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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) revision of documents TC/38/14-CAJ/45/5 “*Ad Hoc* Subgroup of Technical and Legal Experts on Biochemical and Molecular Techniques (‘The BMT Review Group’)” and TC/38/14 Add.-CAJ/45/5 Add “Recommendations of the BMT Review Group and Opinion of the Technical Committee and the Administrative and Legal Committee Concerning Molecular Techniques”;
 - (c) international guidelines on molecular methodologies;
 - (d) *Ad Hoc* Crop Subgroups on Molecular Techniques (Crop Subgroups); and
 - (e) Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular (BMT).
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.

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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. The UPOV Guidelines for DNA-profiling: molecular marker selection and database construction (BMT Guidelines) were adopted by the Council, at its forty-fourth ordinary session, held in Geneva on October 21, 2010. The BMT Guidelines are presented as document UPOV/INF/17/1 (see http://www.upov.int/export/sites/upov/en/publications/pdf/upov_inf_17_1.pdf).

5. It is recalled that the purpose of the BMT Guidelines is “to provide guidance for developing harmonized methodologies with the aim of generating high quality molecular data for a range of applications. The BMT Guidelines are also intended to address the construction of databases containing molecular profiles of plant varieties, possibly produced in different laboratories using different technologies. In addition, the aim is to set high demands on the quality of the markers and on the desire for generating reproducible data using these markers in situations where equipment and/or reaction chemicals might change. Specific precautions need to be taken to ensure quality entry into a database” (see document UPOV/INF/17/1, “Introduction”).

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

Background to the revision of documents TC/38/14-CAJ/45/5 and TC/38/14 Add.-CAJ/45/5 Add.

6. Documents TC/38/14-CAJ/45/5 “*Ad Hoc* Subgroup of Technical and Legal Experts on Biochemical and Molecular Techniques (‘The BMT Review Group’)” and TC/38/14 Add.-CAJ/45/5 Add “Recommendations of the BMT Review Group and Opinion of the Technical Committee and the Administrative and Legal Committee Concerning Molecular Techniques”, summarize the consideration of possible application models proposed by the TC, 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.

7. 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. One of the recommendations of the Consultative Committee was 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.9)” .

8. With regard to the status of documents TC/38/14-CAJ/45/5 and TC/38/14 Add.-CAJ/45/5 Add., the Consultative Committee, at its seventy-eighth session, held in Geneva on October 22, 2009, agreed that, unless otherwise agreed by the Council, documents which set out UPOV policies or guidance, once approved by the relevant UPOV Committees, as appropriate, must be adopted by the Council. In cases where a rapid presentation of a UPOV policy or guidance is required, such that adoption could not be achieved by presentation of a document to the Council, approval would be sought by correspondence from the representatives to the Council of the members of the Union (see document C/43/16 “Report”, paragraph 14(i)).

9. At its forty-fourth session, held in Geneva from April 7 to 9, 2008, 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. 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 “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” (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.

10. At its forty-fifth session, held in Geneva from March 30 to April 1, 2009, the TC recalled that, at its forty-second session, held in Geneva, from April 3 to 5, 2006, it had “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 did not consider that it would be appropriate to make major changes 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, the TC agreed:

(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) 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

(c) to emphasize the importance of the assumptions to be met in each of the options and proposals and to clarify that it is a matter for the relevant authority to consider if the relevant assumptions set out in documents TC/38/14-CAJ/45/5 and TC/38/14 Add.-CAJ/45/5 Add. are met.

11. The TC, at its forty-seventh session, held in Geneva from April 4 to 7, 2011, agreed that document BMT/DUS Draft 5, as amended at that session and subject to agreement by the CAJ at its sixty-third session, to be held in Geneva on April 7, 2011, should be the basis for adoption of document BMT/DUS by the Council at its forty-fifth ordinary session, to be held in Geneva on October 20, 2011 (see document TC/47/26 “Report on the Conclusions”, paragraphs 14 and 15).

12. The CAJ, at its sixty-third session, agreed that document BMT/DUS Draft 5, as amended in accordance with the proposals of the TC at its forty-seventh session, should be the basis for adoption of document BMT/DUS by the Council at its forty-fifth ordinary session, to be held in Geneva on October 20, 2011 (see document CAJ/63/9 “Report on the Conclusions”, paragraphs 26 and 27).

Possible development of document TGP/15

13. The BMT, at its twelfth session of the BMT, held in Ottawa, Canada, from May 11 to 13, 2010, agreed that document TGP/15 should be developed separately, but in parallel, to document BMT/DUS. The content of document BMT/DUS would be similar to BMT/DUS Draft 5, i.e. it would explain the development and consideration of all models within UPOV. However, document TGP/15 would contain only models that had received a positive assessment and for which accepted examples could be provided, i.e. Models “Characteristic-specific molecular markers” (Section 3.1.1) and “Combining phenotypic [characteristics] and molecular distances in the management of variety collections” (Section 3.1.2) for the time being.

14. The TWA, TWV, TWO and TWF, at their respective sessions in 2010, agreed that document TGP/15 should be developed separately, but in parallel, to document BMT/DUS on the basis that document BMT/DUS would provide a report on the development and consideration of all models within UPOV and that document TGP/15 would provide guidance for the use of those models that had received a positive assessment and for which accepted examples could be provided, i.e. Models “Characteristic-specific molecular markers” (Section 3.1.1) and “Combining phenotypic [characteristics] and molecular distances in the management of variety collections” (Section 3.1.2) for the time being. The TWA and TWV agreed that the purpose of both documents should be clarified within the documents and noted that both documents would need to be adopted by the Council. The TWA and TWV agreed that consideration should be given to how to maintain both documents in an efficient way.

15. The TC at its forty-seventh session held in Geneva from April 4 to 7, 2011, and the CAJ, at its sixty-third session held in Geneva on April 7, 2011, agreed that document TGP/15 should be developed separately, but in parallel, to document BMT/DUS on the basis that document BMT/DUS would provide a report on the development and consideration of all models within UPOV and that document TGP/15 would provide guidance for the use of those models that had received a positive assessment and for which accepted examples could be provided, i.e. Models “Characteristic-specific molecular markers” (Section 3.1.1) and “Combining phenotypic [characteristics] and molecular distances in the management of variety collections” (Section 3.1.2) for the time being. It agreed that the purpose of both documents should be clarified within the documents and noted that both documents would need to be adopted by the Council. The TC and CAJ also agreed that consideration should be given to how to maintain both documents in an efficient way (see document TC/47/26 “Report on the Conclusions”, paragraph 16).

16. Subject to the adoption of document BMT/DUS by the Council at its forty-fifth ordinary session, to be held in Geneva on October 20, 2011, a first draft of document TGP/15 will be prepared for consideration by the Enlarged Editorial Committee (TC-EDC) at its meeting on January 11 and 12, 2012.

INTERNATIONAL GUIDELINES ON MOLECULAR METHODOLOGIES

17. At its tenth session, held in Seoul, Republic of Korea, from November 21 to 23, 2006, the BMT discussed the BMT Guidelines. In relation to Section B: 5.2 “Quality criteria”, the BMT was informed that the International Organization for Standardization (ISO) and the Codex Alimentarius Commission were developing guidelines. The BMT agreed that it would

be useful to invite relevant experts to make a presentation on those guidelines at the eleventh session of the BMT.

18. At its eleventh session, held in Madrid, from September 16 to 18, 2008, the BMT received a presentation by ISO, based on document BMT/11/25 and a presentation by Ms. Selma Doyran, Senior Food Standard Officer, Food and Agriculture Organization of the United Nations (FAO), based on document BMT/11/26.

19. At its twelfth session, held in Ottawa, Canada, from May 11 to 13, 2010, the BMT received a presentation by Ms. Cheryl Dollard (International Seed Testing Association (ISTA)), based on document BMT/12/16 “Development of an International Seed Testing Association (ISTA) DNA- Based Approach for Testing Variety Identity”, a copy of which is provided in document BMT/12/16 Add. (see document BMT/12/24 “Report”, paragraphs 60 to 62).

20. Also at its twelfth session, the BMT received a presentation by Mr. Michael Sussman (Chairman of the Subcommittee ISO/TC 34/SC 16 (molecular biomarker analysis)), based on document BMT/12/20 “Horizontal Biomarker Analysis — ISO/TC 34/SC 16”, a copy of which is provided in document BMT/12/20 Add. (see document BMT/12/24 “Report”, paragraphs 63 and 64). Mr. Sussman explained that ISO collaborated with other standard setting organizations; for example, ISO had provided methods to the Codex Alimentarius Commission and had sought to avoid overlap with ISTA work on seed.

21. The TC at its forty-seventh session held in Geneva from April 4 to 7, 2011, noted the information on international guidelines on molecular methodologies presented to the BMT at its twelfth session, as set out in paragraphs 19 and 20 of this document.

AD HOC CROP SUBGROUPS ON MOLECULAR TECHNIQUES (CROP SUBGROUPS)

22. The TC, at its forty-sixth session, held in Geneva from March 22 to 24, 2010, agreed the following plans for meetings of Crop Subgroups (TC/46/16 “Report”, paragraph 137):

“Crop Subgroup for Maize: no subgroup meeting planned. The TC noted that the Office of the Union had contacted the American Seed Trade Association (ASTA) to see if it would be interested in receiving a report on the outcome of the consideration within UPOV on 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” at the meeting of the maize and sorghum breeders’ meeting in the United States of America in 2010;

“Crop Subgroup for Oilseed Rape: no subgroup meeting planned;

“Crop Subgroup for Potato: no subgroup meeting planned. To consider a future meeting according to developments in on-going projects reported at the eleventh session of the BMT;

“Crop Subgroup for Soybean: to consider a meeting to include a report on the work of Argentina and Brazil in the context of a possible Option 2 approach in due course; and

“Crop Subgroup for Wheat and Barley: no subgroup meeting planned. Any on-going work, such as the work in France on barley in the context of a similar approach to that presented for maize in document BMT/10/14, would be reported at the twelfth session of the BMT.”

23. There have been no meetings of the Crop Subgroups since the forty-sixth session of the TC.

24. At its twelfth session, the BMT did not make any recommendation on the establishment of new crop specific subgroups (see document BMT/12/24 “Report”, paragraph 67). It noted that Mr. Joost Barendrecht, Chairman of the Crop Subgroup for Rose, had retired. It was agreed that it would not be necessary to appoint a new chairman unless meetings of the Crop Subgroup for Rose were planned (see document BMT/12/24 “Report”, paragraph 28).

25. The TC, at its forty-seventh session held in Geneva from April 4 to 7, 2011, noted that there had been no meetings of the Crop Subgroups since its forty-sixth session and noted that Mr. Joost Barendrecht, Chairman of the Crop Subgroup for Rose had retired and that it would be necessary to appoint a new chairman of the Crop Subgroup for Rose if a meeting was planned (see document TC/47/26 “Report on the Conclusions”, paragraph 18).

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

26. It is recalled that, 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 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 (the “Breeders’ Day”).

27. The twelfth session of the BMT was held in Ottawa, Canada, from May 11 to 13, 2010, with the preparatory workshop on May 10, 2010. The specific day for the agenda items “The use of molecular techniques in the consideration of essential derivation” and “The use of molecular techniques in variety identification” (the “Breeders’ Day”) was May 11, 2010.

28. In response to the invitation received from Brazil, the BMT agreed to hold its thirteenth session in Brasilia, Brazil, from November 22 to 24, 2011, with the preparatory workshop to be held on November 21, 2011. During its thirteenth session, 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. Reports on the work of the Ad Hoc Crop Subgroups on molecular techniques (Crop Subgroups)

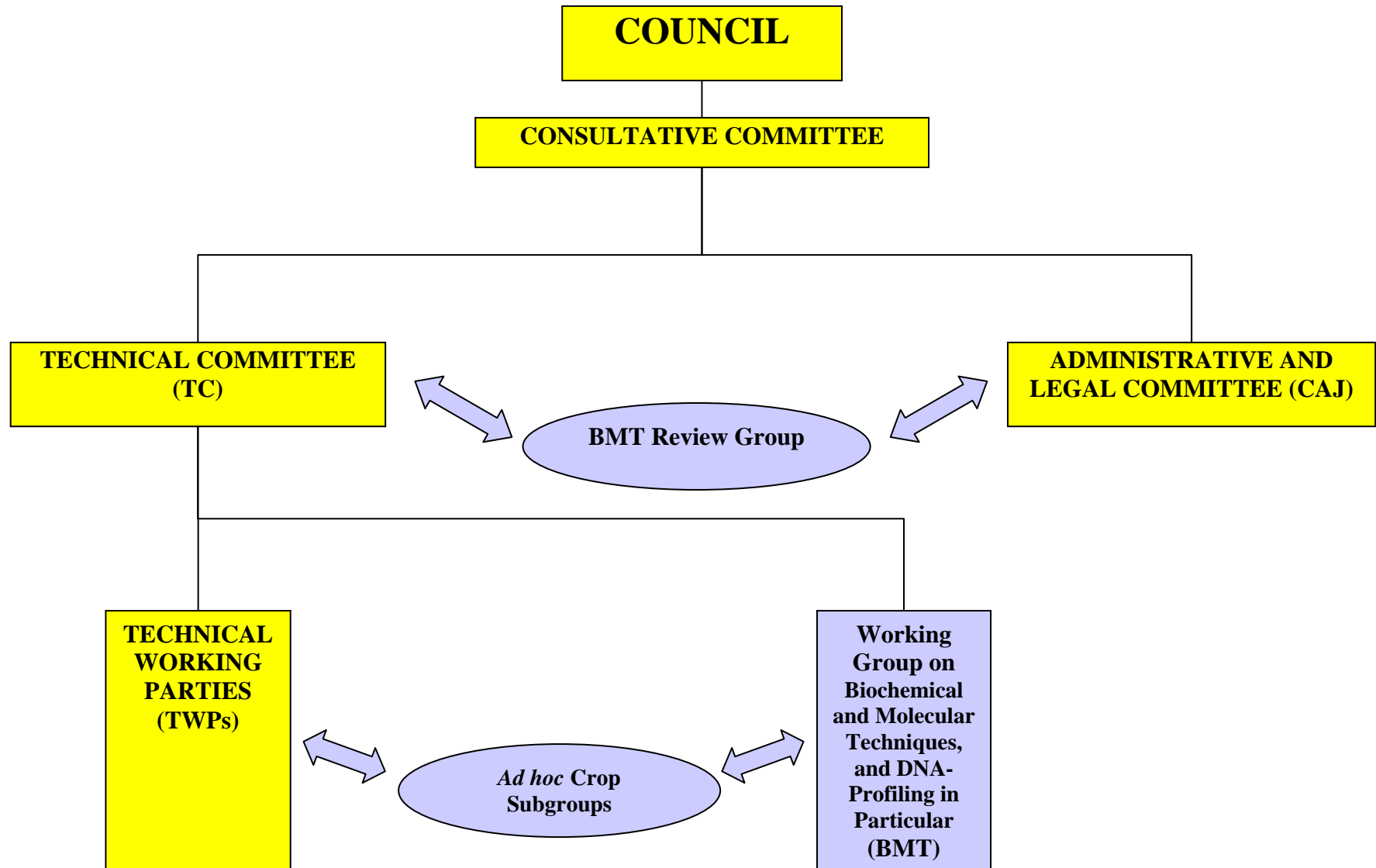
5. Short presentations on new developments in biochemical and molecular techniques by DUS experts, biochemical and molecular specialists, plant breeders and relevant international organizations
6. Report of work on molecular techniques on a crop-by-crop basis:
 - (a) vegetatively propagated crops
 - (b) self-pollinated crops
 - (c) cross-pollinated crops
7. International guidelines on molecular methodologies
8. Variety Description databases
9. Methods for analysis of molecular data
10. The use of molecular techniques in examining essential derivation
11. The use of molecular techniques in variety identification
12. Recommendations on the establishment of new crop specific subgroups
13. Date and place of next session
14. Future program
15. Report of the session (if time permits)
16. Closing of the session

29. The BMT agreed that, in order to encourage the presentation of information in relation to the use of molecular techniques in examining essential derivation and in variety identification, it would be appropriate to dedicate a specific day to items 10 and 11 at the thirteenth session of the BMT. In particular, breeders and other experts would be offered the possibility to attend for that specific day, which would be November 22, 2011.

30. The TC approved the program for the thirteenth session of the BMT, to be held in Brasilia, Brazil, from November 22 to 24, 2011, with the preparatory workshop to be held on November 21, 2011, as set out in paragraphs 28 and 29 of this document. The TC agreed that, in order to encourage the presentation of information in relation to the use of molecular techniques in examining essential derivation and in variety identification, it would be appropriate to dedicate a specific day to those items at the thirteenth session of the BMT. The TC noted that breeders and other experts would be offered the possibility to attend for that specific day, which would be on November 22, 2011.

[Annex 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>Chairperson</u>	<u>TC Session which established</u>
Maize	TWA	Mrs. Beate Rücker (Germany)	thirty-sixth session (2000)
Oilseed Rape	TWA	Mrs. Laetitia Denecheau (France)	thirty-sixth session (2000)
Potato	TWA	Mrs. Beate Rücker (Germany)	thirty-eighth session (2002)
Rose	TWO	Mr. Joost Barendrecht (Netherlands)	thirty-sixth session (2000)
Ryegrass	TWA	Mr. Michael Camlin (United Kingdom)	forty-second session (2006)
Soybean	TWA	Mr. Marcelo Labarta (Argentina)	thirty-eighth session (2002)
Sugarcane	TWA	Mr. Luis Salaices (Spain)	thirty-eighth session (2002)
Tomato	TWV	Mr. Richard Brand (France)	thirty-sixth session (2000)
Wheat and Barley	TWA	Mr. Michael Camlin (United Kingdom)	thirty-sixth session (2000) / forty-second session (2006)

[End of Annex and of document]