

Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular (BMT)

Twelfth Session Ottawa, May 11 to 13, 2010

PREPARATORY WORKSHOP

May 10, 2010

UPOV	PROGRAM
1.	Introduction to UPOV
2.	Overview of the Technical Working Parties (TWPs)
3.	Guidance for DUS Examination - General Introduction (document TG/1/3) - TGP documents - Test Guidelines and characteristics - Cooperation
4.	Role of the TWPs and BMT
5.	Situation in UPOV concerning the Possible Use of Molecular Techniques in the DUS Examination
6.	The Concept of Essentially Derived Varieties
7.	The Role of UPOV in Variety Identification
8.	The UPOV website
9.	Agenda for the BMT session

UPOV

1. INTRODUCTION TO UPOV



UPOV

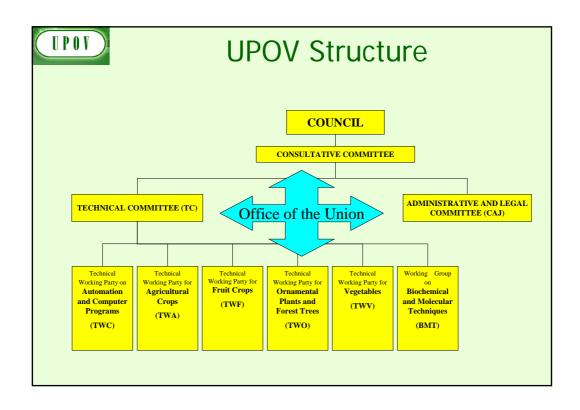
The International Convention for the Protection of New Varieties of Plants established in 1961

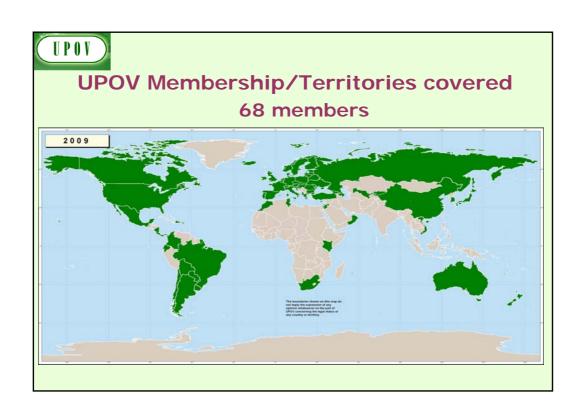
The International Union for the Protection of New Varieties of Plants

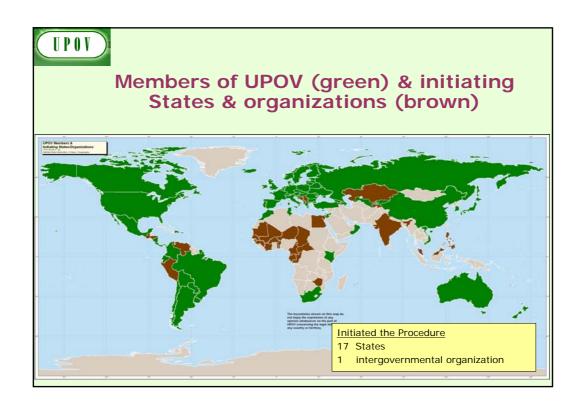
Union internationale pour la protection des obtentions végétales



- Members of the Union
 - -States
 - -Intergovernmental Organization(s)
- Organs established by the Convention
 - -Council
 - -Office of the Union
- Other Bodies



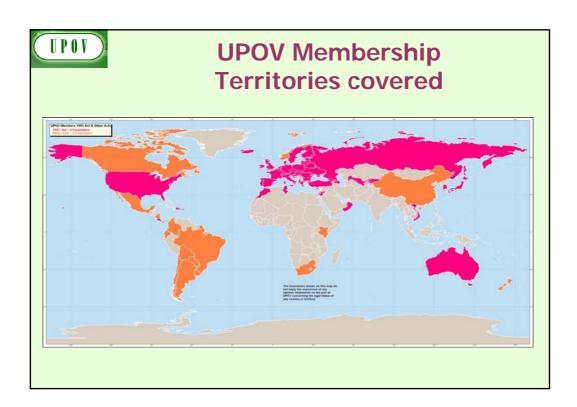


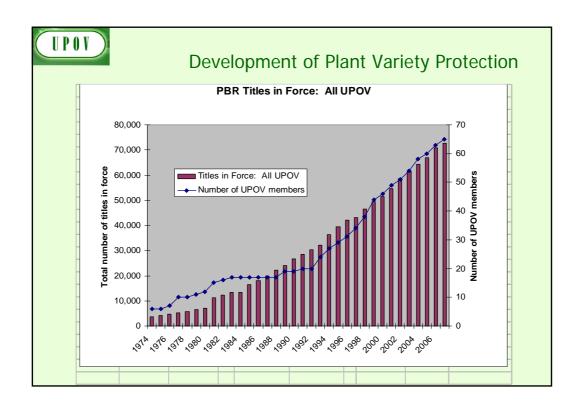


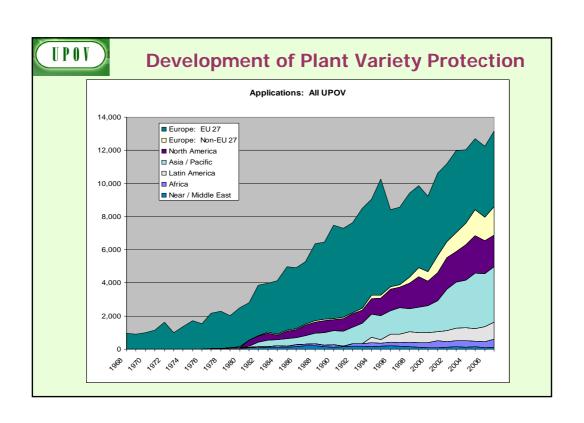
UPOV

PLANT VARIETY PROTECTION SITUATION

- 68 members of the Union
- 17 States have initiated the procedure for becoming members of the Union
- 1 intergovernmental organization has initiated the procedure for becoming members of the Union:
 - OAPI (16 countries)
- 44 States have contacted the Office of the Union for assistance in the development of legislation on plant variety protection



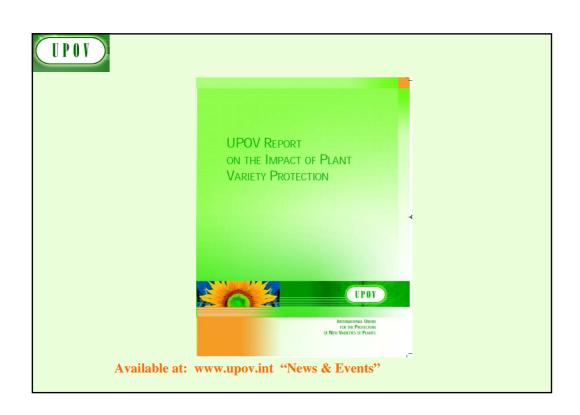






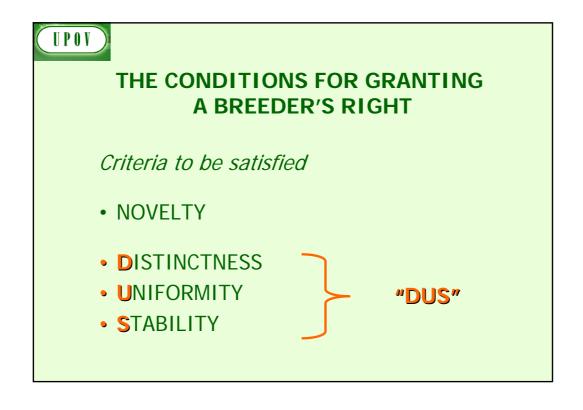
UPOV MISSION STATEMENT

"To provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society"





2. OVERVIEW OF THE UPOV TECHNICAL WORKING PARTIES (THE DUS EXAMINATION)



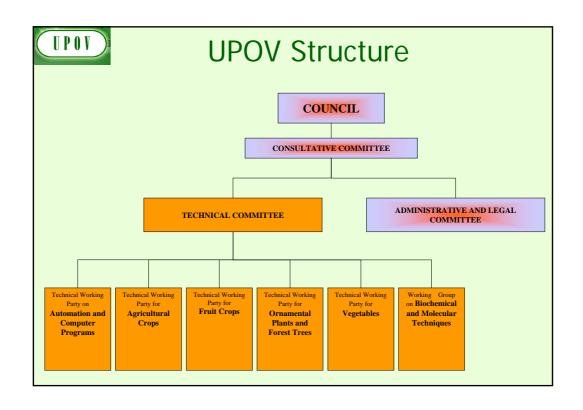


THE CONDITIONS FOR GRANTING A BREEDER'S RIGHT

Other conditions

- VARIETY DENOMINATION
- FORMALITIES
- PAYMENT OF FEES

NO OTHER CONDITIONS!





3. GUIDANCE FOR DUS EXAMINATION



Guidance for DUS Examination

facilitates:

BEST PRACTICE (based on experience)

- => good decisions
- => good definition of the object of protection
 (strong protection)
- => efficiency in method of examination (learn from the best)

HARMONIZATION

- => efficiency
 - mutual acceptance of DUS reports (minimize cost of examination for individual authorities)
 - mutual recognition of variety descriptions (all parties speak the same "language")
 - simple and cheap system for applicants (minimize cost for breeders)



- General Introduction (document TG/1/3)
- TGP documents
- Test Guidelines
- Cooperation



UPOV provides guidance by:

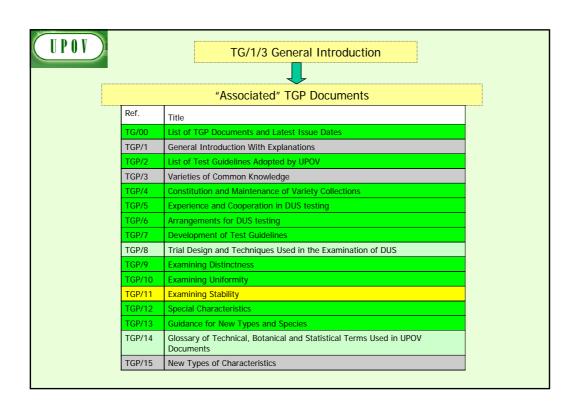
General Introduction (document TG/1/3)

("General Introduction to the Examination of Distinctness, Uniformity and Stability and the Development of Harmonized Descriptions of New Varieties of Plants")

- TGP documents
- Test Guidelines
- Cooperation

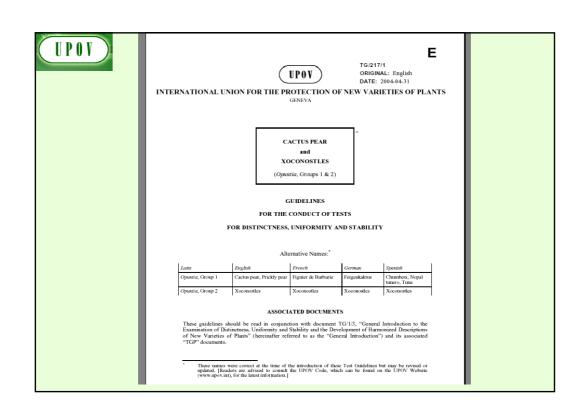


- General Introduction (document TG/1/3)
- TGP documents (associated to General Introduction)
- Test Guidelines
- Cooperation





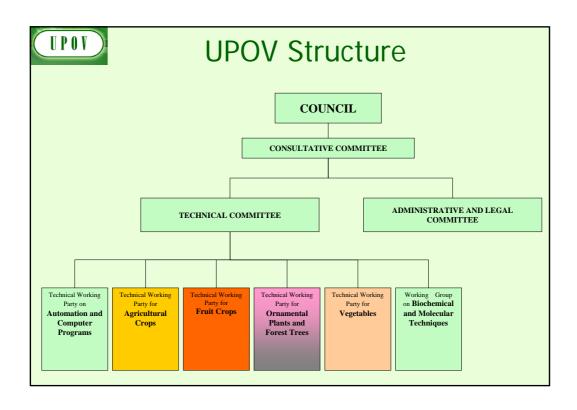
- General Introduction (document TG/1/3)
- TGP documents
- Test Guidelines
- Cooperation

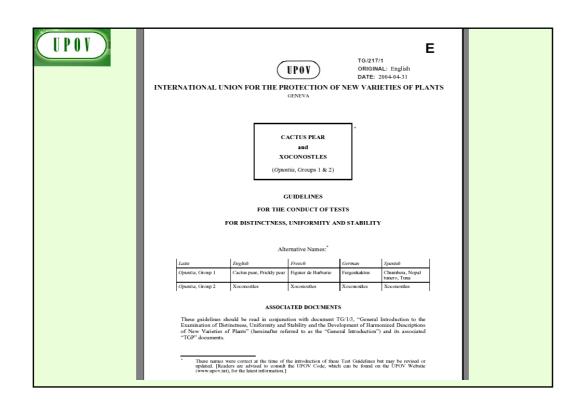




Test Guidelines

- 264 Test Guidelines adopted
- Further 62 to be discussed in 2010
 (38 new Test Guidelines / 17 revisions
 / 7 partial revisions)







10 Chapters of UPOV Test Guidelines

- 1. Subject of the Test Guidelines
- 2. Material Required
- 3. Methods of Examination
- 4. Assessment of Distinctness, Uniformity and Stability
- 5. Grouping of Varieties and Organization of the Growing Trial
- 6. Introduction to the Table of Characteristics

7. Table of Characteristics

- 8. Explanation on the Table of Characteristics
- 9. Literature
- 10. Technical Questionnaire



"CHARACTERISTICS"

- may have direct commercial relevance
 - Flower color (ornamental)
 - Fruit color
- but commercial relevance NOT required
 - Leaf shape



Selection of Characteristics

The basic requirements that a characteristic should fulfill before it is used for DUS testing or producing a variety description are that its expression (TG/1/3: Section 4.2.1):

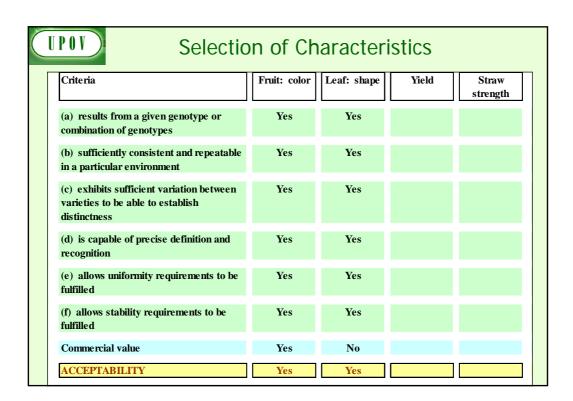
- (a) **results from a given genotype** or combination of genotypes;
- (b) is sufficiently **consistent and repeatable** in a **particular environment**:
- (c) exhibits sufficient **variation between varieties** to be able to establish distinctness;
- (d) is capable of **precise definition and recognition**;
- (e) allows **uniformity requirements** to be fulfilled;
- (f) allows **stability requirements** to be fulfilled, meaning that it produces consistent and repeatable results after repeated propagation or, where appropriate, at the end of each cycle of propagation.



Selection of Characteristics

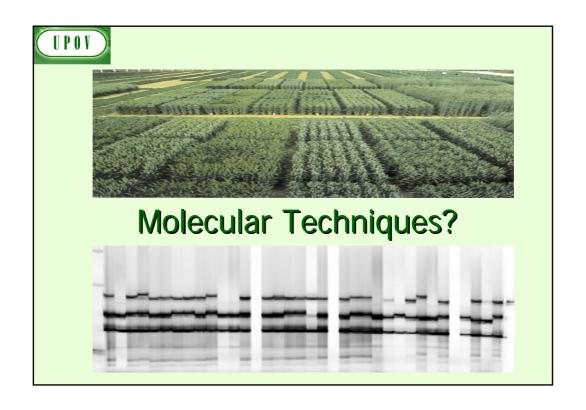
- Yield ???
- Straw strength ???

Etc.



C-444-	E	Tfh	32-13	C4
Criteria	Fruit: color	Leaf: shape	Yield	Straw strength
(a) results from a given genotype or combination of genotypes	Yes	Yes	Yes	Yes
(b) sufficiently consistent and repeatable in a particular environment	Yes	Yes	(No)	(No)
(c) exhibits sufficient variation between varieties to be able to establish distinctness	Yes	Yes	???	???
(d) is capable of precise definition and recognition	Yes	Yes	(No)	???
(e) allows uniformity requirements to be fulfilled	Yes	Yes	???	???
(f) allows stability requirements to be fulfilled	Yes	Yes	???	???
Commercial value	Yes	No	Yes	Yes

Special Charact	eristics: Disease Resistar
Criteria	Disease Resistance
(a) results from a given genotype or combination of genotypes	*Knowledge of nature of genetic control of resistance is important
(b) sufficiently consistent and repeatable in a particular environment	*Standardize conditions (greenhouse / laboratory) & methodology *Standardize inoculum *Ring-test
(c) exhibits sufficient variation between varieties to be able to establish distinctness	*Susceptible / Resistant OR varying degrees of resistance?
(d) is capable of precise definition and recognition	*Define and recognize races and strains
(e) allows uniformity requirements to be fulfilled	see above
(f) allows stability requirements to be fulfilled	see above
	Difficult and expensive





- General Introduction (document TG/1/3)
- TGP documents
- Test Guidelines
- Cooperation

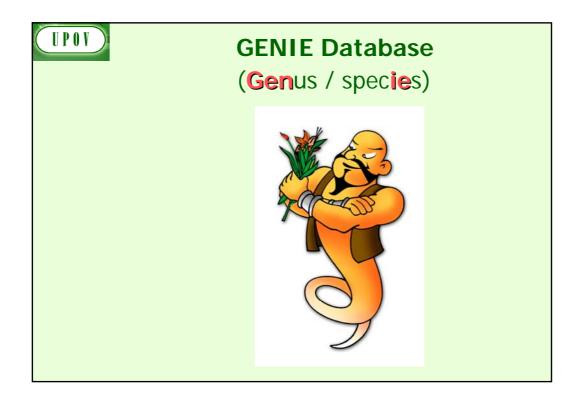


Test Guidelines

• 264 Test Guidelines adopted

but...

 >2,750 genera and species with varieties examined for PBR





GENIE Database 🥞



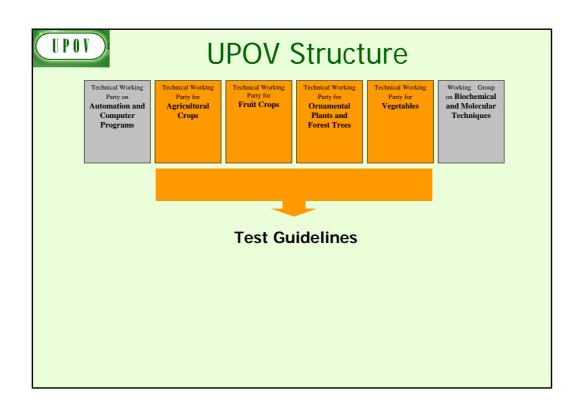
Variety denomination related information Protection offered by UPOV members

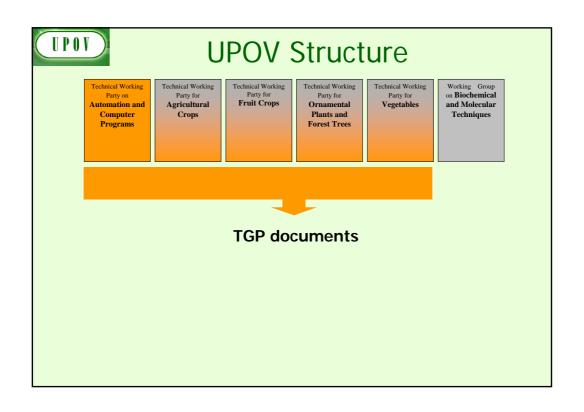
DUS information

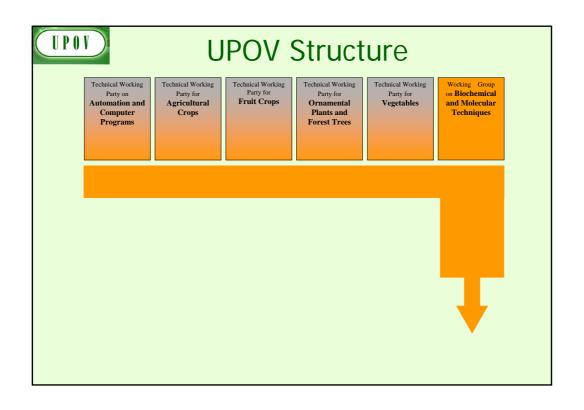
- UPOV Test Guidelines
- practical experience of UPOV (document TC/46/4)
- cooperation in DUS examination (document C/43/5)



4. ROLE OF THE **TECHNICAL WORKING PARTIES AND THE BMT**









Role of the BMT

(see document BMT/12/2: Annex, page 2)

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 [...];
- (v) Consider initiatives from TWPs, for the establishment of crop specific subgroups [...];
- (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.



Role of the BMT

Consider the possible application of biochemical and molecular techniques in DUS testing

(see document BMT/12/2: Annex, page 2)

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

- (iii) Consider the possible application of biochemical and molecular techniques in DUS testing and report its considerations to the TC;
- (v) Consider initiatives from TWPs, for the establishment of crop specific subgroups [...];
- (vii) Receive reports from Crop Subgroups and the BMT Review Group;
 - => BMT/12 agenda items 4, 6 and 12 and
 - => BMT/DUS Draft 3 "Possible Use of Molecular Markers in the Examination of Distinctness, Uniformity and Stability (DUS)"



Role of the BMT

Guidance and harmonization for a range of applications

(see document BMT/12/2: Annex, page 2)

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- (iv) If appropriate, establish guidelines for biochemical and molecular methodologies and their harmonization [...];
- (vi) Develop guidelines regarding the management and harmonization of databases of biochemical and molecular information, in conjunction with the TWC;
 - => BMT Guidelines
 - => BMT/12 agenda items 7 to 9



Role of the BMT

Raise awareness of general developments:

(see document BMT/12/2: Annex, page 2)

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;

=> BMT/12 agenda item 5



Role of the BMT

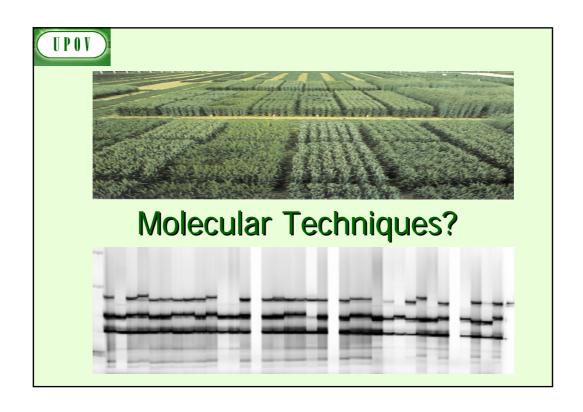
(see document BMT/12/2: Annex, page 2)

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.
 - => BMT/12 agenda items 10 and 11 and
 - => presentations to follow

UPOV

5. Situation in UPOV concerning the possible use of molecular techniques in the DUS Examination





Legal and other considerations

- Conformity with the UPOV Convention
- Potential impact on the strength of protection

Technical considerations

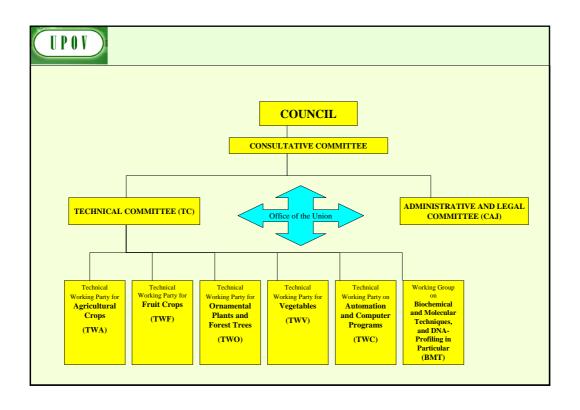
- Reliability and robustness of techniques
- Accessibility of the technology
- Harmonization of methodologies
- Cost of examination
- Implications for breeders (e.g. cost and time involved for new uniformity requirements)

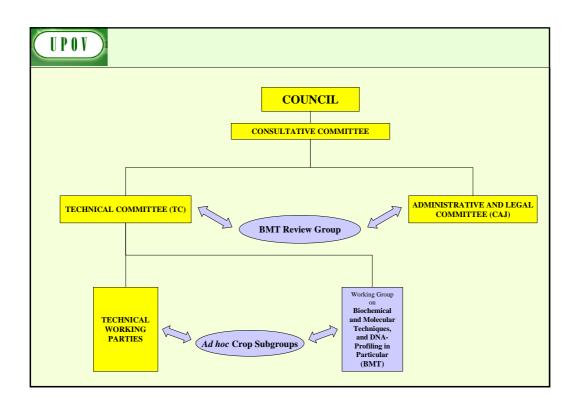


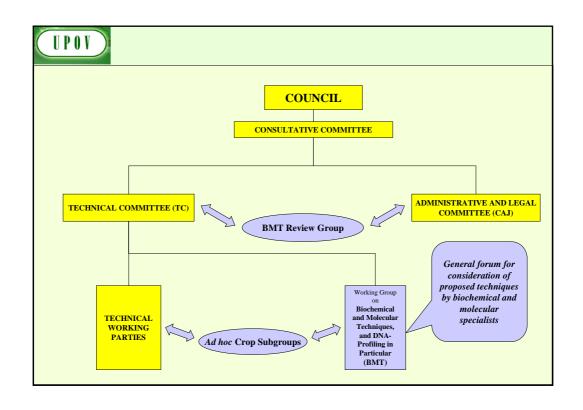
Harmonized approach

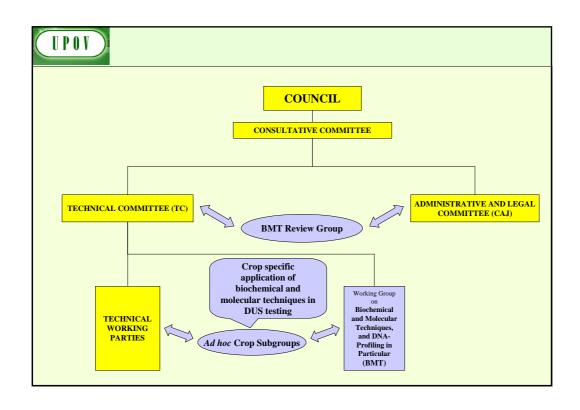
Harmonization

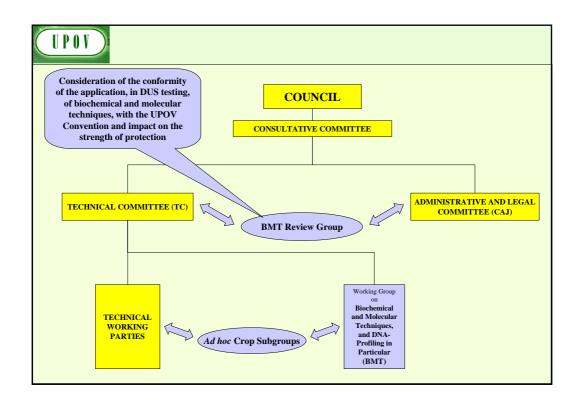
- ⇒ facilitates cooperation in DUS testing
 e.g. purchase of DUS reports
- ⇒ internationally recognized variety descriptions (effective protection)

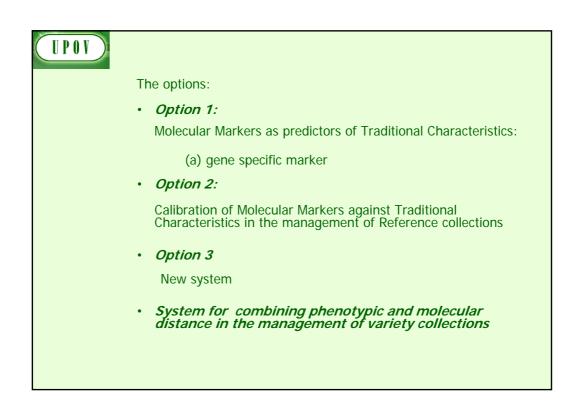












UPOV

OPTION 1 (a)

Molecular Markers as predictors of Traditional Characteristics:

(a) gene specific marker



View of the BMT Review Group, Technical Committee, Administrative and Legal Committee

Option 1(a) for a gene specific marker of a phenotypic characteristic:

Proposal: gene specific marker for herbicide tolerance introduced by genetic modification

was, on the basis of the assumptions in the proposal, acceptable within the terms of the UPOV Convention and would not undermine the effectiveness of protection offered under the UPOV system.



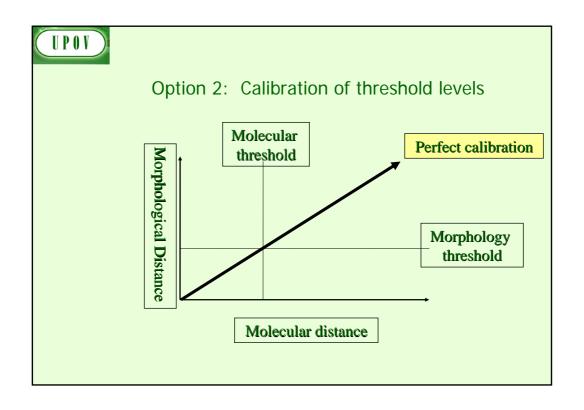
Assumptions for a gene specific marker:

- (a) **DUS examination**: same no. of plants, growing cycles, DUS criteria;
- (b) **Linkage**: ensure that the marker is a reliable predictor;
- (c) **Different markers** for same gene would be treated as different methods for examining the **same characteristic**:
- (d) **Different genes** would be treated as different methods for examining the **same characteristic**;
- (e) **Different markers** linked to **different regulatory elements** for the **same gene** would all be treated as different methods for examining the **same characteristic**. (further consideration would be given to this matter at a later stage)



OPTION 2

Calibration of Molecular Markers against Traditional Characteristics in the management of Reference collections





View of the BMT Review Group, Technical Committee, Administrative and Legal Committee

Option 2: Calibration of threshold levels for molecular characteristics against the minimum distance in traditional characteristics

Proposal: Option 2 for Maize, Oilseed Rape and Rose

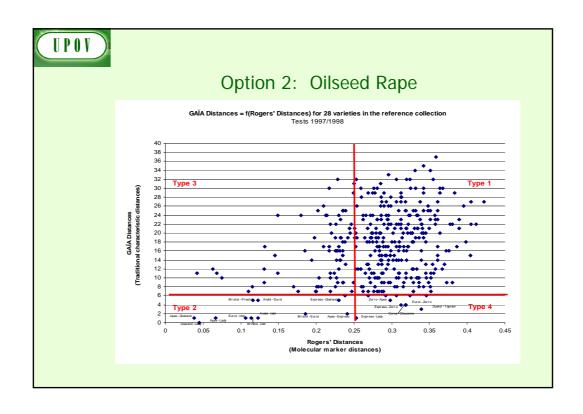
where used for the management of reference collections was, on the basis of the assumptions in the proposals, acceptable within the terms of the UPOV Convention and would not undermine the effectiveness of protection offered under the UPOV system

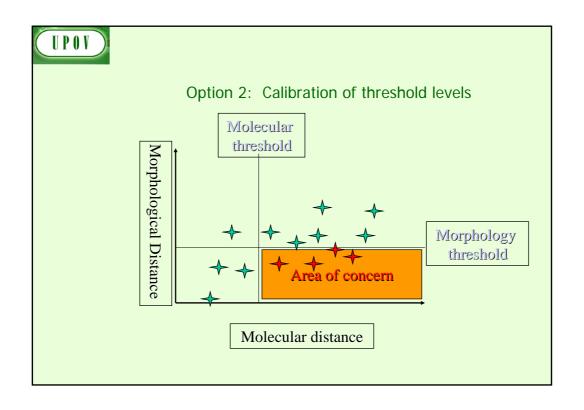
- whilst recognizing the need to improve the relationship between morphological and molecular distances.

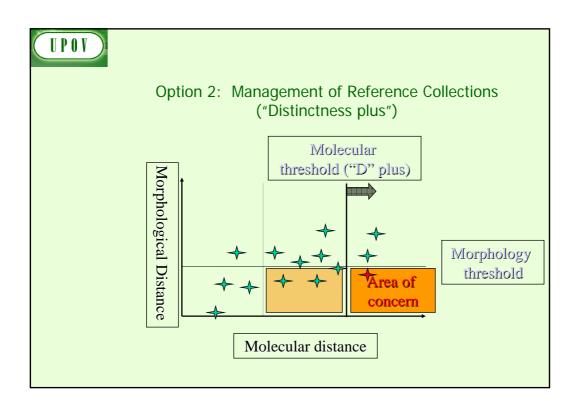


Assumptions for calibration of threshold levels :

- (a) Uniformity and Stability:
 - (i) [molecular] **differences** calculated between varieties **take into account the variation within varieties**;
 - (ii) suitable **uniformity standards** could be developed for molecular markers **without requiring varieties**, in general, **to be more uniform**
- (b) would only be used for the establishment of a "Distinctness plus" threshold in the management of reference collections;
- (c) would meet all the **normal requirements for any characteristic** to be used in the DUS examination and, in particular, would be checked to ensure they are **sufficiently consistent and repeatable**.









OPTION 3

New system



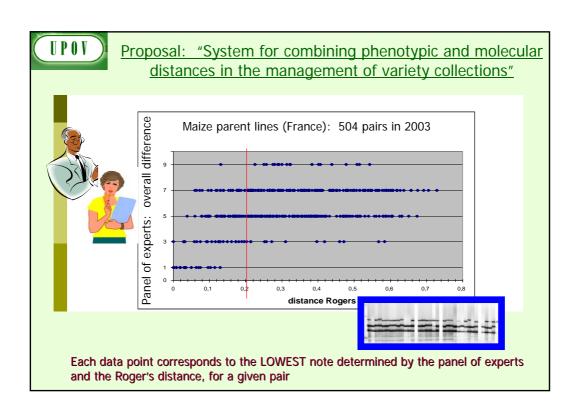
View of the BMT Review Group, Technical Committee, Administrative and Legal Committee

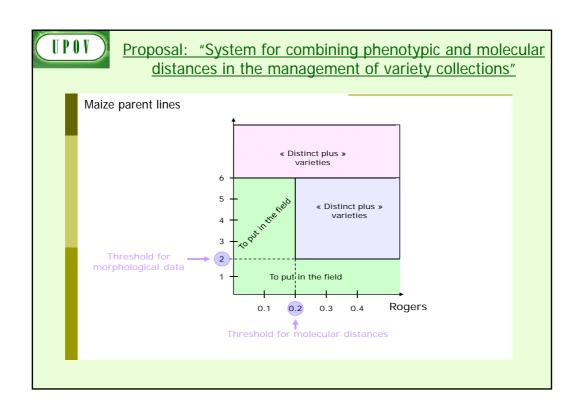
> Option 3: New system Proposal: Option 3 for Rose and Wheat

- no consensus on the acceptability of the Option 3 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, in these proposals, 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



System for combining phenotypic and molecular distances in the management of variety collections







View of the BMT Review Group, Technical Committee, Administrative and Legal Committee

Proposal: "System for combining phenotypic and molecular distances in the management of variety collections (for maize parental lines)

- where used for the management of variety collections, was acceptable within the terms of the UPOV Convention and would not undermine the effectiveness of protection offered under the UPOV system; and
- agreed that the proposal above represented a model that might be applicable to other crops provided that the elements of the proposal were equally applicable. In that respect, it noted, for example, that the proposal above applied only to maize parental lines and did not extend to other types of maize. The BMT Review Group concluded that it was important to consider on a case by-case basis whether the model would be applicable.



Document BMT/DUS Draft 3

Purpose: to provide guidance on the possible use of biochemical and molecular markers in the examination of Distinctness, Uniformity and Stability (DUS)

To be discussed by the BMT and TWPs in 2010



Harmonized approach

Harmonization

- ⇒ facilitates cooperation in DUS testing
 e.g. purchase of DUS reports
- ⇒ internationally recognized variety descriptions (effective protection)

6. THE CONCEPT OF ESSENTIALLY DERIVED VARIETIES



VARIETIES COVERED

- the protected variety
- varieties which are not clearly distinguishable from the protected variety
- varieties whose production requires the repeated use of the protected variety

(e.g. as a parent for a hybrid variety)



ESSENTIAL DERIVATION

PURPOSE:

To ensure sustainable plant breeding development by:

- providing effective protection for the classical breeder and
- encouraging cooperation between classical breeders and developers of new technologies such as genetic modification



- decision on whether to grant protection to a variety does not take into account whether the variety is essentially derived or not: provided the conditions for protection are fulfilled (novelty, DUS, variety denomination, compliance with formalities and payment of fees) the variety will be granted protection.
- if it is subsequently concluded that the variety is an EDV, the breeder of that EDV still has all the rights conferred by the UPOV Convention. However, the breeder of the INITIAL VARIETY will also have rights in that variety. Thus, in the case of an essentially derived variety, the authorization of both the breeder of the essentially derived variety and the breeder of the initial variety is required for its commercialization.



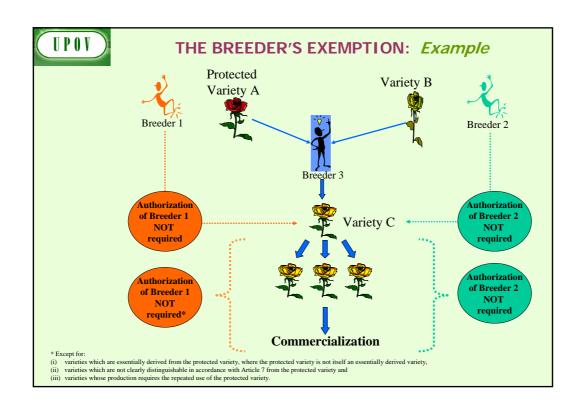
- with regard to establishing whether a variety is an essentially derived variety, a common view expressed by members of the UPOV is that the existence of a relationship of essential derivation between protected varieties is a matter for the holders of plant breeders' rights in the varieties concerned.
- UPOV has established a section on its website where case law relevant to plant breeders' rights, including case law concerning essentially derived varieties, is published.

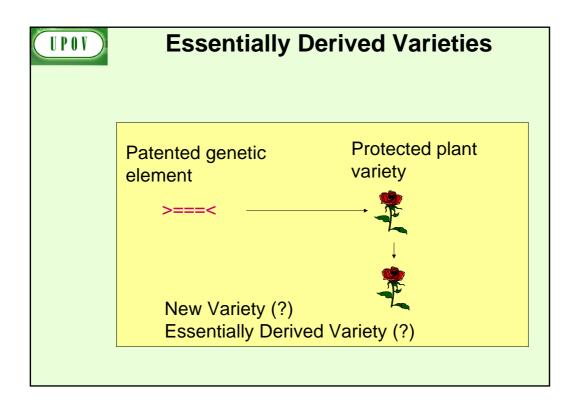


- 1 Introduction
- 2 The concept of essentially derived variety
- 3 Initial variety protected
- 4 Initial variety not protected
- 5 Indirect derivation
- 6 Summary



- 1 Introduction
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Article 14(5): (a) The provisions of paragraphs (1) to (4) shall also apply in relation to (i) varieties which are essentially derived from the protected variety, where the protected variety is not itself an essentially derived variety,

UPOV



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- ...a variety shall be deemed to be essentially derived from another variety ("the initial variety") when
 - (i) it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety,
 - (ii) it is clearly distinguishable from the initial variety and
 - (iii) except for the differences which result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.



May be obtained for example by:

- selection of a natural or induced mutant
- · selection of a somaclonal variant
- selection of a variant individual from plants of the initial variety
- back-crossing
- transformation by genetic engineering



Essentially Derived Varieties

Article 14(5):

- (a) The provisions of paragraphs (1) to (4) * shall also apply in relation to
- (i) varieties which are essentially derived from the protected variety, where the protected variety is not itself an essentially derived variety,

* = COMMERCIALIZATION



Can EDVs be protected?



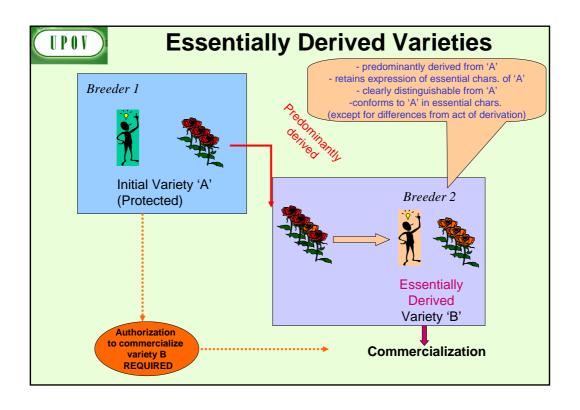
Can EDVs be commercially exploited?



It requires the authorization of the PBR holder of the initial variety

UPOV

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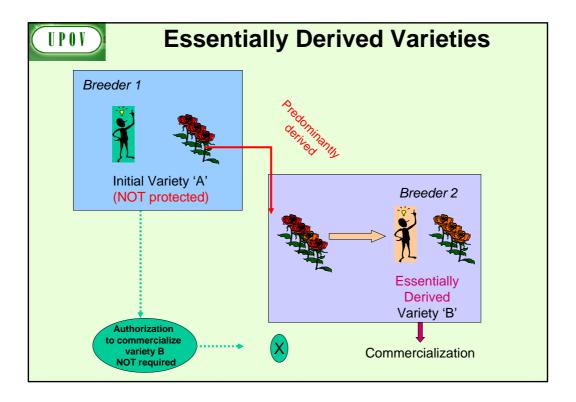


1 - Introduction 2 - The concept of essentially derived variety 3 - Initial variety protected 4 - Initial variety not protected 5 - Indirect derivation 6 - Summary

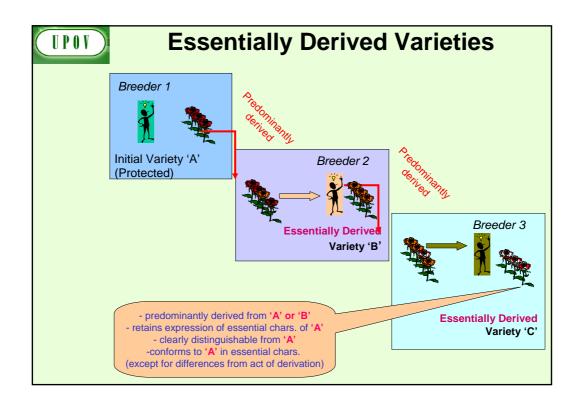


...a variety shall be deemed to be essentially derived from another variety ("the **initial variety**")

INITIAL variety is <u>not</u> restricted to PROTECTED variety



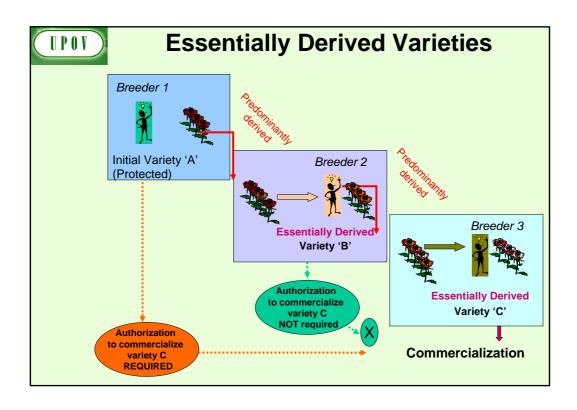
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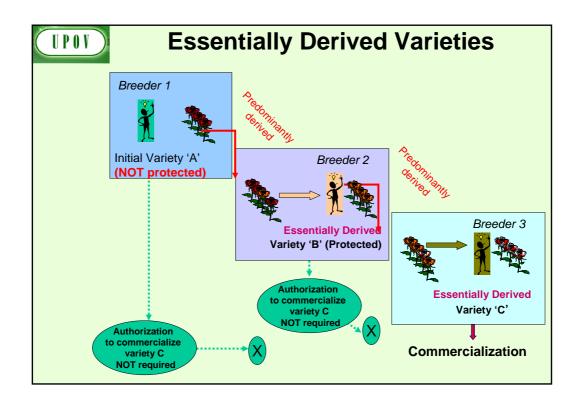


Essentially Derived Varieties

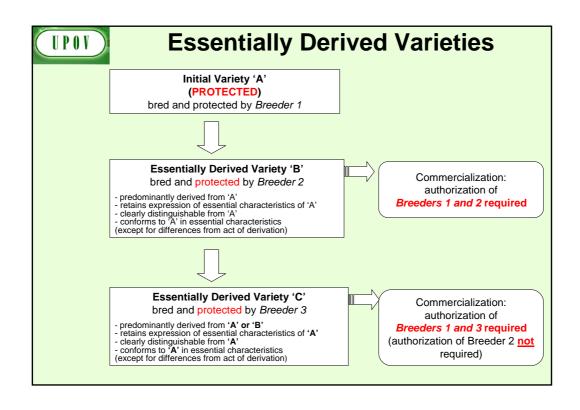
Article 14(5):

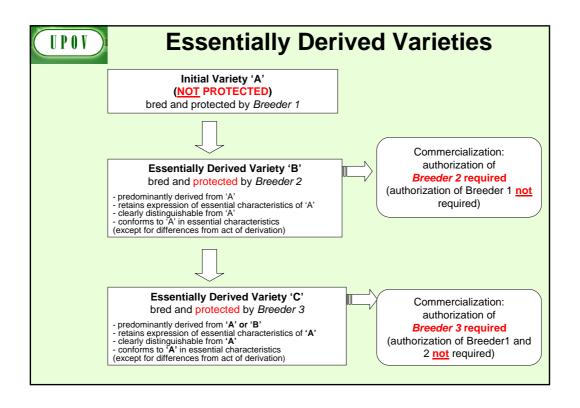
- (a) The provisions of paragraphs (1) to (4) shall also apply in relation to
- (i) varieties which are essentially derived from the protected variety, where the protected variety is not itself an essentially derived variety,





1 - Introduction 2 - The concept of essentially derived variety 3 - Initial variety protected 4 - Initial variety not protected 5 - Indirect derivation 6 - Summary





"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."

UPOV

7. THE ROLE OF UPOV IN VARIETY IDENTIFICATION



VARIETY IDENTIFICATION

"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."



VARIETY IDENTIFICATION

(March 2007)

• The Technical Committee invited the BMT Crop Subgroups to develop proposals concerning the possible use of molecular tools for variety identification [...].



BMT Forum

"BREEDERS' DAY"

at BMT/12, May 11, 2010, Ottawa

Use of molecular techniques in:

- variety identification
- essential derivation

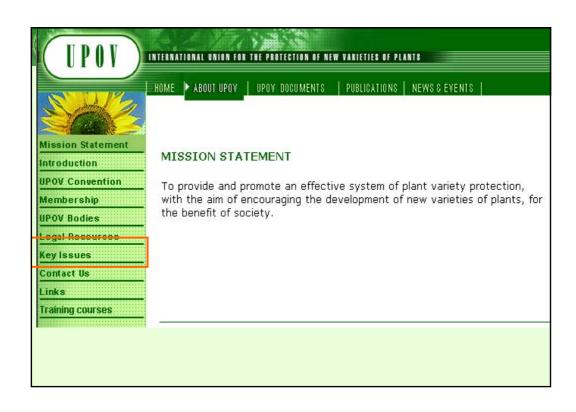


8. THE UPOV WEBSITE

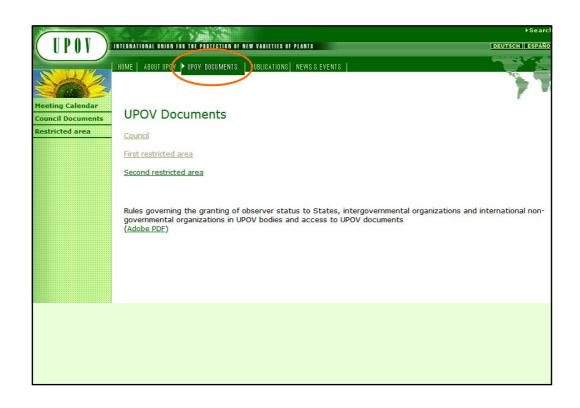
















9. AGENDA FOR THE BMT SESSION

THANK YOU