

TC/47/7

ORIGINAL: English

DATE: March 7, 2011

INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS GENEVA

TECHNICAL COMMITTEE

Forty-Seventh Session Geneva, April 4 to 6, 2011

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.

		P**8* =			
UPOV GUIDELINES FOR DNA-PROFILING: MOLECULAR MARKER SELECTION AND DATABASE CONSTRUCTION (BMT GUIDELINES)					
REVISION OF DOCUMENTS TC/38/14-CAJ/45/5 AND TC/38/14 ADDCAJ/45/5 ADD.					
Ва	ckground to the revi	sion of documents TC/38/14-CAJ/45/5 and TC/38/14 AddCAJ/45/5 Add.	4		
	Comments by the B Background to the p Consideration of do Consideration of do	oraration of document BMT/DUS MT and the TWPs on document BMT/DUS Draft 3 oreparation of document BMT/DUS Draft 5 cument BMT/DUS Draft 5 by the Technical Committee cument BMT/DUS Draft 5 by the Administrative and Legal Committee (CAJ) on of Document BMT/DUS	6 8 10 10		
Po	ssible development o	of document TGP/15	10		
INTE	ERNATIONAL GU	IDELINES ON MOLECULAR METHODOLOGIES	11		
AD H	IOC CROP SUBGI	ROUPS ON MOLECULAR TECHNIQUES (CROP SUBGROUPS)	11		
	RKING GROUP ON FILING IN PARTI	N BIOCHEMICAL AND MOLECULAR TECHNIQUES, AND DNA- CULAR (BMT)	13		
ANN	EX I UPOV S	STRUCTURE: BIOCHEMICAL AND MOLECULAR TECHNIQUES			
3.	The following a	bbreviations 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 Prog	grams		
	TWF:	Technical Working Party for Fruit Crops			
	TWO:	Technical Working Party for Ornamental Plants and Forest T	rees		
	TWV:	Technical Working Party for Vegetables			

Technical Working Party(ies)

DNA-Profiling in Particular

and Molecular Techniques

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

Ad Hoc Crop Subgroup on Molecular Techniques

Working Group on Biochemical and Molecular Techniques, and

TWP(s):

Crop Subgroup:

BMT:

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

- 4. UPOV Guidelines for DNA-profiling: molecular marker and database construction (BMT Guidelines) were adopted by the Council, at its forty-fourth ordinary session, held in Geneva on October The 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").
 - 6. The TC is invited to note the adoption of the "UPOV Guidelines for DNA-profiling: molecular marker selection and database construction (BMT Guidelines)", as document UPOV/INF/17/1.

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

- 7. The purpose of this section is to provide background information in relation to document BMT/DUS Draft 5, to be considered by the TC, at its forty-seventh session, to be held in Geneva from April 4 to 6, 2011, and by the Administrative and Legal Committee (CAJ) at its sixty-third session, to be held on April 7, 2011, and in relation to the possible development of document TGP/15, as follows:
- (a) Background to the revision of documents TC/38/14-CAJ/45/5 and TC/38/14 Add.-CAJ/45/5 Add.;
 - (b) Background to document BMT/DUS Draft 5:
 - (i) Comments of the Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular (BMT) and the Technical Working Parties at their sessions in 2010 on document BMT/DUS Draft 3; and
 - (ii) Comments of the Enlarged Editorial Committee (TC-EDC) on document BMT/DUS Draft 4;
 - (iii) Consideration of document BMT/DUS Draft 5 by the TC;

- (iv) Consideration of document BMT/DUS Draft 5 by the CAJ; and
- (v) Proposal for adoption
- (c) Possible development of document TGP/15.

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

- 8. Documents TC/38/14-CAJ/45/5 "Ad Hoc Subgroup of Technical and Legal Experts on Biochemical and Molecular **Techniques** ('The **BMT** Review Group')" 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.
- 9. 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)".
- 10. status of documents TC/38/14-CAJ/45/5 With regard to the 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)).
- 11. 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.
- 12. 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.
- 13. 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, the TC agreed 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. should 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 (see document TC/45/16 "Report", paragraphs 152 and 153). On that basis, the TC noted that a document could be presented for adoption by the Council in 2010, in conjunction with the BMT Guidelines.
- 14. The CAJ, at its sixtieth session, agreed 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. should 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, the CAJ noted that a document could be presented for adoption by the Council in October 2010, in conjunction with the BMT Guidelines (see document CAJ/60/10 "Report on the Conclusions", paragraph 46).
- 15. In accordance with the procedure set out above, the Office of the Union prepared a revised version 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. That document (document BMT/DUS Draft 1 "Possible Use of Biochemical and Molecular Markers in the Examination of Distinctness, Uniformity and Stability (DUS)") was presented to the TC-EDC, at its meeting on January 7, 2010.
- 16. The TC-EDC, at its meeting on January 7, 2010, did not comment on document BMT/DUS Draft 1 in detail, considering that it would be more appropriate for the TC to make a first assessment of that document at its forty-sixth session. On that basis, document BMT/DUS Draft 2, considered by the TC at its forty-sixth session, and by the CAJ at its sixty-first session, contained no changes to the text of document BMT/DUS Draft 1.

However, the TC-EDC recommended that the TC consider whether the document might take on the reference "document TGP/15" (TGP/15 currently has the title "New Types of Characteristics"), subject to an appropriate change of title of document TGP/15.

17. At its forty-sixth session, held in Geneva from March 22 to 24, 2010 (see document TC/46/15 "Report on the Conclusions", paragraphs 43 to 45), the TC agreed the following amendments to document BMT/DUS Draft 2:

Title	to read "Possible Use of Molecular Markers in the Examination of Distinctness, Uniformity and Stability ("DUS")"				
Structure	to differentiate the models into those which received a positive endorsement by the BMT Review Group, CAJ and TC and those where was no consensus on their acceptability. Within the models which received a positive endorsement by the BMT Review Group, CAJ and TC, to consider a further separation of the models for which further work was required.				
Title of models	to seek to develop a short title for each model				

- 18. The TC noted that the CAJ, at its sixtieth session, had agreed that a document could be presented for adoption by the Council in October 2010, in conjunction with the document BMT Guidelines. However, the TC agreed that a new draft of the document BMT/DUS should be prepared by the Office of the Union, in conjunction with the TC Chairman and the BMT Chairman, for consideration by the BMT and the TWPs at their sessions in 2010 and a further draft prepared on the basis of the comments of the BMT, TWPs and CAJ for consideration by the TC at its forty-seventh session.
- 19. The TC agreed that the possibility of document BMT/DUS Draft 2 becoming document TGP/15, with an appropriate change of title for TGP/15, should be considered at a later stage.
- 20. The CAJ, at its sixty-first session, held in Geneva on March 25, 2010 (see document CAJ/61/11 "Report on the Conclusions", paragraphs 60 to 62), noted the conclusions of the TC on document BMT/DUS Draft 2. The CAJ noted that the TC had agreed that a new draft of the document BMT/DUS should be prepared by the Office of the Union, in conjunction with the TC Chairman and the BMT Chairman, for consideration by the BMT and the TWPs at their sessions in 2010 and a further draft prepared on the basis of the comments of the BMT and TWPs for consideration by the TC at its forty-seventh session.

Background to the preparation of document BMT/DUS

Comments by the BMT and the TWPs on document BMT/DUS Draft 3

- 21. The Technical Working Party on Automation and Computer Programs (TWC), at its twenty-eighth session, held in Angers, France, from June 29 to July 2, 2010, made no comments on document BMT/DUS Draft 3.
- 22. The following comments were made on document BMT/DUS Draft 3, as indicated, by:

- (a) the BMT, at its twelfth session, held in Ottawa from May 11 to 13, 2010, considered document BMT/DUS Draft 3 (see document BMT/12/24 "Report", paragraphs 7 and 8);
- (b) the Technical Working Party for Agricultural Crops (TWA), at its thirty-ninth session, held in Osijek, Croatia, from May 24 to 28, 2010 (see document TWA/39/27 "Report", paragraphs 29 to 32);
- (c) the Technical Working Party for Vegetables (TWV), at its forty-fourth session, held in Veliko Tarnovo, Bulgaria, from July 5 to 9, 2010 (see document TWV/44/34 "Report", paragraphs 25 to 27);
- (d) The Technical Working Party for Ornamental Plants and Forest Trees (TWO), at its forty-third session, held in Cuernavaca, Morelos State, Mexico, from September 20 to 24, 2010 (see document TWO/43/29 Rev. "Report", paragraphs 24 to 26); and
- (e) the Technical Working Party for Fruit Crops (TWF), at its forty-first session, held in Cuernavaca, Morelos State, Mexico, from September 27 to October 1, 2010 (see document TWF/41/30 Rev. "Report", paragraph 24).

General	(BMT, agreed by TWA and TWV) to delete all references to the terms "Option" and "Proposal" and to replace with the terms "Model" and "Example"	
	(BMT, agreed by TWA and TWV) to replace all references to "molecular characteristics" with an appropriate term such as "molecular markers".	
	The TWA noted that "molecular markers" were a tool and concluded that the term "molecular markers" might not be an appropriate term to refer to the data or information generated by those markers. It considered that terms such as "molecular data", "molecular marker data" and "molecular polymorphism", should be considered.	
	The TWV agreed that the term "molecular data" would be a suitable broad term.	
	(TWA, agreed by TWV) to seek to develop shorter names for the models and to avoid any use of numbering in association with the models, i.e. to remove the indications of 3.1.1, 3.1.2, 3.1.3 and 3.2.1.	

3.1.2	(BMT, agreed by TWA and TWV) to clarify that the phenotypic distance is based on phenotypic characteristics and to indicate that the GAIA threshold would need to be selected on a case-by-case basis.
	The TWV noted that the model "System for combining phenotypic and molecular distances in the management of variety collections" would not necessarily require the GAIA method to be used to calculate phenotypic distance, but noted that any other method would need to be based on a similar "combination of differences observed on phenotypic characteristics, where each difference contributes to the distance according to the reliability of the characteristics, especially regarding its variability and its susceptibility to environment" (see document BMT/DUS Draft 3, Annex 4, Section 1.4.1) in order to fall within the model.
3.1.3	(BMT, agreed by TWA) to read "Calibration of molecular distances in the management of variety collections (see Annex 2)"
	The TWV agreed that the title should read "Calibration of molecular and traditional distances in the management of variety collections (see Annex 2)" or "Calibration of distances in the management of variety collections (see Annex 2)"
Annex 2	(TWO) paragraph 12 to be amended to read "[] The situation in which different decisions on distinctness would result can only be investigated where varieties are rejected for <u>lack of</u> distinctness in the growing trial. This would require analysis of pairs of varieties rejected for <u>lack of</u> distinctness in the past or, if such material is unavailable, a system of "parallel running" of the two systems in real time on candidate varieties. []"

Background to the preparation of document BMT/DUS Draft 5

23. On the basis of the comments of the BMT and the Technical Working Parties at their sessions in 2010, the following proposals were developed by the Chairman of the Technical Committee, Mr. Joël Guiard, the Chairman of the BMT, Mr. Andrew Mitchell, and the Office of the Union, and were incorporated in document BMT/DUS Draft 4:

General	to delete all references to the terms "Option" and "Proposal" and to replace with the terms "Model" and "Example"		
	document BMT/DUS Draft 4: done		
	to replace all references to "molecular characteristics" with an appropriate term such as "molecular markers".		
	document BMT/DUS Draft 4: the term "molecular characteristics" were replaced by "molecular markers"		

	to seek to develop shorter names for the models and to avoid any use of numbering in association with the models, i.e. to remove the indications of 3.1.1, 3.1.2, 3.1.3 and 3.2.1.		
	document BMT/DUS Draft 4: the following short names were proposed:		
	Characteristic-specific molecular markers $(previously\ Option\ l(a))$		
	Combining phenotypic and molecular distances ("New" model – maize example)		
	Calibration of molecular distance (previously Option 2)		
	Use of molecular markers as independent characteristics (previously Option 3)		
3.1.2	to clarify that the phenotypic distance is based on phenotypic characteristics and to indicate that the GAIA threshold would need to be selected on a case-by-case basis.		
	The TWV noted that the model "System for combining phenotypic and molecular distances in the management of variety collections" would not necessarily require the GAIA method to be used to calculate phenotypic distance, but noted that any other method would need to be based on a similar "combination of differences observed on phenotypic characteristics, where each difference contributes to the distance according to the reliability of the characteristics, especially regarding its variability and its susceptibility to environment" (see document BMT/DUS Draft 5, Annex 4, Section 1.4.1) in order to fall within the model.		
	No change proposed in document BMT/DUS Draft 4: to be considered by the Technical Committee		
3.1.3	to read "Calibration of molecular distances in the management of variety collections (see Annex 2)"		
	The TWV agreed that the title should read "Calibration of molecular and traditional distances in the management of variety collections (see Annex 2)" or "Calibration of distances in the management of variety collections (see Annex 2)"		
	document BMT/DUS Draft 4: see proposed new titles under "General"		
Annex 2	(TWO) paragraph 12 to be amended to read "[] The situation in which different decisions on distinctness would result can only be investigated where varieties are rejected for <u>lack of</u> distinctness in the growing trial. This would require analysis of pairs of varieties rejected for <u>lack of</u> distinctness in the past or, if such material is unavailable, a system of "parallel running" of the two systems in real time on candidate varieties. []"		
	document BMT/DUS Draft 4: done		

24. Amendments to document BMT/DUS Draft 4, proposed by the Enlarged Editorial Committee (TC-EDC) at its meeting on January 6, 2011, are shown in yellow highlighting and indicated by an endnote in document BMT/DUS Draft 5.

Consideration of document BMT/DUS Draft 5 by the Technical Committee

25. The TC will be invited to consider document BMT/DUS Draft 5 at its forty-seventh session, to be held in Geneva from April 4 to 6, 2011.

Consideration of document BMT/DUS Draft 5 by the Administrative and Legal Committee (CAJ)

26. The CAJ will be invited to consider document BMT/DUS Draft 5 at its sixty-third session, to be held in Geneva on April 7, 2011. The comments of the TC at its forty-seventh session will be reported to the CAJ at its sixty-third session.

Proposal for Adoption of Document BMT/DUS

27. Subject to the approval of the TC at its forty-seventh session and the CAJ at its sixty-third session, document BMT/DUS would be put forward for adoption by the Council at its forty-fifth ordinary session, to be held in Geneva on October 20, 2011. That document would be included in the UPOV/INF series of documents.

28. The TC is invited to consider document BMT/DUS Draft 5 as the basis for adoption of document BMT/DUS, as set out in paragraph 27 of this document.

Possible development of document TGP/15

- 29. 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.
- 30. 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.

31. The TC is invited to consider whether to prepare a draft document TGP/15, which would provide guidance for the use of models that had received a positive assessment and for which accepted examples could be provided, as set out in paragraph 30 of this document.

INTERNATIONAL GUIDELINES ON MOLECULAR METHODOLOGIES

- 32. 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.
- 33. 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.
- 34. 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).
- 35. 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.
 - 36. The TC is invited to note the information on international guidelines on molecular methodologies presented to the BMT at its twelfth session, as set out in paragraphs 34 and 35 of this document.

AD HOC CROP SUBGROUPS ON MOLECULAR TECHNIQUES (CROP SUBGROUPS)

37. 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."

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

39. 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).

40. The TC is invited to:

- (a) note that there have been no meetings of the Crop Subgroups since its forty-sixth session; and
- (b) note that Mr. Joost Barendrecht, Chairman of the Crop Subgroup for Rose has retired and that it would be necessary to appoint a new chairman of the Crop Subgroup for Rose if a meeting is planned.

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

- 41. 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"). At its eleventh session, the BMT proposed to continue that approach for its twelfth session.
- 42. 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.
- 43. The papers presented under each of the agenda items of the twelfth session of the BMT were as follows:

MAY 11, 2010 ("BREEDERS' DAY")

The use of molecular techniques in examining essential derivation

Standards for Helping to Determine EDV Status in Maize (Zea Mays L.) using SSRs and Future Prospects Using SNPs (document BMT/12/14)

EDV - The ISF approach (document BMT/12/22)

The use of molecular techniques in variety identification

Project of Preserving Specimens and DNA of Protected Varieties in Japan (document BMT/12/6)

The Use of Temperature Switch PCR for SNP Genotyping in Barley (document BMT/12/7)

An Overview of DNA-Based Variety Identification at the Canadian Grain Commission (document BMT/12/8)

Application of SSR and SNP in Maize Variety Identification and Database Construction (document BMT/12/9)

Evaluation of Simple Sequence Repeat (SSR) Markers for Identification of Peas Varieties Registered in Canada (document BMT/12/11)

Application of Amplified Fragment Length Polymorphism (AFLP) Based Genotyping for Variety Identification of Berberis Thunbergii (DC) (Japanese Barberry) in a Regulatory Diagnostic Laboratory (document BMT/12/12) TC/47/7 page 14

Varietal Identification in Maize: Are Sixteen SNP Markers Sufficient? (document BMT/12/15)

Use of a molecular marker-based system for identification of varieties in Brazil: Soybean and Rice (document BMT/12/21)

Variety Tracer Program (document BMT/12/23)

MAY 12 and 13, 2010

Short presentations on new developments in biochemical and molecular techniques by DUS experts, biochemical and molecular specialists, plant breeders and relevant international organizations

The Use of Molecular Methods for Determining Distinctness Within U.S. PVP (document BMT/12/17)

Report of work on molecular techniques on a crop-by-crop basis

(a) vegetatively propagated crops

Evaluation of Simple Sequence Repeat (SSR) Markers on the Canadian Reference Potato DNA Collection (document BMT/12/10)

(b) self-pollinated crops

Functional SNP Markers for the Vernalization Requirement in Barley: An Option 1 Approach (document BMT/12/5)

Demonstration of Significant Process Towards an Option 1 Approach in Barley (document BMT/12/13)

The Use of Molecular Techniques for the Management of Soybean Reference Collections (document BMT/12/18)

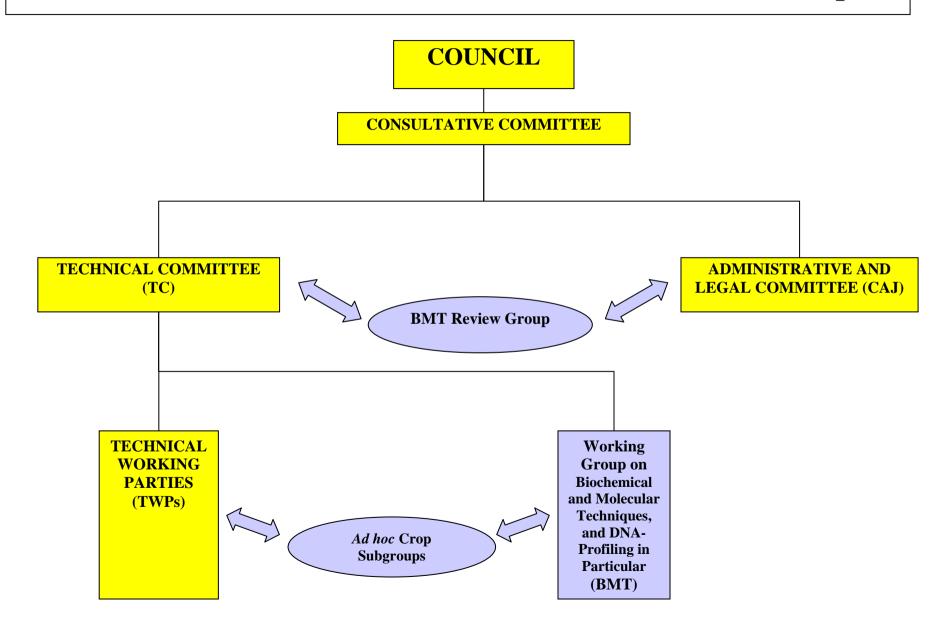
Combining Phenotypic and Molecular Distances in the Management of Reference Collections: Application to Spring Barley (document BMT/12/19)

- 44. 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
- 45. 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.
 - 46. The TC is invited to note the report on developments in the BMT, as set out in paragraphs 41 to 43 of this document and to approve the program for the thirteenth session of the BMT, as set out in paragraphs 44 and 45 of this document.

[Annex follows]

UPOV Structure: Biochemical and Molecular Techniques



TC/47/7 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.

TC/47/7 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.

TC/47/7 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:	TWP	Chairperson	TC Session which established
crop subgroup jor.	1 111	<u>Chairperson</u>	1 C Bession which established
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)