

CAJ/57/3

ORIGINAL: English

DATE: January 28, 2008

INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS GENEVA

ADMINISTRATIVE AND LEGAL COMMITTEE

Fifty-Seventh Session Geneva, April 10, 2008

MOLECULAR TECHNIQUES

Document prepared by the Office of the Union

- 1. The purpose of this document is to report on developments concerning molecular techniques since the fifty-sixth session of the Administrative and Legal Committee (CAJ), held in Geneva on October 22 and 23, 2007 and to invite the CAJ to consider:
- (a) the UPOV Guidelines for DNA-profiling: molecular marker selection and database construction (BMT Guidelines); and
- (b) whether an approach discussed at the *Ad Hoc* Crop Subgroup on Molecular Techniques (Crop Subgroup) for Maize, should be put forward for consideration at the *Ad Hoc* Subgroup of Technical and Legal Experts on Biochemical and Molecular Techniques (BMT Review Group) as a potential option for the use of molecular markers in DUS examination.
- 2. An overview of the UPOV bodies involved in the consideration of biochemical and molecular techniques is provided on the first restricted area of the UPOV website at http://www.upov.int/restrict/en/upov_structure_index.html. That overview is also attached as the Annex to this document.

3. The following abbreviations are used in this document:

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

TWV: Technical Working Party for Vegetables

TWP(s): Technical Working Party(ies)

BMT: Working Group on Biochemical and Molecular Techniques, and

DNA-Profiling in Particular

BMT Review Group: Ad Hoc Subgroup of Technical and Legal Experts on Biochemical

and Molecular Techniques

Crop Subgroup: Ad Hoc Crop Subgroup on Molecular Techniques

POSSIBLE USE OF MOLECULAR TOOLS FOR VARIETY IDENTIFICATION IN RELATION TO THE ENFORCEMENT OF PLANT BREEDERS' RIGHTS, TECHNICAL VERIFICATION AND THE CONSIDERATION OF ESSENTIAL DERIVATION

4. At its seventy-second session, held in Geneva on October 18, 2006, the Consultative Committee noted that the role of the Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular (BMT) included the following:

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

[...]

- "(viii) Provide a forum for discussion on the use of biochemical and molecular techniques in the consideration of essential derivation and variety identification."
- 5. The Consultative Committee noted that this provision enabled the BMT to provide a forum for discussion on the use of biochemical and molecular techniques in the consideration of variety identification. The Vice Secretary-General noted that, with regard to the use of molecular tools for variety identification, the current terms of reference of the BMT appeared to be sufficiently broad. As a consequence, there was no immediate need to change the terms of reference of the BMT nor of the *Ad Hoc* Subgroup of Technical and Legal Experts on Biochemical and Molecular Techniques (BMT Review Group). The BMT could continue its work and report to the Technical Committee (TC) and the CAJ. The TC and CAJ could identify any matters which the Consultative Committee might need to consider.
- 6. At its forty-third session, held in Geneva, from March 26 to 28, 2007, the TC noted the conclusion of the Consultative Committee. The TC noted the importance of the Technical Working Parties (TWPs) in the consideration of biochemical and molecular techniques and the contact between other UPOV bodies dealing with those matters. It noted the importance of communication between the TWPs, BMT, TC, CAJ and the Council within the existing UPOV structure. The TC also noted the importance of the *Ad Hoc* Crop Subgroup on Molecular Techniques (Crop Subgroups) as a forum for DUS experts and molecular specialists to consider matters at a crop specific level. It agreed to invite the Crop Subgroups

to develop proposals concerning the possible use of molecular tools for variety identification in relation to the enforcement of plant breeders' rights, technical verification and the consideration of essential derivation.

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

- 7. In order to encourage the presentation of information in relation to the use of molecular techniques in the consideration of essential derivation and in variety identification, the BMT agreed at its tenth session, held in Seoul, Republic of Korea, from November 21 to 23, 2006, that it would be appropriate to dedicate a specific day to the agenda items "The use of molecular techniques in the consideration of essential derivation" and "The use of molecular techniques in variety identification", at the eleventh session of the BMT. In particular, breeders and other experts would be offered the possibility to attend for that specific day.
- 8. At its forty-first ordinary session, held in Geneva on October 25, 2007, the Council approved the calendar of meetings for 2008, which indicated that the eleventh session of the BMT would be held in Puerto de la Cruz, Tenerife, Spain from May 12 to 14, 2008. However, in order to facilitate greater participation by breeders, the date and location of the BMT has been changed. The eleventh session of the BMT will be held in Madrid, Spain, from September 16 to 18, 2008.
 - 9. The CAJ is invited to note the change of date and location of the eleventh session of the BMT.

UPOV GUIDELINES FOR DNA-PROFILING: MOLECULAR MARKER SELECTION AND DATABASE CONSTRUCTION (BMT GUIDELINES)

- 10. The CAJ has not previously considered a draft of document BMT Guidelines.
- 11. At its eighth session held in Tsukuba, Japan, from September 3 to 5, 2003, the BMT concluded 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 should prepare a guidance document (BMT Guidelines).
- 12. At its forty-third session, the TC considered document BMT Guidelines (proj.8) and agreed the following amendments:
 - Section 6.3.1 (c): to change "locus" to "allele", subject to confirmation by Mr. Sylvain Grégoire (France), the drafter of that section.
- 13. The TC agreed that, subject to the amendment above, document BMT Guidelines (proj.8) should be put forward for adoption by the Council at its forty-first ordinary session, to be held in Geneva on October 25, 2007.

- 14. Following the forty-third session of the TC, Mr. Grégoire confirmed that Section 6.3.1 (c) should read as follows:
 - "(c) Allele code:

"indicates name or code of the <u>allele of a given</u> locus for the species concerned, e.g. 1, 123, etc."

(underlining indicates added text)

15. In preparing the document for adoption by the Council, the Office of the Union realized that Section A, paragraph 2, of document BMT Guidelines (proj.8) made reference to an annex which did not exist. Therefore, in conjunction with the Chairperson of the TC, it was proposed by means of Circular E-554, issued to the TC, that the text be amended as follows:

"With regard to the possible use of molecular markers in the examination of Distinctness, Uniformity and Stability (DUS), the current situation within UPOV is explained in the Annex to this document. documents TC/38/14-CAJ/45/5 and TC/38/14 Add.-CAJ/45/5 Add."

- 16. No objections were received in response to Circular E-554 and document BMT Guidelines (proj.9) was put forward for adoption by the Council at its forty-first ordinary session, held in Geneva on October 25, 2007, on the basis of the amendments above.
- 17. At its seventy-fourth session, held in Geneva on October 24, 2007, the Consultative Committee made a preliminary examination of document BMT Guidelines (proj.9), proposed for adoption by the Council. The Consultative Committee made the following recommendations:

"[…]

- "(b) consideration be given to the status of documents TC/38/14-CAJ/45/5 and TC/38/14 Add.-CAJ/45/5 Add. with regard to their reference in the introduction of document BMT Guidelines (proj.9); and
- "(c) in response to the comments made by some delegations concerning the need for editorial improvements, the Consultative Committee agreed that a circular be sent to the Consultative Committee, the Technical Committee (TC) and the CAJ providing an opportunity to comment within four weeks on documents TGP/4/1 Draft 10, TGP/9/1 Draft 10 and BMT Guidelines (proj.9). Based on the comments received, new drafts of those documents would be prepared for consideration by the [Enlarged] Editorial Committee (TC-EDC) at its meeting on January 8, 2008. Relevant drafts incorporating the comments by the TC-EDC would subsequently be presented to the TC, the CAJ, the Consultative Committee and the Council in April 2008."
- 18. In accordance with the recommendations of the Consultative Committee, Circular E-606 was issued, inviting comments on document BMT Guidelines (proj.9) to be sent to the Office of the Union.
- 19. The Office of the Union received comments from China, Ukraine and the United States of America on document BMT Guidelines (proj.9). Those comments were incorporated in document BMT Guidelines (proj.10), which was considered by the TC-EDC, at its meeting on January 8, 2008. The TC-EDC noted a number of the comments received concerned technical

aspects of the BMT Guidelines and concluded that those were matters which would need to be addressed by the TC in conjunction with the BMT, as considered appropriate.

20. An oral report of the conclusions of the TC at its forty-fourth session will be made at the fifty-seventh session of the CAJ.

21. The CAJ is invited to consider document BMT Guidelines (proj.11), in conjunction with an oral report on the conclusions of the TC (see paragraphs 19 and 20).

AD HOC CROP SUBGROUPS ON MOLECULAR TECHNIQUES (CROP SUBGROUPS)

- 22. Since the fifty-sixth session of the CAJ, the Crop Subgroup for Maize held its second session in Chicago, United States of America, on December 3, 2007. All documents considered at that session can be found on the UPOV website at http://www.upov.int/restrict/en/bmt_cropsubgroups/maize.htm). With regard to proposals to the TWA and the BMT, the Crop Subgroup for Maize concluded as follows¹ concerning the possible use of molecular techniques in the examination of distinctness, uniformity and stability:
 - the Crop Subgroup for Maize agreed to propose that the TWA, the TC and the CAJ discuss the acceptability of the approach presented in documents BMT/10/14 and BMT-TWA/2/11, and suggested that the approach might be put forward for consideration at the BMT Review Group as a potential option for the use of molecular markers in DUS examination. It noted that a possible timetable for that process could be for the TWA, TC and CAJ to consider the proposal at their respective sessions in 2008, with a view to convening a possible meeting of the BMT Review Group in April 2009.
- 23. The Crop Subgroup for Maize agreed that its next session could take place in Autumn/Winter 2009, tentatively in conjunction with the maize and sorghum breeders' meeting in the United States of America. It anticipated that such a timetable would allow for the collection of further substantial data in relation to the approach presented in documents BMT/10/14 and BMT-TWA/2/11 and would also allow a report of the views of the TWA, TC, CAJ and BMT Review Group on that approach.
- 24. The TC will consider the proposal of the Crop Subgroup for Maize at its forty-fourth session, to be held in Geneva from April 7 to 9, 2008, and an oral report on its conclusions will be made to the CAJ at its fifty-seventh session.

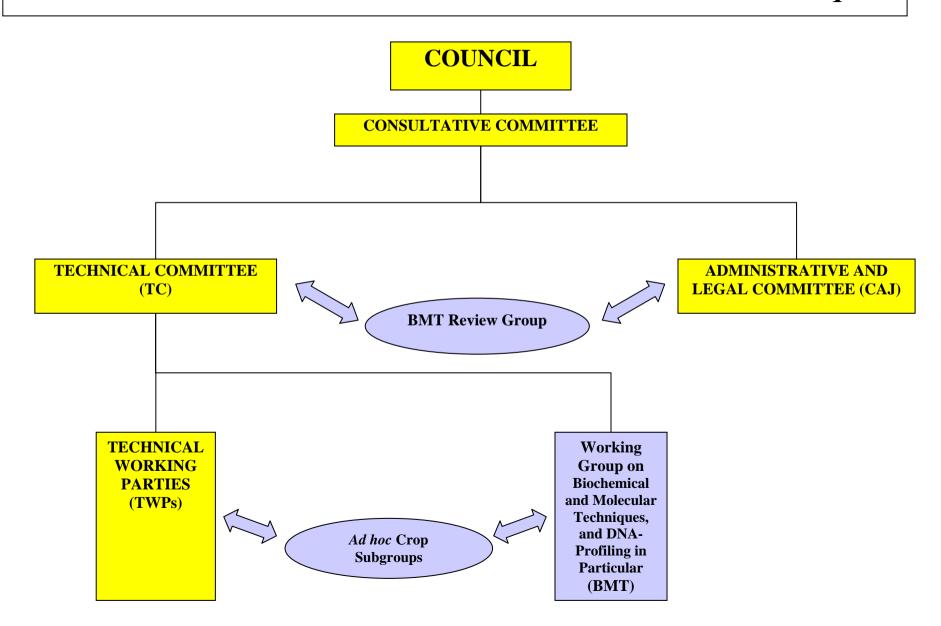
The conclusions presented are an extract from the draft report of the second session of the Crop Subgroup for Maize (document BMT-TWA/Maize/2/12 Prov.). The report of that session (document BMT-TWA/Maize/2/12), once adopted, will be posted on the UPOV website (http://www.upov.int/restrict/en/bmt_cropsubgroups/maize.htm).

CAJ/57/3 page 6

25. The CAJ is invited to consider whether the approach set out in documents BMT/10/14 and BMT-TWA/2/11 (see paragraph 21) be put forward for consideration at the BMT Review Group as a potential option for the use of molecular markers in DUS examination.

[Annex follows]

UPOV Structure: Biochemical and Molecular Techniques



CAJ/57/3 Annex, page 2

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.

CAJ/57/3 Annex, page 3

TERMS OF REFERENCE OF *AD HOC* SUBGROUP OF TECHNICAL AND LEGAL EXPERTS ON BIOCHEMICAL AND MOLECULAR TECHNIQUES ("BMT REVIEW GROUP")

(as agreed by the Administrative and Legal Committee at its forty-third session, held on April 5, 2001 (see document CAJ/43/8, paragraph 58))

- 1. The BMT Review Group should assess possible application models proposed by the Technical Committee, on the basis of the work of the BMT and crop subgroups, for the utilization of biochemical and molecular techniques in the examination of Distinctness, Uniformity and Stability in relation to the following:
 - (a) conformity with the UPOV Convention, and
- (b) potential impact on the strength of protection compared to that provided by current examination methods and advise if this could undermine the effectiveness of protection offered under the UPOV system.
- 2. In conducting its assessment, the BMT Review Group may refer specific aspects to the Administrative and Legal Committee or the Technical Committee for clarification or further information as considered appropriate.
- 3. The BMT Review Group will report its assessment, as set out in paragraph 1 above, to the Administrative and Legal Committee, but this assessment will not be binding for the position of the Administrative and Legal Committee.

CAJ/57/3 Annex, page 4

AD HOC CROP SUBGROUPS ON MOLECULAR TECHNIQUES (CROP SUBGROUPS)

At its thirty-sixth session, held in Geneva, from April 3 to 5, 2000 the Technical Committee agreed to the creation of the *Ad hoc* Crop Subgroups proposed by the BMT at its sixth session, held in Angers, France from March 1 to 3, 2000 (see document TC/36/11, paragraph 123).

Extract from document TC/36/3 Add.

- "23. [At its sixth session, held in Angers, France from March 1 to 3, 2000] The BMT agreed that real progress could not be expected without intensive discussion in small groups on specific species. It therefore decided to propose establishing *ad hoc* crop subgroups during the eighteen month interval until the next session to make real progress in discussions on possibilities and consequences of the introduction of molecular techniques in DUS testing, the management of reference collection and the judgement of essential derivation.
- "24. The BMT discussed the role of *ad hoc* crop subgroups and its relationship with the Technical Working Parties. It agreed that testing experts in the Technical Working Party should be involved with the discussion in the *ad hoc* crop subgroups. It also agreed that the chairmen of the *ad hoc* crop subgroups should be chosen from experts in the Technical Working Party in question. The role of the *ad hoc* crop subgroups would not be to make any decisions, but to prepare documents that could be a basis of further discussions in the BMT, the Technical Working Parties and the Technical Committee. The BMT confirmed that the Technical Working Parties should be the decision-making bodies for the introduction of new characteristics into DUS testing for each species.

[...]

"26. The BMT discussed the selection of species for the subgroups. A majority of experts supported two criteria, (i) the need for the introduction of molecular techniques in DUS testing (species for which a limited number of characteristics are available and species which urgently need effective methods for the management of reference collection) and (ii) the availability of DNA profiling data and on-going studies."

At its forty-third session, held in Geneva, from March 26 to 28, 2007, the Technical Committee agreed to invite the Crop Subgroups to develop proposals concerning the possible use of molecular tools for variety identification in relation to the enforcement of plant breeders' rights, technical verification and the consideration of essential derivation.

The list of Crop Subgroups established by the Technical Committee (TC) is as follows:

Crop Subgroup for:	\underline{TWP}	TC Session which established
Maize	TWA	thirty-sixth session (2000)
Oilseed Rape	TWA	thirty-sixth session (2000)
Potato	TWA	thirty-eighth session (2002)
Rose	TWO	thirty-sixth session (2000)
Ryegrass	TWA	forty-second session (2006)
Soybean	TWA	thirty-eighth session (2002)
Sugarcane	TWA	thirty-eighth session (2002)
Tomato	TWV	thirty-sixth session (2000)
Wheat and Barley	TWA	thirty-sixth session (2000) / forty-second session (2006)

[End of Annex and of document]