



TC/41/7

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INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS
GENEVA

TECHNICAL COMMITTEE

Forty-First Session
Geneva, April 4 to 6, 2005

MOLECULAR TECHNIQUES

Document prepared by the Office of the Union

1. The purpose of this document is to report on developments concerning:
 - (a) the document “Situation in UPOV concerning the possible use of molecular markers in DUS examination”;
 - (b) “Guidelines for molecular marker selection and database construction (“BMT Guidelines”)”;
 - (c) the proposal of the Technical Committee (TC) for matters concerning the possible use of molecular tools for variety characterization in relation to the enforcement of plant breeders’ rights, technical verification of identity and the consideration of essential derivation to be considered by the *Ad hoc* Subgroup of Technical and Legal Experts of Biochemical and Molecular Techniques (BMT Review Group);
 - (d) proposals concerning the *Ad Hoc* Crop Subgroups on Molecular Techniques (“Crop Subgroups”); and
 - (e) proposals concerning the Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular (BMT).

Document “Situation in UPOV Concerning the Possible Use of Molecular Markers in DUS Examination”

2. At its fortieth session, held in Geneva from March 29 to 31, 2004, the TC considered the Annex to document TC/40/9, which contained a draft document on the possible use of molecular markers in the DUS examination, prepared in accordance with the request of the TC at its thirty-ninth session. In relation to that draft, it was agreed that the section providing an overview of relevant molecular techniques (Section 3) should be deleted and a separate document developed to address molecular techniques. Amendments were also made to the remaining sections in the Annex of document TC/40/9 and, on that basis, the TC agreed a document which would be a suitable summary of the current UPOV position. That document, which is reproduced in the Annex to this document, was presented by correspondence to the TC as the Annex to document TC/40/9 Add. and was also presented to the Technical Working Parties (TWPs) at their sessions in 2004. The TC also proposed that the CAJ be invited to examine that document.

3. The Technical Working Party for Agricultural Crops (TWA), at its thirty-third session held in Poznań, Poland, from June 28 to July 2, 2004, discussed the text of the Annex to document TC/40/9 Add. and proposed that the situation with regard to Section 3.3 “Current Status of Molecular Techniques”, which is reproduced as the Annex to this document, might be further clarified by the addition of the following paragraph:

“3.3.4 Summary of current UPOV position

“In conclusion, the current UPOV position is that, subject to fulfillment of the assumptions set out in relation to the proposals, approaches under Options 1(a) and 2 may be pursued. The current UPOV position is that approaches under Option 3 have not been agreed”.

and recommended that the CAJ be invited to consider this addition when reviewing the document. The Technical Working Party for Ornamental Plants and Forest Trees (TWO) and the Technical Working Party for Fruit Crops (TWF) proposed that the final sentence of the TWA proposal be changed to read “Approaches under Option 3 have not, so far, been agreed”.

4. The document, as agreed by the TC, was presented as the Annex to document CAJ/50/4 for consideration by the Administrative and Legal Committee (CAJ) at its fiftieth session, held in Geneva on October 18 and 19, 2004. The CAJ did not have sufficient time to discuss that document at its fiftieth session. The Chair of the CAJ presented the CAJ apologies to the TC for not having had the chance, on that occasion, to give the advice requested by the TC on molecular techniques and confirmed that that agenda item would be dealt with at the fifty-first session of the CAJ to be held in Geneva on April 7, 2005.

Guidelines for Molecular Marker Selection and Database Construction (“BMT Guidelines”)

5. At its fortieth session, the TC heard that the BMT had concluded, at its eighth session in Tsukuba, Japan, from September 3 to 5, 2003, that there was an urgent need to harmonize methodologies for the generation of molecular data in order to ensure that the quality of the data produced would be universally acceptable for use in variety characterization. It was also noted that it would be useful to provide guidance on the planning of databases for molecular

data based on different types of markers. On that basis, the BMT agreed that the Office of the Union (Office) should prepare a guidance document (“BMT Guidelines”).

6. In accordance with the request of the BMT, the Office produced a first draft of the BMT Guidelines (document BMT Guidelines (proj.1)) in May 2004 for consideration by the subgroup of interested experts from Australia, France, Netherlands, the United Kingdom and the International Seed Federation (ISF). On the basis of the comments received from that subgroup, the Office prepared a second draft (document BMT Guidelines (proj.2)) which was considered by the Crop Subgroups for Potato, Sugarcane and Wheat at their sessions on June 28, 2004. The Crop Subgroup for Wheat (see document BMT-TWA/Wheat/2/3 Prov.), supported by the Crop Subgroups for Potato and Sugarcane (see documents BMT-TWA/Potato/1/7 Prov. and BMT-TWA/Sugarcane/2/4 Prov.) agreed that that document should be redrafted by an expert/experts with suitable knowledge and experience of the use of molecular techniques. On that basis, it agreed that Mr. Robert Cooke (United Kingdom) should undertake the redrafting, with the assistance of Mrs. Françoise Blouet (France) in connection with Section 5.

7. In conjunction with the Chairpersons of the TC, the BMT and the Technical Working Party on Automation and Computer Programs (TWC), it is proposed that a new draft of the BMT Guidelines (document BMT Guidelines (proj.3)) be presented to the ninth session of the BMT, to be held in Washington, D.C., United States of America, from June 21 to 23, 2005, and to the twenty-third session of the TWC to be held in Ottawa, Canada, from June 13 to 16, 2005. On the basis of the comments received at the BMT and TWC sessions, a new draft would then be prepared for consideration by the Enlarged Editorial Committee (TC-EDC) and by the forty-second session of the TC in April 2006.

8. The TC may wish to consider whether the documents “Situation in UPOV concerning the possible use of molecular markers in DUS examination” and the document “BMT Guidelines”, once approved, might be the basis for a new section (Section 4) within TGP/12 “Special characteristics” or the basis for TGP/15 “New types of characteristics”.

Consideration of the Possible Use of Molecular Tools for Variety Characterization

9. At its fortieth session, the TC agreed to propose to the CAJ that it consider the possible use of molecular tools for variety characterization in relation to the enforcement of plant breeders’ rights, technical verification and the consideration of essential derivation. In that respect, it proposed that those might be matters relevant for consideration by the BMT Review Group. The TC noted that work concerning the use of molecular tools for variety characterization was being undertaken by the International Seed Testing Association (ISTA).

10. The TC proposal for the CAJ to consider the possible use of molecular tools for variety characterization and for that matter to be referred to the BMT Review Group was presented to the CAJ at its fiftieth session in document CAJ/50/4. As noted in paragraph 4, the CAJ did not have sufficient time to discuss that document at its fiftieth session. That agenda item will be dealt with at its fifty-first session of the CAJ to be held in Geneva on April 7, 2005.

11. The TC may wish to consider whether it wishes to add any further comments or elaboration to assist the CAJ at its fifty-first session when it considers the matter of the possible use of molecular tools for variety characterization and, in addition, whether it wishes

to identify particular issues which should be considered by the BMT Review Group, should it be requested by the CAJ to take up this matter.

Proposals Concerning the Crop Subgroups

(a) *Chairmanship of the Crop Subgroup for Wheat*

12. The TWA, at its thirty-third session in June 2004, heard from Mr. Michael Camlin (United Kingdom) that he had taken on the chairmanship of the Crop Subgroup for Wheat on a temporary basis and proposed that the chairmanship should be resolved. At the proposal of Mr. Camlin, the TWA agreed to propose to the TC that Mr. Robert Cooke (United Kingdom) be appointed as the Chairman of the Crop Subgroup for Wheat. It further agreed that Mr. Cooke take up that role for the second session of the Crop Subgroup for Wheat, which would be held later that day.

(b) *New Crop Subgroups*

13. At the proposal of the expert from Denmark, at its thirty-third session in June 2004, the TWA agreed to propose to the TC and the BMT that a crop subgroup be established for ryegrass, noting that laboratories in Denmark and the United Kingdom were working on that crop. It was agreed that Mr. Michael Camlin (United Kingdom) should be proposed as Chairman. Mr. Camlin noted that ryegrass, being a cross-pollinated species, would pose particular difficulties, but remarked on the need for tools to help in the management of reference collections and the potential for an Option 2 approach.

(c) *Program for Crop Subgroups*

14. The TWA, at its thirty-third session in June 2004, agreed that the work on molecular techniques in maize, oilseed rape, potato, soybean, sugarcane and wheat should be kept under review and future meetings of the relevant Crop Subgroups considered as required.

15. At its thirty-seventh session held in Hanover, Germany, from July 12 to 16, 2004, the TWO heard that there had been no meetings of the *Ad hoc* Crop Subgroup for Rose since the thirty-sixth session of the TWO. It noted that a meeting would be arranged as and when there were sufficient papers for discussion. In that regard, an expert from the Community Plant Variety Office (CPVO) informed the TWO that results from the European Rose Project, as reported in his oral report, should be available by 2006. The expert from France reported that BIOGEVES was working on the use of molecular techniques in relation to commercial applications, but not in relation to DUS testing.

16. The TWV agreed to: dissolve the *Ad hoc* Subgroup for Mushroom on the basis that further developments were not expected in the foreseeable future; to update the information on the work on the use of molecular techniques for the DUS testing of tomato varieties; and to keep an item on the agenda for future TWV sessions to exchange information on the use of molecular techniques for the DUS testing of vegetable varieties.

17. On the basis of the discussions in the TWPs, the situation with regard to the program of the Crop Subgroups is that the following Crop Subgroups will meet, subject to the availability of sufficient papers for discussion, at a date and location to be proposed to the TC by the

relevant TWP, or at a date and location agreed jointly between the Chairpersons of the TC, the relevant TWP, the relevant Crop Subgroup and the Office:

<i>Crop Subgroup for:</i>	<i>Chairperson</i>	<i>TWP</i>
Maize	Mrs. Beate Rücker (Germany)	TWA
Oilseed Rape	Mrs. Françoise Blouet (France)	TWA
Potato	Mrs. Beate Rücker (Germany)	TWA
Rose	Mr. Joost Barendrecht (Netherlands)	TWO
Ryegrass	Mr. Michael Camlin (United Kingdom)	TWA
Soybean	Mr. Marcelo Labarta (Argentina)	TWA
Sugarcane	Mr. Luis Salaices (Spain)	TWA
Tomato	Mr. Richard Brand (France)	TWV
Wheat	Mr. Robert Cooke (United Kingdom)	TWA

and that the following Crop Subgroup will be discontinued:

<i>Crop Subgroup for:</i>	<i>Chairperson</i>	<i>TWP</i>
Mushroom	Mr. Nico van Marrewijk (Netherlands)	TWV

Proposals Concerning the BMT

18. The TWC proposed that its Chairman, the Chairman of the BMT and the Office should consider possible content for the agenda of the sessions of the TWC and BMT in 2005 to take most advantage of the fact that those sessions would be held back-to-back in North America in 2005.

19. *The TC is invited to:*

(a) consider the amendments proposed by the TWPs to document "Situation in UPOV concerning the possible use of molecular markers in DUS examination" as presented in paragraph 3;

(b) approve the program for the development of the BMT Guidelines as set out in paragraph 7;

(c) consider whether the documents “Situation in UPOV concerning the possible use of molecular markers in DUS examination” and the document “BMT Guidelines”, once approved, might be the basis for a new section (Section 4) within TGP/12 “Special characteristics” or the basis for TGP/15 “New types of characteristics” (see paragraph 8);

(d) consider whether it wishes to add any further comments or elaboration to assist the CAJ at its fifty-first session when it considers the matter of the possible use of molecular tools for variety characterization and, in addition, whether it wishes to identify particular issues which should be considered by the BMT Review Group, should it be requested by the CAJ to take up this matter (see paragraph 11);

(e) appoint Mr. Robert Cooke (United Kingdom) as the Chairman of the Crop Subgroup for Wheat (see paragraph 12);

(f) approve the establishment of a crop subgroup for ryegrass, with Mr. Michael Camlin (United Kingdom) as Chairman (see paragraph 13);

(g) approve the program for the Crop Subgroups as set out in paragraph 17; and

(h) request the Chairman of the TWC, the Chairman of the BMT and the Office to establish appropriate agendas for the back-to-back sessions of the TWC and BMT (see paragraph 18).

[Annex follows]

[reproduced from document TC/40/9 Add.]

SITUATION IN UPOV CONCERNING THE POSSIBLE USE OF MOLECULAR MARKERS IN DUS EXAMINATION

[...]

3. CONSIDERATION OF THE USE OF MOLECULAR TECHNIQUES IN THE DUS EXAMINATION

[...]

3.3 Current Status of Molecular Techniques

3.3.1 *Proposals considered by the BMT Review Group*

At the request of the TC, the following options, developed by the Crop Subgroups and the BMT, have been considered by the BMT Review Group on the basis of detailed proposals presented by the relevant member of the Union as presented in Appendix 2 to this document:

Option 1: Molecular characteristics as a predictor of traditional characteristics

(a) Use of molecular characteristics which are directly linked to traditional characteristics (gene specific markers);

Option 2: Calibration of threshold levels for molecular characteristics against the minimum distance in traditional characteristics;

Option 3: Development of a new system.

3.3.2 Recommendations of the BMT Review Group

3.3.2.1 The BMT Review Group concluded as follows:

The proposal under Option 1(a) (Gene specific marker of a phenotypic characteristic) was, on the basis of the assumptions in the proposal, acceptable within the terms of the UPOV Convention and would not undermine the effectiveness of protection offered under the UPOV system.

The proposal under Option 2 (Calibration of threshold levels for molecular characteristics against the minimum distance in traditional characteristics for Oilseed Rape, Maize and Rose, respectively), where used for the management of reference collections was, on the basis of the assumptions in the proposal, acceptable within the terms of the UPOV Convention and would not undermine the effectiveness of protection offered under the UPOV system.

Regarding the proposals under Option 3 for Rose and for Wheat, it noted there was no consensus on the acceptability of these proposals within the terms of the UPOV Convention and no consensus on whether they would undermine the effectiveness of protection offered under the UPOV system. Concerns were raised that, in these proposals, using this approach, it might be possible to use a limitless number of markers to find differences between varieties. The concern was also raised that differences would be found at the genetic level which were not reflected in morphological characteristics.

3.3.2.2 The following general remarks were also made. Firstly, concern was raised regarding the accessibility of techniques covered by patents. Secondly, the BMT Review Group emphasized the importance of considering if there were cost benefits arising from any new approaches. Thirdly, the importance of the relationship between phenotypic characteristics and molecular techniques was discussed. Finally, the importance of examining uniformity and stability on the same characteristics as used for distinctness was emphasized.

3.3.3 *Opinion of the TC and the CAJ regarding the recommendations of the BMT Review Group*

3.3.3.1 The TC considered the conclusions of the BMT Review Group and agreed with those conclusions, namely that proposals under Options 1(a) and 2 could be pursued on the basis of the assumptions, whilst recognizing the need for further work to examine these assumptions and, in the case of the Option 2 proposal, to improve the relationship between morphological and molecular distances. It also noted the divergence of views which had been expressed regarding the proposals under Option 3.

3.3.3.2 The CAJ agreed with the conclusions of the BMT Review Group and endorsed the opinion of the TC.

3.4 Ongoing Developments

3.4.1 Section 3.3 sets out the current position within UPOV concerning molecular techniques. However, the situation is under continual review in the light of ongoing developments concerning molecular techniques and the need to develop suitable molecular techniques within the current position. In particular, the ongoing work can be summarized as follows:

(a) Development of advanced proposals under Option 1(a), in which the assumptions have been evaluated and issues of cost, accessibility and uniformity and stability have been addressed. Such advanced proposals to be considered by the relevant Crop Subgroup, the BMT Review Group, the TC and the CAJ;

(b) Development of advanced proposals under Option 2, in which the assumptions have been evaluated, issues of cost, accessibility and uniformity and stability have been addressed and the relationship between morphological and molecular distances has been improved. Such advanced proposals to be considered by the relevant Crop Subgroup, the BMT Review Group, the TC and the CAJ;

(c) Consideration of new proposals under Option 1, Option 2, or Option 3, by the BMT, the relevant Crop Subgroup, the BMT Review Group, the TC and the CAJ;

(d) The Crop Subgroups to continue to consider developments at the crop specific level, with the establishment of new Crop Subgroups according to need; and

(e) The BMT to continue to monitor developments in molecular techniques and to develop guidelines and facilitate harmonization concerning the use of molecular techniques.

3.4.2 This document will be updated to reflect any substantial developments.

[End of Annex and of document]