWO considered documents TWV/49/2, TWC/33/2, TWA/44/2, TWF/46/2 and TWO/48/2 "Molecular Techniques", respectively.
- 5. The TWV, TWC, TWA, TWF and TWO noted:
- (a) the developments concerning the Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular (BMT);
- (b) that the TC, at its fifty-first session, held in Geneva, from March 23 to 25, 2015, had agreed to develop a joint document explaining the principal features of the systems of the OECD, UPOV and ISTA;
- (c) that the TC, at its fifty-first session, had agreed 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;
- (d) that the TC, at its fifty-first session, had agreed the proposal for the BMT, at its fifteenth session, to develop lists of possible joint initiatives with OECD and ISTA in relation to molecular techniques for consideration by the TC; and

- (e) that the OECD/UPOV/ISTA Joint Workshop on Molecular Techniques had agreed that it would be useful to repeat the joint workshop at relevant meetings of the OECD and ISTA, and, in that regard, that the Technical Working Group Meeting of the OECD Seed Schemes, had agreed that another OECD/UPOV/ISTA Joint Workshop on Molecular Techniques should be organized either back-to-back with the Annual Meeting of the OECD Seed Schemes or in conjunction with the OECD Technical Working Group Meeting.
- 6. The TWC, at its thirty-third session, held in Natal, Brazil from June 30 to July 2, 2015, noted an oral report by Mr. Kees van Ettekoven, Chairman of the BMT, highlighting the developments on molecular techniques presented at the fourteenth session of the BMT, held in Seoul, Republic of Korea from November 10 to 13, 2014, in particular: a presentation by the Republic of Korea (see document BMT/14/16 Rev.2 "Use of Molecular Marker Techniques for Selection of 'Similar Variety' about 'Candidate Variety"); the United States of America (see documents BMT/14/5 and BMT/14/5 Add. "The Use of Reference Varieties in Varietal Distinctness: An Approach under Investigation in the United States of America for Potential Application in Plant Variety Protection"); the Netherlands (see Document BMT/14/11 "Ownership and Use of DUS Samples and of DNA and DNA Data During and After the DUS Tests") and on cooperation between UPOV, OECD and ISTA on molecular techniques (see document TWC/33/30 "Report", paragraph 110).
- 7. The TWF, at its forty-sixth session, held in Mpumalanga, South Africa, from August 24 to 28, 2015, noted that molecular marker techniques were being used by many UPOV members for variety identification and were an important tool in cases of enforcement of plant breeder's rights (PBR). The TWF agreed that it would be useful to provide information to a wider audience that molecular marker techniques were widely used in the context of PBR for variety identification and enforcement of the breeder's rights (see document TWF/46/29 Rev. "Revised Report", paragraphs 73 to 75).
- 8. The TWF noted that France had been using molecular distances in combination with phenotypical distance for optimizing the size of trials in fruit crops since 2000. The TWF agreed that molecular markers also provided useful information on species which the authorities did not hold standard samples of living material.
- 9. The TWF noted that in many UPOV members breeders were requesting authorities to accept molecular marker information with applications for plant breeder's rights. The TWF noted that authorities did not require molecular marker information with the application for plant breeder's rights although some authorities accepted it as complementary information. The TWF noted the concern expressed by some members on matters relating to the confidentiality of molecular marker information and whether such information could be made available to the public.
- 10. The TWO, at its forty-eighth session, held in Cambridge, United Kingdom, from September 14 to 18, 2015, noted that some breeders were providing molecular marker information with applications for plant breeders' rights and agreed that unless the information was validated by the authorities it would not have a proven link to the material used in the examination of DUS (see document TWO/48/26 "Report", paragraph 81).

WORKING GROUP ON BIOCHEMICAL AND MOLECULAR TECHNIQUES, AND DNA-PROFILING IN PARTICULAR

- 11. The role of the BMT is reproduced in the Annex to this document.
- 12. The BMT, at its fourteenth session, held in Seoul, Republic of Korea, from November 10 to 13, 2014, agreed to an invitation from the Russian Federation to hold its fifteenth session in Moscow in May 2016, with a preparatory workshop in May 2016. The BMT planned to discuss the following items:
 - 1. Opening of the session
 - 2. Adoption of the agenda
 - 3. Reports on developments in UPOV concerning biochemical and molecular techniques
 - 4. Short presentations on new developments in biochemical and molecular techniques by DUS experts, biochemical and molecular specialists, plant breeders and relevant international organizations
 - 5. Report of work on molecular techniques in relation to DUS examination
 - 6. International guidelines on molecular methodologies
 - 7. Variety description databases

- 8. Methods for analysis of molecular data
- 9. The use of molecular techniques in examining essential derivation
- 10. The use of molecular techniques in variety identification1
- 11. Cooperation between OECD, UPOV, ISTA and ISO
- 12. Date and place of next session
- 13. Future program
- 14. Report of the session (if time permits)
- 15. Closing of the session
- 13. The TC, at its fifty-first session, held in Geneva, from March 23 to 25, 2015, approved the program for the fifteenth session of the BMT, to be held in 2016, including the dedication of a particular date ("Breeders' Day"), for the items on the use of molecular techniques in the consideration of essential derivation and in variety identification, as set out in paragraph 13 above (see document TC/51/39 "Report", paragraph 176).
- 14. The fifteenth session of the BMT will be held from May 24 to 27, 2016, in Moscow, Russian Federation, with a preparatory workshop on May 23, 2016.

OECD/UPOV/ISTA JOINT WORKSHOP ON MOLECULAR TECHNIQUES

Background

- 15. The OECD/UPOV/ISTA Joint Workshop on Molecular Techniques was held in Seoul, Republic of Korea, on November 12, 2014, in conjunction with the fourteenth session of the BMT, held in Seoul, Republic of Korea, from November 10 to 13 (see document TC/51/11 Rev. "Molecular Techniques", paragraph 23).
- 16. The papers presented under each of the agenda items of the OECD/UPOV/ISTA Joint Workshop were as follows (see document TC/51/11 Rev. "Molecular Techniques", paragraph 24).

Introduction to the OECD Seed Schemes and the Situation with Regard to Molecular Techniques (document BMT/14/Joint/6)

Introduction to UPOV and the Situation with Regard to Molecular Techniques (document BMT/14/Joint/4 Rev.)

Introduction to ISTA and the Situation with Regard to Molecular Techniques (document/BMT/14/Joint/3 Rev.)

Introduction to ISO and the Situation with Regard to Molecular Techniques (document BMT/14/Joint/2)

Existing Areas of Cooperation between OECD, UPOV and ISTA (document/BMT/14/Joint/5)

- 17. The Workshop agreed that it would be useful to develop a joint document explaining the principal features (e.g. DUS, variety identification, variety purity, etc.) of the systems of OECD, UPOV and ISTA. It was also agreed that it would be useful for mutual understanding, to repeat the joint workshop at relevant meetings of the OECD and ISTA (see document TC/51/11 Rev. "Molecular Techniques", paragraph 25).
- 18. The Workshop agreed to propose an inventory by UPOV, OECD and ISTA of the use of molecular marker techniques, by crop, with a view to developing a document containing that information, in a similar format to UPOV document UPOV/INF/16 "Exchangeable Software". It was noted that OECD had already collected some information regarding the use of molecular techniques by its designated authorities (see document TC/51/11 Rev. "Molecular Techniques", paragraph 26).
- 19. The Workshop further agreed to propose to invite UPOV, OECD and ISTA to develop lists of possible joint initiatives in relation to molecular techniques. It was noted that, in the case of UPOV, the list could be drafted by the BMT at its fifteenth session, subject to approval by the Technical Committee (see document TC/51/11 Rev. "Molecular Techniques", paragraph 27).

OECD/UPOV/ISTA Joint Workshop on Molecular Techniques at the relevant meetings of the OECD and ISTA

- 20. The TC, at its fifty-first session, noted that the OECD/UPOV/ISTA Joint Workshop on Molecular Techniques had agreed that it would be useful to repeat the joint workshop at relevant meetings of OECD and ISTA and, in that regard, that the Technical Working Group Meeting of the OECD Seed Schemes had agreed that another OECD/UPOV/ISTA Joint Workshop on Molecular Techniques should be organized either back-to-back with the Annual Meeting of the OECD Seed Schemes, to be held in Paris, in June 2015, or in conjunction with the Technical Working Group Meeting to be held in January 2016 (see document TC/51/39 "Report", paragraph 178).
- 21. On January 4, 2016, the OECD issued document TAD/CA/S/RD(2016)7 "Preliminary Draft Programme of the Joint OECD/UPOV/ISTA/AOSA Workshop on Biochemical and Molecular Techniques" for consideration by the Technical Working Group Meeting of the OECD Seed Schemes, held in Cape Town, South Africa, from January 26 to 29, 2016, which indicated that a Joint OECD/UPOV/ISTA/AOSA Workshop on Biochemical and Molecular Techniques would be held in Paris, France, on June 7 or 8, 2016.

Principal features of the systems of OECD, UPOV and ISTA

- 22. The TC, at its fifty-first session, agreed to develop a joint document explaining the principal features of the systems of OECD, UPOV and ISTA (e.g. DUS, variety identification, variety purity, etc.), subject to the approval of the Council and in coordination with OECD and ISTA (see document TC/51/39 "Report", paragraph 177).
- 23. The comments by OECD and ISTA on the possible development of a joint document explaining the principal features of the systems of OECD, UPOV and ISTA will be reported to the TC, at its fifty-third session, to be held in Geneva in 2017.

Inventory on the use of molecular marker techniques

- 24. The TC, at its fifty-first session, agreed 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", as set out in paragraph 26 of document TC/51/11, subject to the approval of the Council and in coordination with OECD and ISTA. It agreed that it would be necessary to establish criteria and a process for information to be added to the document (see document TC/51/39 "Report", paragraph 179).
- 25. The comments by OECD and ISTA on the possible development of an inventory on the use of molecular marker techniques, by crop, will be reported to the TC, at its fifty-third session, to be held in Geneva in 2017.

Lists of possible joint initiatives with OECD and ISTA

- 26. The OECD/UPOV/ISTA Joint Workshop on Molecular Techniques agreed to propose to invite UPOV, OECD and ISTA to develop lists of possible joint initiatives in relation to molecular techniques. It was noted that, in the case of UPOV, the list could be drafted by the BMT at its fifteenth session, subject to approval by the Technical Committee (see document TC/51/11 Rev. "Molecular Techniques", paragraph 27).
- 27. The TC, at its fifty-first session, agreed the proposal for the BMT, at its fifteenth session, to develop lists of possible joint initiatives with OECD and ISTA in relation to molecular techniques for consideration by the TC (see document TC/51/39 "Report", paragraph 180).
- 28. The BMT, at its fifteenth session, will be invited to develop a list of possible joint initiatives with OECD and ISTA. The list of possible joint initiative will be presented to the TC, at its fifty-third session, to be held in Geneva in 2017.

PRESENTATION OF INFORMATION ON THE SITUATION IN UPOV WITH REGARD TO THE USE OF MOLECULAR TECHNIQUES

Background

- 29. The TC, at its forty-ninth session, held in Geneva from March 18 to 20, 2013, agreed that there was a need to provide suitable information on the situation in UPOV with regard to the use of molecular techniques to a wider audience, including breeders and the public in general. That information should explain the potential advantages and disadvantages of the techniques, and the relationship between genotype and phenotype, which lay behind the situation in UPOV (see document TC/49/41 "Report on the Conclusions", paragraph 136).
- 30. The Consultative Committee, at its eighty-sixth session, held in Geneva on October 23 and 24, 2013, considered a series of answers to frequently asked questions. One of the questions included was "Does UPOV allow molecular techniques (DNA profiles) in the DUS examination?". In that regard, the Consultative Committee agreed that the answer should be developed via the Technical Committee. The Consultative Committee agreed to consider draft answers to this and other frequently asked questions at its eighty-seventh session, held in Geneva on April 11, 2014.
- 31. The TC, at its fiftieth session, held in Geneva from April 7 to 9, 2014 and the CAJ, at its sixty-ninth session, held in Geneva on April 10, 2014, agreed the proposed explanation of the situation in UPOV with regard to the use of molecular techniques.
- 32. With regard to a wider audience, the TC agreed that the question was not framed in an appropriate way and, therefore, it would not be appropriate to seek to develop an answer to that question. The TC agreed that the question should be rephrased after clarification of the issues of interest to a wider audience (see document TC/50/36 "Report on the Conclusions", paragraph 83 to 85).
- 33. The Consultative Committee, at its eighty-eighth session, held in Geneva, on October 15, 2014, agreed that the draft FAQ concerning information on the situation in UPOV with regard to the use of molecular techniques for a wider audience, including the public in general, should be referred to the TC for consideration (see document C/48/19 "Report by the President on the work of the eighty-sixth session of the Consultative Committee; adoption of recommendations, if any, prepared by that Committee", paragraph 48).
- 34. The TC, at its fifty-first session, held in Geneva from March 23 to 25, 2015, considered the development of a draft question and answer concerning the information on the situation in UPOV with regard to the use of molecular techniques for a wider audience, including the public in general. The TC agreed to request the TWPs, at their sessions in 2015, to consider the following initial draft discussed during the TC session (see document TC/51/39 "Report", paragraph 181);

"Is it possible to obtain protection of a variety on the basis of its DNA-profile?

"For a variety to be protected, it needs to be clearly distinguishable from all existing varieties on the basis of characteristics that are physically expressed, e.g. plant height, time of flowering, fruit color, disease resistance etc. [Molecular techniques (DNA profiles) may be used as supporting information].

"A more detailed explanation is provided in the FAQ 'Does UPOV allow molecular techniques (DNA profiles) in the examination of Distinctness, Uniformity and Stability ("DUS")?'

"See also:

"What are the requirements for protecting a new plant variety?"

Comments by the Technical Working Parties in 2015

- 35. The TWV, at its forty-ninth session, held in Angers, France from June 15 to 19, 2015, and the TWC, at its thirty-third session, held in Natal, Brazil from June 30 to July 2, 2015, agreed with the initial draft question and answer concerning the information on the situation in UPOV with regard to the use of molecular techniques for a wider audience, including the public in general, discussed during the TC, at its fifty-first session (see documents TWV/49/32 Rev. "Revised Report", paragraph 15 and TWC/33/30 "Report", paragraph 110).
- 36. The TWA, at its forty-fourth session, held in Obihiro, Japan from July 6 to 10, 2015, the TWF, at its forty-sixth session, held in Mpumalanga, South Africa from August 24 to 28, 2015, and the TWO, at its forty-eighth session, held in Cambridge, United Kingdom from September 14 to 18, 2015, agreed to propose

the text of the initial draft question and answer concerning the information on the situation in UPOV with regard to the use of molecular techniques for a wider audience, including the public in general, discussed during the TC, at its fifty-first session, to read as follows (see documents TWA/44/23 "Report", paragraph 70, TWF/46/29 Rev. "Revised Report", paragraph 72 and TWO/48/26 "Report", paragraph 80):

"Is it possible to obtain protection of a variety on the basis of its DNA-profile?

"A variety cannot be protected on the basis of DNA profiles. For a variety to be protected, it needs to be clearly distinguishable from all existing varieties on the basis of characteristics that are physically expressed, e.g. plant height, time of flowering, fruit color, disease resistance etc. [Molecular techniques (DNA profiles) may be used as supporting information].

"A more detailed explanation is provided in the FAQ 'Does UPOV allow molecular techniques (DNA profiles) in the examination of Distinctness, Uniformity and Stability ("DUS")?'

"See also:

"What are the requirements for protecting a new plant variety?"

Comments by the TC-EDC

37. The TC-EDC, at its meeting held in Geneva, on January 6 and 7, 2016, considered the initial draft discussed by the TC at its fifty-first session in conjunction with the comments of the TWPs and proposed to revise the initial draft as follows:

"Is it possible to obtain protection of a variety on the basis of its DNA-profile?

"For a variety to be protected, it needs to be clearly distinguishable from all existing varieties on the basis of characteristics that are physically expressed, e.g. plant height, time of flowering, fruit color, disease resistance etc. A variety cannot be protected on the basis of its DNA-profile, although this information may be used in the examination of Distinctness, Uniformity and Stability ("DUS"). [Molecular techniques (DNA profiles) may be used as supporting information].

"A more detailed explanation is provided in the FAQ 'Does UPOV allow molecular techniques (DNA profiles) in the examination of Distinctness, Uniformity and Stability ("DUS")?'

"See also:

"What are the requirements for protecting a new plant variety?"

38. The TC is invited to:

- (a) note the report on developments in the TWPs and BMT, as set out in paragraphs 5 to 15 of this document:
- (b) note the plans for the OECD Seed Schemes to organize a Joint OECD/UPOV/ISTA/AOSA Workshop on Biochemical and Molecular Techniques in Paris, France, on June 7 and 8, 2016;
- (c) note that the comments of OECD and ISTA on principal features of the systems of OECD, UPOV and ISTA will be reported to the TC, at its fifty-third session;
- (d) note that the comments of OECD and ISTA on the use of molecular marker techniques, by crop, will be reported to the TC, at its fifty-third session;
- (e) note that the BMT, at its fifteenth session, will be invited to develop a list of possible joint initiatives with OECD and ISTA, to be presented at the TC, at its fifty-third session; and

TC/52/11 page 8

(f) consider a draft question and answer concerning the information on the situation in UPOV with regard to the use of molecular techniques for a wider audience, including the public in general, as set out in paragraph 38 of this document.

[Annex follows]

TC/52/11

ANNEX

ROLE OF THE WORKING GROUP ON BIOCHEMICAL AND MOLECULAR TECHNIQUES, AND DNA-PROFILING IN PARTICULAR (BMT)

(as agreed by the Technical Committee at its thirty-eighth session, held in Geneva, from April 15 to 17, 2002 (see document TC/38/16, paragraph 204))

The BMT is a group open to DUS experts, biochemical and molecular specialists and plant breeders, whose role is to:

- (i) Review general developments in biochemical and molecular techniques;
- (ii) Maintain an awareness of relevant applications of biochemical and molecular techniques in plant breeding;
- (iii) Consider the possible application of biochemical and molecular techniques in DUS testing and report its considerations to the TC;
- (iv) If appropriate, establish guidelines for biochemical and molecular methodologies and their harmonization and, in particular, contribute to the preparation of document TGP/15, "New Types of Characteristics." These guidelines to be developed in conjunction with the Technical Working Parties;
- (v) Consider initiatives from TWPs, for the establishment of crop specific subgroups, taking into account available information and the need for biochemical and molecular methods;
- (vi) Develop guidelines regarding the management and harmonization of databases of biochemical and molecular information, in conjunction with the TWC;
- (vii) Receive reports from Crop Subgroups and the BMT Review Group;
- (viii) Provide a forum for discussion on the use of biochemical and molecular techniques in the consideration of essential derivation and variety identification.

[End of Annex and of document]