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INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS GENEVA

TECHNICAL WORKING PARTY FOR FRUIT CROPS

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DEVELOPMENTS IN UPOV CONCERNING THE USE OF MOLECULAR TECHNIQUES

Document prepared by the Office of the Union

1. The purpose of this document is to report on:

(a) the situation in UPOV concerning the possible use of molecular markers in DUS examination;

(b) 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;

(c) UPOV Guidelines for molecular marker selection and database construction (BMT Guidelines); and

(d) developments concerning the *Ad Hoc* Crop Subgroups on Molecular Techniques (Crop Subgroups)

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: Technical Working Party
 - 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

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

4. The situation in UPOV concerning the possible use of molecular markers in DUS examination is set out in documents TC/38/14 -CAJ/45/5 and TC/38/14 Add.-CAJ/45/5 Add.. Those documents present the proposals developed in the Ad Hoc Crop Subgroups on Molecular Techniques (Crop Subgroups), the recommendations of the Ad Hoc Subgroup of Technical and Legal Experts on Biochemical and Molecular Techniques (BMT Review Group) concerning those proposals and the opinion of the Technical Committee (TC) and the Administrative and Legal Committee (CAJ) regarding the recommendations of the BMT Review Group.

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

5. 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."

6. 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 BMT Review Group. The BMT could continue its work and report to the TC and the CAJ. The TC and CAJ could identify any matters which the Consultative Committee might need to consider.

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, which was proposed to be held in Spain in May 2008. In particular, breeders and other experts would be offered the possibility to attend for that specific day.

8. 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 BMT 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.

GUIDELINES FOR MOLECULAR MARKER SELECTION AND DATABASE CONSTRUCTION (BMT GUIDELINES)

9. 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).

10. At its at its forty-third session, the TC considered document BMT Guidelines (proj.8) (see http://www.upov.int/restrict/en/tc/43/BMT_Guidelines_proj_8.pdf) 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.

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.

11. 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]

12. The TC agreed that relevant experts be invited to make a presentation concerning ISO and Codex guidelines, in relation to quality criteria in molecular techniques, at the eleventh session of the BMT.

13. At its forty-second session, the TC agreed to investigate the possibility of a practical exercise, involving a small number of crops, in the development of an exchangeable database. It agreed that it would be necessary to set clear terms of reference for that work and agreed that such terms of reference should be considered at its forty-third session. In the meantime, it agreed to invite the BMT, at its tenth session, to suggest suitable crops where such a practical exercise might be appropriate. At its tenth session, the BMT agreed to suggest oilseed rape, potato and rose as suitable crops where a practical exercise in the development of an exchangeable database might be appropriate. It was agreed that the terms of reference to be established by the TC for that work should clarify what was meant by an exchangeable database and whether it referred to the structure of the database or the quality of the data and whether it would involve a test data set rather than the complete set of data which an authority had for the crop concerned. At its forty-third session, the TC agreed that the BMT Crop Subgroups for Rose, for Potato and for Oilseed Rape should be invited to consider how to take that matter forward. With respect to the terms of reference for such an exercise, the TC agreed that the exercise should consider both the quality and structure of the data.

PROPOSALS CONCERNING THE *AD HOC* CROP SUBGROUPS ON MOLECULAR TECHNIQUES (CROP SUBGROUPS)

14. A list of the Crop Subgroups is contained in the Annex to this document, in accordance with the changes agreed by the TC at its forty-third session (see document TC/43/12 "Report on Conclusions", paragraph 47).

15. The Technical Working Party for Vegetables (TWV), at its fortieth session, held in Guanajuato, Guanajuato State, Mexico, from June 12 to 16, 2006, agreed that it would be useful for experts to provide information on work in relation to the use of molecular markers, in particular in relation to disease resistance. Experts from the European Community (tomato), France (tomato, melon, chicory, shallots), Netherlands (tomato, lettuce, asparagus), Spain (pepper and tomato) and the International Seed Federation (ISF) (tomato in relation to essentially derived varieties) agreed to prepare documents for information and discussion at the forty-first session of the TWV.

16. At its forty-third session, the TC:

(a) noted the intention to provide information at the forty-first session of the TWV on work in relation to the use of molecular markers, in particular in relation to disease resistance;

(b) agreed that specific sessions should be organized at the BMT for vegetatively propagated, self-pollinated and cross-pollinated crops and, on that basis, agreed to discontinue the Vegetatively Propagated Crop Subgroup;

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(c) noted the support of the TWA for the work of the Crop Subgroups and noted that the TWA would be invited to propose a new Chairperson for the Crop Subgroup for Wheat and Barley at its thirty-sixth session;

(d) noted the following planned program for meetings of the Crop Subgroups for Potato, Rose and Maize:

Crop Subgroup for Rose: to meet in early 2007; Crop Subgroup for Potato: to meet in Spring 2007; and Crop Subgroup for Maize: to meet around the end of 2007 or early 2008

(e) 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.

Crop Subgroup for Potato

17. The Crop Subgroup for Potato held its second session in Quimper, France, on April 17, 2007. All documents considered at that session can be found on the UPOV website at http://www.upov.int/restrict/en/bmt_cropsubgroups/potato_2.htm). With regard to proposals to the TWA and the BMT, the Crop Subgroup for Potato concluded as follows¹:

Molecular techniques in the examination of distinctness, uniformity and stability

18. At the proposal of the Chairperson, the Crop Subgroup for Potato agreed the following conclusions in relation to the possible use of molecular information in relation to the DUS examination;

(a) molecular information alone should not be used for the assessment of distinctness, but might be considered in combination with morphological information in relation to the management of reference collections;

(b) the use of molecular markers could improve the management of reference collections used for DUS examination, in particular in relation to improving the coverage of reference collections; and

(c) the creation of a database containing both molecular and phenotypic data would be a necessary step for the use of molecular data in the management of reference collections. In that respect, it was also noted that there was still a need for work to be done on the harmonization of descriptions of morphological characteristics in order to be able to use such data from different sources. The next steps should include an assessment of the way in which the molecular and phenotypic data might be used, in particular in relation to the thresholds which might be applied. In that respect, there was recognition of the need for expertise in both morphological and molecular aspects. In considering such an approach, the Crop Subgroup for Potato expressed a favorable response to the approach developed by the experts

¹ The conclusions presented are an extract from the draft report of the second session of the Crop Subgroup Potato (document BMT-TWA/Potato/2/6 Prov.). The report of that for session (document BMT-TWA/Potato/2/6) will posted the UPOV website be on (http://www.upov.int/restrict/en/bmt_cropsubgroups/potato_2.htm) once adopted)

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from France for maize in document BMT/10/14, whilst noting that the issues facing reference collections of potato were somewhat different to those in Maize.

Molecular techniques in variety identification

19. The Chairperson noted that consideration of the purpose of the variety identification was an important aspect and the levels of molecular information required for variety identification could be different. She noted that molecular tools were already being successfully used for variety identification and had been very effective. In relation to variety identification, uniformity and stability was not a problem.

Essentially derived varieties

20. It was noted that there was no work by the international breeders' organizations in developing essentially derived variety (EDV) thresholds for potato.

Exchangeable database of molecular markers

21. The Crop Subgroup for Potato agreed that it would be useful for the experts working on the project for Community Plant Variety Office (CPVO) of the European Community (see document BMT-TWA/Potato/2/2) and at the *Institut national de la recherche agronomique* (INRA - France), to cooperate in order to investigate the compatibility of data obtained using different technologies.

Crop Subgroup for Rose

22. The Crop Subgroup for Rose held its second session in Angers, France, on April 18, 2007. All documents considered at that session can be found on the UPOV website at http://www.upov.int/restrict/en/bmt_cropsubgroups/rose_1.htm). With regard to proposals to the TWO and the BMT, the Crop Subgroup for Rose concluded as follows²:

Possible Use of Molecular Technique in the DUS Examination

23. The Crop Subgroup for Rose concluded that there was not an urgent requirement to introduce molecular markers in the DUS examination of rose, but noted that the use of molecular markers in combination with morphological characteristics could be useful for the management of reference collections.

Variety Identification

24. The Crop Subgroup for Rose agreed on the importance of considering the following matters at the UPOV level:

² The conclusions presented are an extract from the draft report of the second session of the Crop Subgroup for Rose (document BMT-TWO/Rose/2/5 Prov.). The report of that session (document BMT-TWO/Rose/2/5) will be posted on the UPOV website (http://www.upov.int/restrict/en/bmt_cropsubgroups/rose_1.htm) once adopted)

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(a) whether it would be useful for authorities to attach a DNA fingerprint to the official variety description;

(b) for which crops DNA fingerprints attached to the official variety description might be of most interest and why; and

(c) whether it would be useful for authorities to conserve DNA samples.

Exchangeable Databases

25. Concerning the development of an exchangeable database, the Crop Subgroup for Rose was informed that the Technical Committee, at its forty-third session held in March 2007, had invited BMT Crop Subgroups for Rose, for Potato and for Oilseed Rape to consider how to take that matter forward.

26. An expert from France reported that, at the Congress of the International Seed Testing Association (ISTA) to be held in Brazil in May 2007, the ISTA Variety Committee would discuss a protocol for variety identification, and observed that a link between the work being done within ISTA and that taking place within UPOV would be important.

Future Program

27. The Crop Subgroup for Rose agreed to hold its third session in May 2008, in Spain, in association with the eleventh session of the BMT.

[Annex follows]

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UPOV Structure: Biochemical and Molecular Techniques



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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.

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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.

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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>	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)

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