



CAJ/59/4

ORIGINAL: English

DATE: February 5, 2009

INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS
GENEVA

ADMINISTRATIVE AND LEGAL COMMITTEE

Fifty-Ninth Session
Geneva, April 2, 2009

MOLECULAR TECHNIQUES

Document prepared by the Office of the Union

1. The purpose of this document is to report on developments concerning the:
 - (a) UPOV Guidelines for DNA-profiling: molecular marker selection and database construction (BMT Guidelines);
 - (b) proposals for the utilization of biochemical and molecular techniques in the examination of Distinctness, Uniformity and Stability to be considered by the *Ad hoc* Subgroup of Technical and Legal Experts of Biochemical and Molecular Techniques (BMT Review Group); and
 - (c) revision of documents TC/38/14-CAJ/45/5 and TC/38/14 Add.-CAJ/45/5 Add.
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 Annex I to this document.
3. The following abbreviations are used in this document:

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
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:	<i>Ad Hoc</i> Subgroup of Technical and Legal Experts on Biochemical and Molecular Techniques
Crop Subgroup:	<i>Ad Hoc</i> Crop Subgroup on Molecular Techniques

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

4. 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).

5. 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.

6. 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.”

7. 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.

8. 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.

9. At its forty-fourth session, held in Geneva from April 7 to 9, 2008, the TC noted the comments from China, Ukraine and the United States of America incorporated in document BMT Guidelines (proj.11). It noted that a number of the comments concerned technical aspects of the BMT Guidelines and concluded that, in the first instance, those were matters which would need to be addressed by the BMT. The TC agreed that the BMT should be invited to consider those matters in the form of a new draft of the BMT Guidelines at its eleventh session, to be held in Madrid, from September 16 to 18, 2008.

10. The TC noted the request of the Consultative Committee that 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.11). The TC noted that documents TC/38/14-CAJ/45/5 and TC/38/14 Add.-CAJ/45/5 Add. would need to be reviewed in conjunction with discussions on the approach presented in documents BMT/10/14 and BMT-TWA/2/11, as explained in document TC/44/7, paragraph 30. On that basis, it agreed that it would be appropriate to submit a revised version of documents TC/38/14-CAJ/45/5 and TC/38/14 Add.-CAJ/45/5 Add. to the Council in conjunction with the BMT Guidelines.

11. At its eleventh session, held in Madrid, from September 16 to 18, 2008, the BMT considered document BMT Guidelines (proj.12), and made its recommendations. Those recommendations were incorporated in document BMT Guidelines (proj.13), which was considered by the TC-EDC at its meeting on January 8, 2009.

12. The TC-EDC made no proposals to amend document BMT Guidelines (proj.13), as agreed by the BMT at its eleventh session. With regard to the status of documents TC/38/14-CAJ/45/5 and TC/38/14 Add.-CAJ/45/5 Add., the TC-EDC agreed that a solution would be to delete the second paragraph of Section A. "Introduction" on the basis that documents TC/38/14-CAJ/45/5 and TC/38/14Add. CAJ/45/5Add. were planned to be revised. However, in its discussion on document TGP/12/1 Draft 6 (see documents TC/45/5 and CAJ/59/2, paragraph 9), the TC-EDC also noted a question as to whether that documents TC/38/14-CAJ/45/5 and TC/38/14 Add.-CAJ/45/5 Add. might be considered to be approved by the Council when it "noted the work of the Technical Committee, the Technical Working Parties and the Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular, as given in document C/36/10 ["Progress report of the work of the Technical Committee, the Technical Working Parties and the Working Group on Biochemical and Molecular Techniques and DNA-Profiling in Particular"]" (see document C/36/13 "Report", paragraph 21). The TC-EDC agreed that it would be a matter for the Consultative Committee to consider that question.

13. The highlighted text in document BMT Guidelines (proj.14), to be considered by the TC, indicates text that has been amended with respect to the text presented to the Council at its forty first ordinary session, held in Geneva on October 25, 2007 (document BMT Guidelines (proj.9)).

14. A new draft of the BMT Guidelines (BMT Guidelines (proj.15)), to be prepared on the basis of the conclusions of the TC at its forty-fifth session, will be presented for consideration by the CAJ at its sixtieth session, to be held in Geneva on October 19 and 20, 2009. On the basis of the conclusions of the TC and CAJ at their sessions in 2009, a draft of the BMT Guidelines will be prepared for approval by the TC and CAJ in March 2010, in anticipation of adoption of the BMT Guidelines by the Council in 2010. That timetable also anticipates the submission of a revised version of documents TC/38/14-CAJ/45/5 and TC/38/14 Add.-CAJ/45/5 Add. to the Council for adoption in conjunction with the BMT Guidelines (see paragraph 10 above).

15. The CAJ is invited to consider the timetable for the approval and adoption of the BMT Guidelines, as set out in paragraph 14.

PROPOSALS FOR THE UTILIZATION OF BIOCHEMICAL AND MOLECULAR TECHNIQUES IN THE EXAMINATION OF DUS TO BE CONSIDERED BY THE BMT REVIEW GROUP

16. At its forty-fourth session, the TC agreed to propose to the CAJ that the approach presented in documents BMT/10/14 and BMT-TWA/Maize/2/11 “Possible use of molecular techniques in DUS testing on maize: how to integrate a new tool to serve the effectiveness of protection offered under the UPOV system”, prepared by experts from France, be put forward for consideration at the BMT Review Group as a potential option for the use of molecular markers in DUS examination (see document TC/44/13 “Report”, paragraph 152(c)).

17. At its fifty-seventh session, held in Geneva on April 10, 2008, the CAJ agreed with the proposal of the TC, that the approach presented in documents BMT/10/14 and BMT-TWA/Maize/2/11 should be put forward for consideration at the BMT Review Group as a potential option for the use of molecular markers in DUS examination.

18. The TWA at its thirty-seventh session, held in Nelspruit, South Africa, from July 14 to 18, 2008, agreed that the proposed approach for the use of molecular techniques in DUS testing of maize, based on document BMT-TWA/Maize/2/11, should be put forward for consideration by the BMT Review Group. It agreed that the principles underlying GAIA, including in particular the weighting of differences, and the use of a reliable number of markers for establishing molecular distance, should be explained in that proposal.

19. A meeting of the BMT Review Group has been organized for April 1, 2009. The composition of the BMT Review Group is provided in Annex II to this document.

20. The assessment of the BMT Review Group will be presented for consideration by the CAJ at its sixtieth session, to be held in Geneva on October 19 and 20, 2009, and by the TC at its forty-sixth session, in 2010. In the meantime, an oral report of the BMT Review Group meeting will be made at the fifty-ninth session of the CAJ, to be held in Geneva on April 2, 2009, the report of the BMT Review Group will be posted on the first-restricted area of the UPOV website and a report on the conclusions will be made to the Technical Working Parties at their sessions in 2009.

21. *The CAJ is invited to approve the program for consideration of the approach presented in documents BMT/10/14 and BMT-TWA/Maize/2/11 “Possible use of molecular techniques in DUS testing on maize: how to integrate a new tool to serve the effectiveness of protection offered under the UPOV system”, as set out in paragraph 20.*

REVISION OF DOCUMENTS TC/38/14-CAJ/45/5 AND TC/38/14 ADD.-CAJ/45/5 ADD.

22. As noted in paragraph 10 above, at its forty-fourth session, the TC noted that documents TC/38/14-CAJ/45/5 and TC/38/14 Add.-CAJ/45/5 Add. would need to be reviewed in conjunction with discussions on the approach presented in documents BMT/10/14 and BMT-TWA/2/11, as explained in document TC/44/7, paragraph 30 (see document TC/44/13 “Report”, paragraph 150). On that basis, it agreed that it would be appropriate to submit a revised version of documents TC/38/14-CAJ/45/5 and TC/38/14 Add.-CAJ/45/5 Add. to the Council in conjunction with the BMT Guidelines.

23. With regard to the revision of documents TC/38/14-CAJ/45/5 and TC/38/14 Add.-CAJ/45/5 Add., it is recalled that the TC, at its forty-second session, held in Geneva, from April 3 to 5, 2006, “reaffirmed its support for the presentation of the situation, set out in documents TC/38/14-CAJ/45/5 and TC/38/14 Add.-CAJ/45/5 Add., which presented the proposals developed in the *Ad hoc* Crop Subgroups, the recommendations of the BMT Review Group concerning those proposals and the opinion of the TC and the CAJ regarding the recommendations of the BMT Review Group. [...]”. Therefore, it is not anticipated that major changes should be envisaged to the structure and form of the information provided in documents TC/38/14-CAJ/45/5 and TC/38/14 Add.-CAJ/45/5 Add. However, to assist the Office of the Union in the preparation of the revision of documents TC/38/14-CAJ/45/5 and TC/38/14 Add.-CAJ/45/5 Add., with the aim of developing a document for adoption by the Council, consideration of the following proposals and notes would be of assistance:

(a) to consolidate document TC/38/14-CAJ/45/5, paragraphs 9 and 10 and the Annex, and document TC/38/14 Add.-CAJ/45/5 Add., paragraphs 3 to 7, into a single document;

(b) to consider whether the consolidated document for adoption by the Council should present only those proposals (currently Proposals 1 to 4) that have received a positive endorsement by the BMT Review Group, the TC and the CAJ. With regard to the proposals put forward under Option 3 (Proposals 5 and 6), it could be explained that “Proposals under Option 3 were also put forward to the BMT Review Group in 2002. However, for the proposals under Option 3, there was no consensus in the BMT Review Group on the acceptability of those 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, 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.”;

(c) subject to a positive assessment by the BMT Review Group of the approach presented in documents BMT/10/14 and BMT-TWA/Maize/2/11 and endorsement by the TC and CAJ, to add a section concerning the approach presented in documents BMT/10/14 and BMT-TWA/Maize/2/11; and

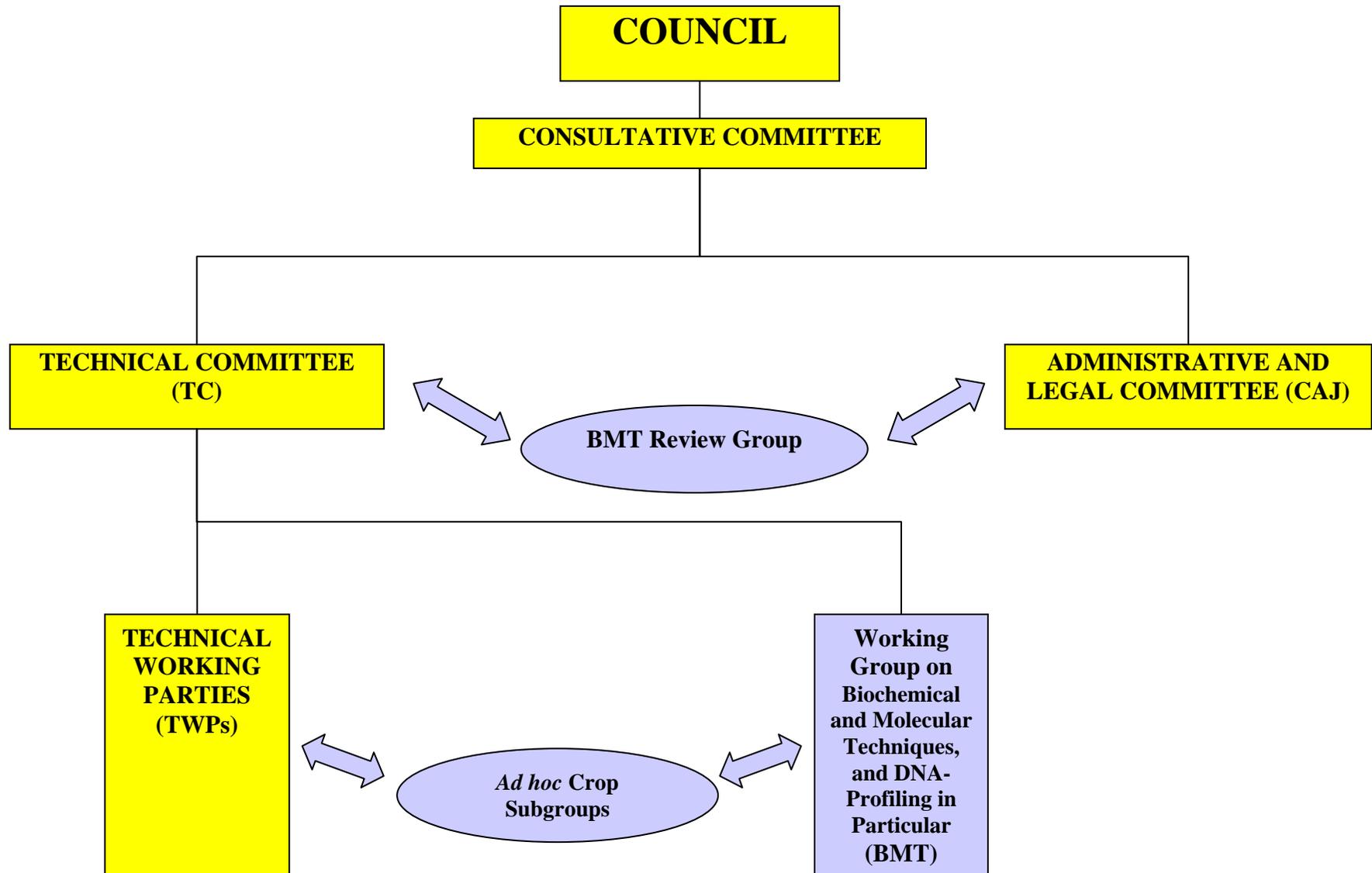
(d) the BMT, at its eleventh session, noted that an approach under Option 1(a) was conditional on the assumptions set out in document TC/38/14-CAJ/45/5 being met. The BMT noted that it would be a matter for the relevant authority to consider if those assumptions had been met (see document BMT/11/29 “Report”, paragraph 93). Guidance is sought on whether it is appropriate and sufficiently clear that it would be a matter for the relevant authority to consider if the relevant assumptions set out documents TC/38/14-CAJ/45/5 and TC/38/14 Add.-CAJ/45/5 Add. had been met.

24. Subject to a positive assessment by the BMT Review Group of the approach presented in documents BMT/10/14 and BMT-TWA/Maize/2/11 and an endorsement by the CAJ at its sixtieth session, it is proposed that a first draft of the revised version of documents TC/38/14-CAJ/45/5 and TC/38/14 Add.-CAJ/45/5 Add. would be prepared for consideration by the TC at its forty-sixth session and by the CAJ at its sixty-first session, both in March 2010. On that basis, a document could be presented for adoption by the Council in 2010, in conjunction with the BMT Guidelines (see paragraph 14).

25. The CAJ is invited to consider the proposals and timetable for the revision of documents TC/38/14-CAJ/45/5 and TC/38/14 Add.-CAJ/45/5 Add., as set out in paragraphs 23 and 24.

[Annex I follows]

UPOV Structure: Biochemical and Molecular Techniques



**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.

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.

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:

<u>Crop Subgroup for:</u>	<u>TWP</u>	<u>TC Session which established</u>
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)

[Annex II follows]

ANNEX II

BMT REVIEW GROUP

- Chairman: Mr. Rolf Jördens (Office)
- Members: Ms. Carmen Gianni (AR and Chair of the CAJ)
Mr. Doug Waterhouse (AU and President of the Council)
Mr. Bart Kiewiet / Mr. Carlos Godinho (European Community)
Mr. Michael Köller (DE)
Ms. Nicole Bustin (FR)
Mr. Joël Guiard (FR)
Herr Yasuhiro Kawai (JP)
Mr. Henk Bonthuis (NL) (ex-Chairman of the BMT)
Mr. Chris Barnaby (NZ) (Chairman of the TC)
Mr. Michael Camlin (GB)
Mr. Andy Mitchell (GB and Chairman of the BMT)
Mrs. Beate Rücker (DE) (Chairperson of the *Ad Hoc* Crop Subgroup on
Molecular Techniques for Maize)
- Observers: International Community of Breeders of Asexually Reproduced Ornamental
and Fruit-Tree Varieties (CIOPORA)
International Seed Federation (ISF)
- Office: Mr. Peter Button
Mr. Raimundo Lavignolle
Mr. Makoto Tabata
Mrs. Yolanda Huerta

[End of Annex II and of document]