BMT/14/2 Rev2.
ORIGINAL: English
DATE: November 24, 2014

INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS

Geneva

WORKING GROUP ON BIOCHEMICAL AND MOLECULAR TECHNIQUES AND DNA PROFILING IN PARTICULAR

Fourteenth Session

Seoul, Republic of Korea, November 10 to 13, 2014

REPORTS ON DEVELOPMENTS IN UPOV CONCERNING BIOCHEMICAL AND MOLECULAR TECHNIQUES

Document prepared by the Office of the Union

Disclaimer: this document does not represent UPOV policies or guidance

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

   (a) Use of biochemical and molecular markers in the examination of Distinctness, Uniformity and Stability (DUS)

   (b) *Ad Hoc* Crop Subgroups on Molecular Techniques (Crop Subgroups); and

   (c) Presentation of information on the situation in UPOV with regard to the use of molecular techniques to a wider audience, including breeders and the public in general.

2. The following abbreviations are used in this document:

BMT:	Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular
CAJ:	Administrative and Legal Committee
TC:	Technical Committee
TC-EDC:	The Enlarged Editorial Committee

USE OF BIOCHEMICAL AND MOLECULAR MARKERS IN THE EXAMINATION OF DISTINCTNESS, UNIFORMITY AND STABILITY (DUS)

3. The situation with regards to the use of biochemical and molecular markers is set out in the following documents, which have been adopted by the Council of UPOV;

UPOV/INF/18/1 "Possible use of Molecular Markers in the Examination of Distinctness, Uniformity and Stability (DUS)

4. The purpose of document UPOV/INF/18 is to provide guidance on the possible use of biochemical and molecular markers in the examination of Distinctness, Uniformity and Stability (DUS).

TGP/15/1 "Guidance on the Use of Biochemical and Molecular Markers in the Examination of Distinctness, Uniformity and Stability (DUS)"

5. Document UPOV/INF/18 "Possible Use of Molecular Markers in the Examination of Distinctness, Uniformity and Stability (DUS)" considers possible application models for the use of biochemical and molecular markers in the examination of DUS that were proposed to the Ad hoc Subgroup of Technical and Legal Experts of Biochemical and Molecular Techniques (BMT Review Group) by the Technical Committee, on the basis of the work of the Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular (BMT) and Ad Hoc Crop Subgroups on Molecular Techniques (Crop Subgroups) (see http://www.upov.int/about/en/organigram.html). The assessment of the BMT Review Group and the views of the Technical Committee, the Administrative and Legal Committee (CAJ) on those models are presented in document UPOV/INF/18.

6. The purpose of document TGP/15 is to provide guidance on the use of biochemical and molecular markers in the examination of Distinctness, Uniformity and Stability (DUS) on the basis of the models in document UPOV/INF/18 that have received a positive assessment and for which accepted examples have been provided.

UPOV/INF/17/1 "Guidelines for DNA-Profiling: Molecular Marker Selection and Database Construction ("BMT Guidelines")"

7. 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.

Joint Workshop on DUS Testing and Molecular Techniques

8. On September 23 and 24, 2013, a Joint Workshop on DUS Testing and Molecular Techniques (Workshop) was held in Beijing, China, organized by the State Forestry Administration, China, in cooperation with the Ministry of Agriculture, China, and the Office of the Union. A copy of the program is attached as Annex I to this document.

9. At the Workshop, experts from China and the Republic of Korea reported on their use of molecular techniques to supplement the selection of varieties to be included in the DUS field trial on the basis of descriptions based on morphological characteristics (see document TC/50/13 "Molecular Techniques", paragraph 4 and 5).

10. At its fiftieth session, held in Geneva, from April 7 to 9, 2014, the TC encouraged experts from China, the Republic of Korea and other members of the Union to make presentations at the fourteenth session of the BMT, on the use of molecular techniques to supplement the selection of similar varieties for inclusion in the growing trial, as set out in document TC/50/13, paragraph 6 (see document TC/50/36 "Report on the Conclusion", paragraph 77).

AD HOC CROP SUBGROUPS ON MOLECULAR TECHNIQUES (CROP SUBGROUPS)

11. There have been no meetings of the Crop Subgroups since the twelfth session of the BMT.

12. At its thirteenth session, held in Brasilia, Brazil, from November 22 to 24, 2011, the BMT did not make any recommendation on the establishment of new crop specific subgroups. The BMT proposed to the TC to consider the possibility of the discontinuation of the meeting of the *Ad-hoc* Crop Subgroups and to include the individual species discussion within the BMT sessions (see document BMT/13/36 "Report", paragraph 69).

13. The TC, at its forty-eighth session, held in Geneva, from March 26 to March 28, 2012, agreed to discontinue separate meetings of the *Ad-hoc* Crop Subgroups and to include the discussions within the BMT sessions (see document TC/48/22 "Report on the Conclusions", paragraph 83).

PRESENTATION OF INFORMATION ON THE SITUATION IN UPOV WITH REGARD TO THE USE OF MOLECULAR TECHNIQUES TO A WIDER AUDIENCE, INCLUDING BREEDERS AND THE PUBLIC IN GENERAL

14. The TC, at its forty-ninth session, held in Geneva from March 18 to 20, 2013, agreed that there was a need to provide suitable information on the situation in UPOV with regard to the use of molecular techniques to a wider audience, including breeders and the public in general. That information should explain the potential advantages and disadvantages of the techniques, and the relationship between genotype and phenotype, which lay behind the situation in UPOV (see document TC/49/41 "Report on the Conclusions", paragraph 136).

15. The Consultative Committee, at its eighty-sixth session, held in Geneva on October 23 and 24, 2013, considered a series of answers to frequently asked questions. One of the questions included was "does UPOV allow molecular techniques (DNA profiles) in the DUS examination?" In that regard the Consultative Committee agreed that the answer should be developed via the Technical Committee.

16. The TC, at its fiftieth session, held in Geneva on April 7 to 9, 2014 and the CAJ, at its sixty-ninth session, held in Geneva on April 10, 2014, agreed the proposed explanation of the situation in UPOV with regard to the use of molecular techniques, as set out below:

> Question: Does UPOV allow molecular techniques (DNA profiles) in the DUS examination?
>
> Answer: "It is important to note that, in some cases, varieties may have a different DNA profile but be phenotypically identical, whilst, in other cases, varieties which have a large phenotypic difference may have the same DNA profile for a particular set of molecular markers (e.g. some mutations).
>
> "In relation to the use of molecular markers that are not related to phenotypic differences, the concern is that it might be possible to use a limitless number of markers to find differences between varieties at the genetic level that are not reflected in phenotypic characteristics.
>
> "On the above basis, UPOV has agreed the following uses of molecular markers in relation to DUS examination:
>
> "(a) Molecular markers can be used as a method of examining DUS characteristics that satisfy the criteria for characteristics set out in the General Introduction if there is a reliable link between the marker and the characteristic.
>
> "(b) A combination of phenotypic differences and molecular distances can be used to improve the selection of varieties to be compared in the growing trial if the molecular distances are sufficiently related to phenotypic differences and the method does not create an increased risk of not selecting a variety in the variety collection which should be compared to candidate varieties in the DUS growing trial.
>
> "The situation in UPOV is explained in documents TGP/15 'Guidance on the Use of Biochemical and Molecular Markers in the Examination of Distinctness, Uniformity and Stability (DUS)' and UPOV/INF/18 'Possible use of Molecular Markers in the Examination of Distinctness, Uniformity and Stability (DUS)'".

17. With regard to a wider audience, the TC agreed that the question was not framed in an appropriate way and, therefore, it would not be appropriate to seek to develop an answer to that question. The TC agreed that the question should be rephrased after clarification of the issues of interest to a wider audience.

18. The Council, at its thirty-first extraordinary session, held in Geneva, April 12, 2014, adopted the answers to the frequently asked questions (see document C(Extr.)/31/5 "Report on the Decisions", paragraph 15) including the FAQ as set out in paragraph 13 above.

19. The answers to Frequently Asked Questions are published on the website at http://www.upov.int/about/en/faq/.

20. The Annex to this document contains a copy of a presentation "Report on Developments in UPOV Concerning Biochemical and Molecular Techniques" to be made at its fourteenth session of the Working Group on Biochemical and Molecular Techniques and DNA-Profiling in particular (BMT).

21. The BMT is invited to note the report on developments concerning:

(a) documents UPOV/INF/18/1 "Possible use of Molecular Markers in the Examination of Distinctness, Uniformity and Stability (DUS)", TGP/15/1 "Guidance for Members of UPOV on Ongoing Obligations and Related Notifications and on the Provision of Information to Facilitate Cooperation" and UPOV/INF/17/1 "Guidelines for DNA-Profiling: Molecular Marker Selection and Database Construction ("BMT Guidelines")";

(b) discontinuation of the Ad Hoc *Subgroups on Biochemical and Molecular Techniques (Crop subgroups); and*

(c) development of an FAQ concerning the use of molecular techniques in the DUS examination.

[Annex follows]

ANNEX

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

Report on developments in UPOV concerning biochemical and molecular techniques

Seoul, Republic of Korea
November 10-13, 2014

Preview

- Developments in UPOV
- Developments concerning biochemical and molecular techniques

UPOV status in 2014

Members of UPOV (72)
Initiating States (16) and Organization (1)
States (24) and Organization (1) in contact with the UPOV Office

3

OAPI

(Organisation Africaine de la Propriété Intellectuelle)

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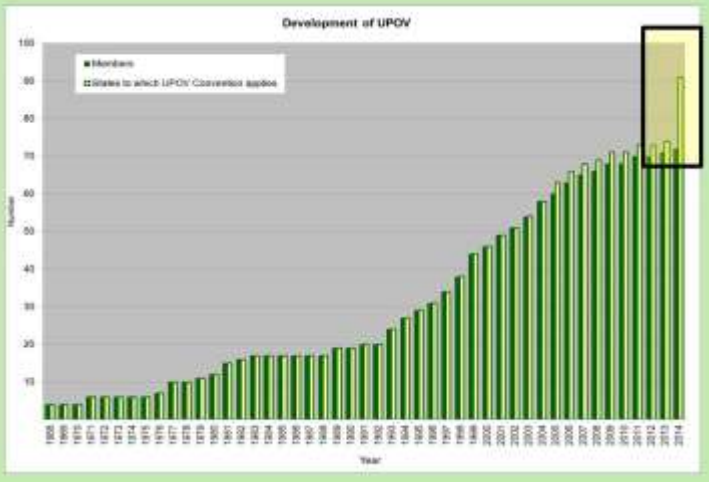
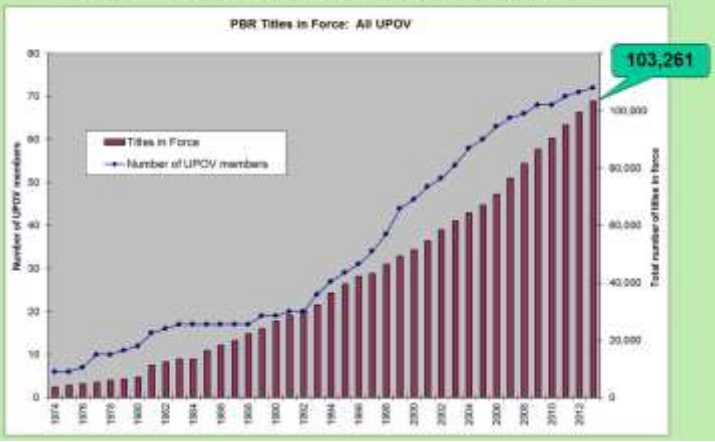


Plant variety protection statistics



Plant variety protection statistics

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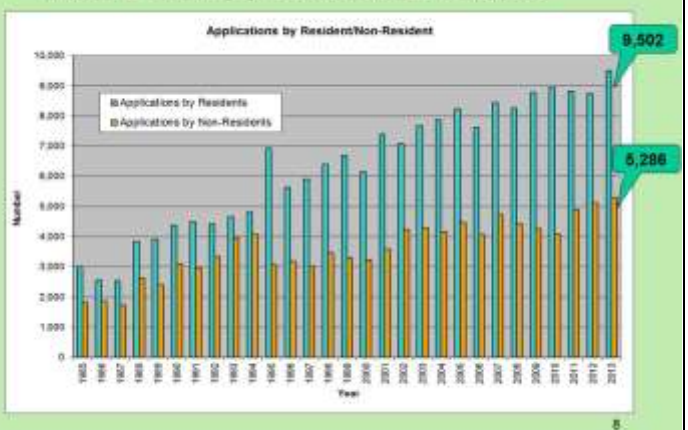
Plant variety protection statistics



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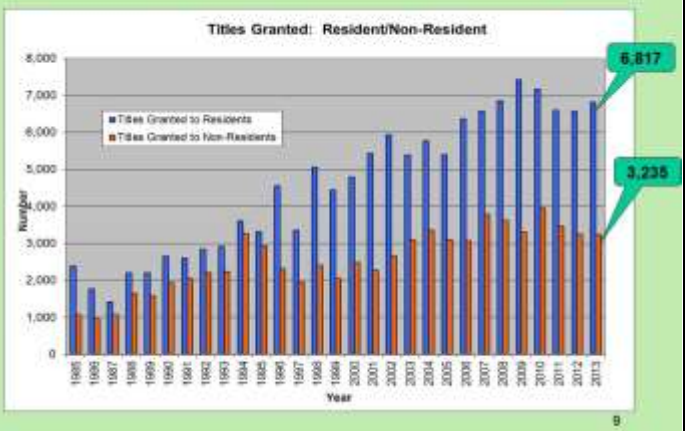
Plant variety protection statistics



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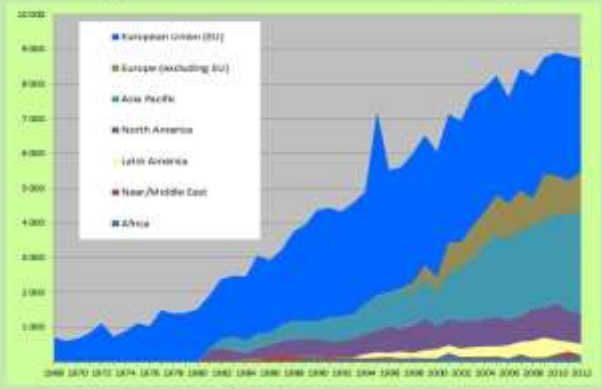
Development of Plant Variety Protection
Applications for Plant Breeders' Rights



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SITUATION in UPOV

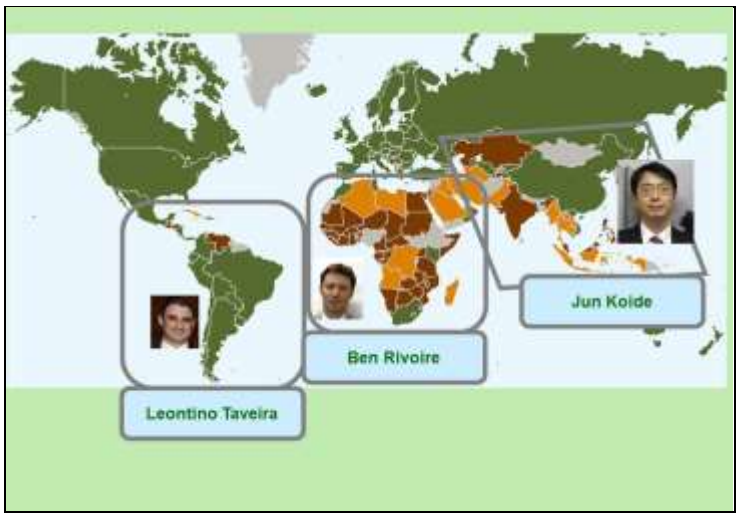
Examination of Laws

	Council session	Advice
Bosnia and Herzegovina (Law)	October 24, 2013	Positive
Draft ARIPO Protocol (African Regional Intellectual Property Organization)	April 11, 2014	Positive
Plant Breeders' Rights Act of Zanzibar	October 16, 2014	Positive

11

ARIPO
(African Regional Intellectual Property Organization)

12



Harmonization and Cooperation

	Harmonization	Cooperation	
PVP Law	• UPOV Convention • Explanatory Notes	• UPOV Lex	• Distance Learning course • UPOV events & activities • Assistance by individual UPOV members
IMPLEMENTATION ➢ Applications	• Model Application Form • Data standard	• EAF project	
➢ Variety Denomination	• INF/12: "Explanatory Notes on Variety Denominations" • UPOV Code	• PLUTO database	
➢ DUS Testing	• General Introduction • TGP Documents • Test Guidelines	• GENIE Database • Exchangeable software	

E

UPOV

UPOV/EXN/EDV/1
ORIGINAL: English
DATE: October 22, 2009

INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS
GENEVA

EXPLANATORY NOTES ON
ESSENTIALLY DERIVED VARIETIES
UNDER THE 1991 ACT OF THE UPOV CONVENTION

adopted by the Council
at its forty-third ordinary session
on October 22, 2009

Seminar on Essentially Derived Varieties (EDVs)

CLOSING REMARKS

Kitisri Sukhapinda
President of the Council of UPOV

Geneva, October 22, 2013

Session 1:
Technical and legal aspects of essentially derived varieties and the possible impact on breeding and agriculture

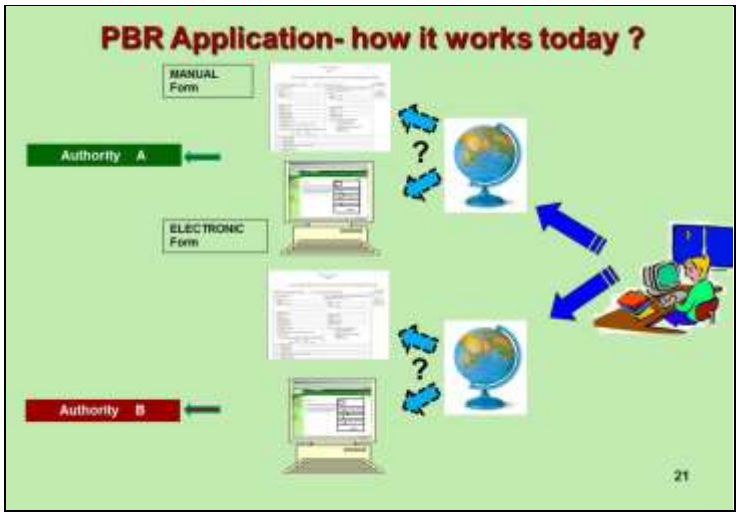
- The [1991] Diplomatic Conference requested the Secretary-General of UPOV to start work immediately after the Conference on the establishment of draft standard guidelines [...]
- Key elements of the guidelines on EDV were considered at 1992 Meeting with Intergovernmental Organizations (IOM/6/2) – and provide a good starting point for future work.
- Currently, genetic distance measurements are not well correlated with phenotypic differences.
- Guidelines would need to consider the situation in different crops/species and methods of breeding, e.g. mutants.
- Two possible starting points:
  - predominant derivation (genetic conformity)
  - essential characteristics (phenotype)
- Need to consider impact on breeders, including farmer-breeders, farmers, growers and society as a whole.

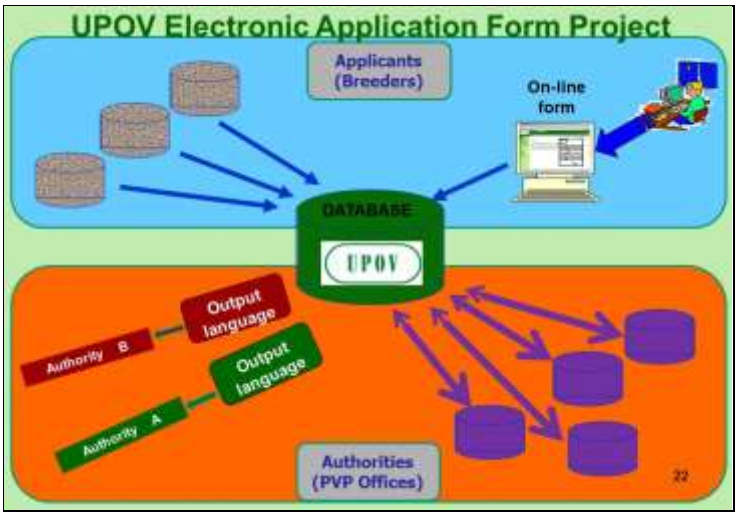
Session 2:
Experience in relation to essentially derived varieties

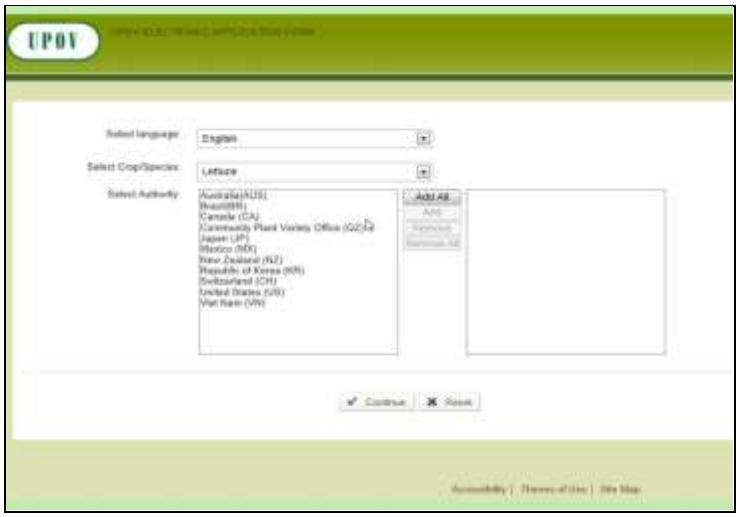
- Australian PBR law provides a workable "bright line" on EDV
- Japan: certain examples which may be considered as EDVs are provided, but it is a matter for the courts
- Court case experience in the Netherlands:
  - for a variety to be qualified an EDV the differences with the Initial Variety should not be more than one or very few inheritable characteristics (both in terms of genetics and phenotype)
  - breeders need clear guidance
- Court case experience in Israel:
  - if there exists a genetic or a morphological conformity between the two varieties, the assumption is that the defendant actually used the original variety to produce the EDV: this is only prima facie evidence, by which the burden of proof is shifted to the defendant, who now has to explain the suspicious conformity

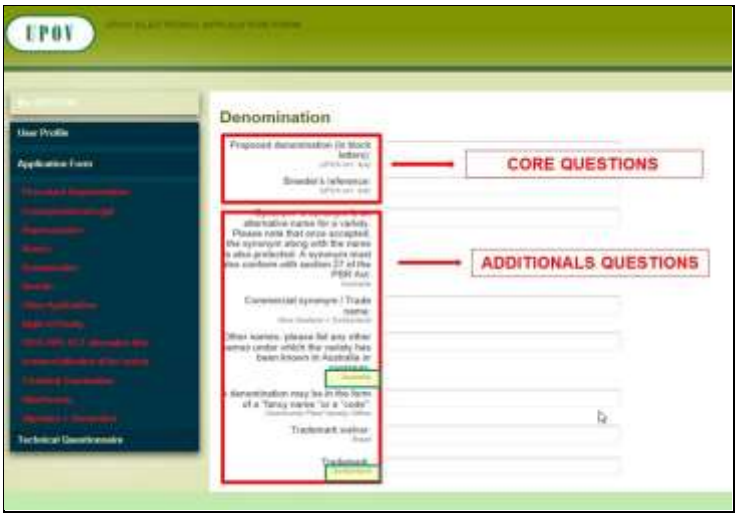
Session 3:
Possible role of future UPOV guidance on essentially derived varieties

- "Soft law" is an option, e.g. Guidelines.
- Guidelines that embrace a broad spectrum of stakeholders and interests may be more credible and persuasive for the Courts.
- The international standing of UPOV may help in the use of guidelines by Courts.
- Alternative Dispute Resolution (ADR) mechanisms - Mediation, Arbitration and/or Expert Determination - could be useful tools for EDV
- ISF and WIPO provide ADR options
- Publication of an anonymized summary of ADR outcomes could offer guidance and could lead to harmonization









Prototype Electronic Application Form

Participating UPOV members

- Argentina
- Australia
- Brazil
- Canada
- Colombia
- Dominican Republic
- Ecuador
- European Union
- France
- Germany
- Japan
- Mexico
- Netherlands
- New Zealand
- Paraguay
- Republic of Korea
- Switzerland
- United States of America
- Viet Nam
- (China)

Partners

- UPOV Office
- WIPO
- CPVO
- ISF
- CIOPORA

≥ 60% of the total applications within UPOV members

25

Preview

- Developments in UPOV
- Developments concerning biochemical and molecular techniques

Overview

- Use of biochemical and molecular markers in the examination of Distinctness, Uniformity and Stability (DUS)
- *Ad Hoc* Crop Subgroups on Molecular Techniques (Crop Subgroups)
- Frequently Asked Questions in molecular techniques (FAQ)

STATUS OF UPOV DOCUMENTS CONCERNING MOLECULAR TECHNIQUES

1. ADOPTED in OCT. 2010 (UPOV/INF/17) and OCT. 2011 (UPOV/INF/18)

Document reference	Title
UPOV/INF/17/1	Guidelines for DNA Profiling: Molecular Marker Selection and Database Construction ("BMT Guidelines")
UPOV/INF/18/1	Possible Use of Molecular Markers in the Examination of Distinctness, Uniformity and Stability

2. ADOPTED in OCT. 2013

Document reference	Title
TGP/15	Guidance on the Use of Biochemical and Molecular Markers in the Examination of Distinctness, Uniformity and Stability (DUS)

UPOV/INF/17/1 (INFormation document)

"Guidelines for DNA Profiling: Molecular Marker Selection and Database Construction ("BMT Guidelines")"

The purpose of this document (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 […]

UPOV/INF/18/1 (INFormation document)

"Possible Use of Molecular Markers in the Examination of Distinctness, Uniformity and Stability"

The purpose of this document is to provide guidance on the possible use of biochemical and molecular markers in the examination of Distinctness, Uniformity and Stability (DUS). […]

→ *Both documents have been **adopted and published on UPOV website**.*

UPOV/INF/18 POSSIBLE APPLICATION MODELS

MODELS WITH A POSITIVE ASSESSMENT

- Characteristic-specific molecular markers
- Combining phenotypic and molecular distances in the management of variety collections
- Calibrated molecular distances in the management of variety collections

MODELS WITHOUT A POSITIVE ASSESSMENT

- Use of molecular marker characteristics

TGP/15/1 (Technical Guidelines Protocol)

"Guidance on the Use of Biochemical and Molecular Markers in the Examination of Distinctness, Uniformity and Stability (DUS)"

The purpose of this document is to provide guidance on the use of biochemical and molecular markers in the examination of Distinctness, Uniformity and Stability (DUS) on the basis of the models in document UPOV/INF/18 that have received a positive assessment and for which accepted examples have been provided.

→ ***Adopted by the Council of UPOV in October, 2013.***

APPLICATION MODELS in TGP/15 (brown part)

MODELS WITH A POSITIVE ASSESSMENT

- Characteristic-specific molecular markers
- Combining phenotypic and molecular distances in the management of variety collections
- Calibrated molecular distances in the management of variety collections

MODELS WITHOUT A POSITIVE ASSESSMENT

- Use of molecular marker characteristics

APPLICATION MODEL: Characteristic-specific molecular markers

Molecular markers can be used as a method of examining DUS characteristics that satisfy the criteria for characteristics set out in the General Introduction (TGP/1), Chapter 4, section 4.2, on the following basis:

(a) the test for the marker is conducted on the same number of individual plants, with the same criteria for DUS as for the examination of the characteristic by a bioassay;

(b) there is verification of the reliability of the link between the marker and the characteristic;

APPLICATION MODEL: Characteristic-specific molecular markers (Cont.)

(c) different markers for the same characteristic are different methods for examining the same characteristic;

(d) markers linked to different genes conferring expression of the same characteristic are different methods for examining the same characteristic; and

(e) markers linked to different regulatory elements for the same gene conferring expression of the same characteristic are different methods for examining the same characteristic

(see TGP/15, Section 2.1)

APPLICATION MODEL: Combining phenotypic and molecular distances in the management of variety collections

A key feature of the process of eliminating varieties of common knowledge prior to the DUS growing trial is that the threshold is set with a suitable margin of safety. This threshold is termed the "Distinctness plus" threshold, which means that the distances between a candidate variety and "Distinct plus" varieties are robust enough to take a decision without direct comparison in the growing trial.

APPLICATION MODEL:
Combining phenotypic and molecular distances in the management of variety collections (Cont.)

A combination of phenotypic differences and molecular distances can be used to identify within the variety collection, those varieties which need to be compared with candidate varieties in order to improve the selection of "Distinct plus" varieties, on the following basis:

APPLICATION MODEL:
Combining phenotypic and molecular distances in the management of variety collections (Cont.)

(a) there is reliable information that the molecular distances are sufficiently related to phenotypic differences, such that

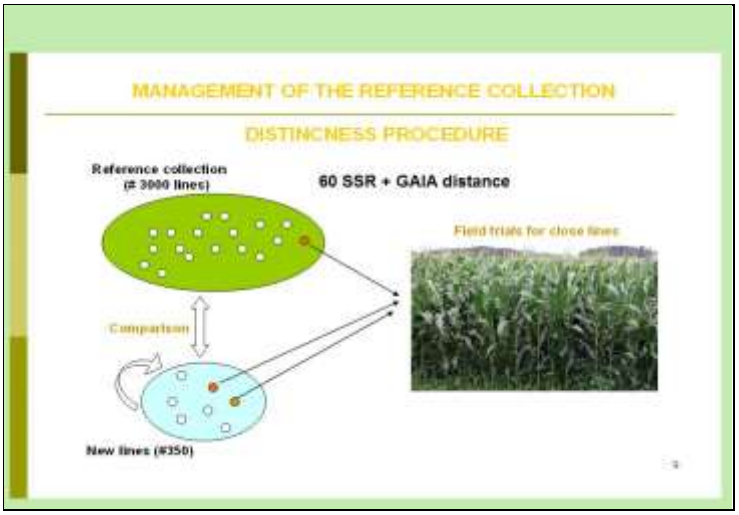
(b) the method selects varieties in the variety collection which are similar to the candidate varieties; and

(c) the method does not create an increased risk of not selecting a variety in the variety collection which needs to be compared to the candidate varieties in the field.

(see TGP/15 Section 2.2)

TGP/15 Annex II: Example of Parent Lines in Maize

The objective of this example is to develop an efficient tool, based on a combination of phenotypic and molecular distances, to identify within the variety collection, those varieties which need to be compared with candidate varieties in order to improve the selection of "distinct plus" varieties and so to limit the workload without decreasing the quality of the test. The challenge is to develop a secure system that:
(a) only selects varieties which are similar to the candidate varieties; and
(b) limits the risk of not selecting a variety in the variety collection which needs to be compared
in the field, especially when there is a large or expensive variety collection.



Visual assessment by maize crop experts:

Scale of similarity:

1. the two varieties are similar or very close

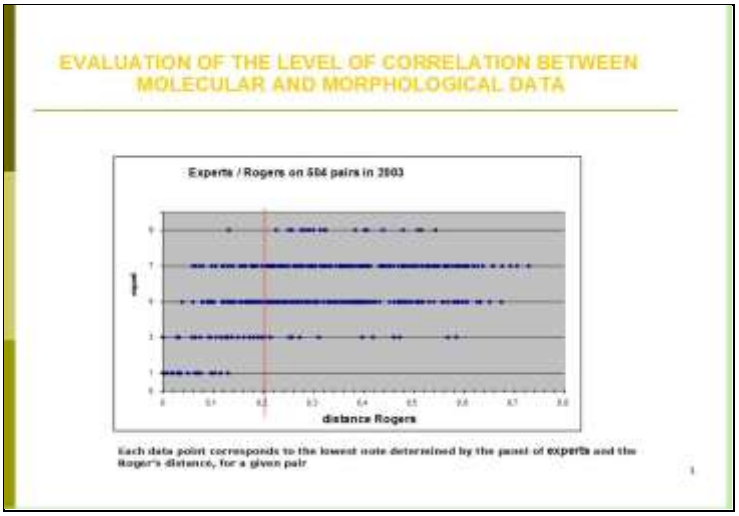
3. the two varieties are distinct but close

5. the comparison was useful, but the varieties are clearly distinct

7. the comparison should have been avoided because the varieties are very different

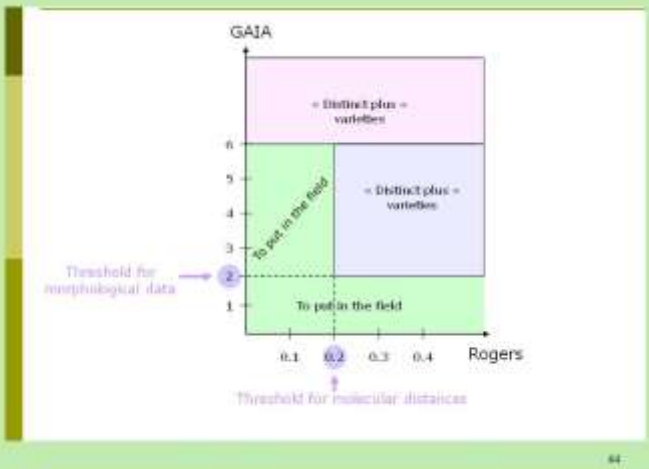
9. the comparison should have been avoided because the varieties are totally different

("even" notes are not used in the scale)



Over view

- Use of biochemical and molecular markers in the examination of Distinctness, Uniformity and Stability (DUS)
- *Ad Hoc* Crop Subgroups on Molecular Techniques (Crop Subgroups)
- Frequently Asked Questions in molecular techniques (FAQ)



Over view

- Use of biochemical and molecular markers in the examination of Distinctness, Uniformity and Stability (DUS)
- *Ad Hoc* Crop Subgroups on Molecular Techniques (Crop Subgroups)
- Frequently Asked Questions in molecular techniques (FAQ)

Crop Subgroups

- No meeting since BMT/12 (May 2010)
- No recommendation made at BMT/13 (November 2011)
- TC/48 (March 2012) agreed to discontinue

(see document TC/48/22 "Report on the Conclusions", paragraph 83)

Question: Does UPOV allow molecular techniques (DNA profiles) in the DUS examination?

- It is important to note that, in some cases, varieties may have a different DNA profile but be phenotypically identical, whilst, in other cases, varieties which have a large phenotypic difference may have the same DNA profile for a particular set of molecular markers (e.g. some mutations).
- In relation to the use of molecular markers that are not related to phenotypic differences, the concern is that it might be possible to use a limitless number of markers to find differences between varieties at the genetic level that are not reflected in phenotypic characteristics.

On the above basis, UPOV has agreed the following uses in relation to DUS examination:

Background

- TC/49 (March 2013) agreed the need to provide suitable information on the situation in UPOV with regard to the use of molecular techniques.
- CC/68 (October 2013) considered FAQs including "does UPOV allow molecular techniques (DNA profiles) in the DUS examination?".
- TC/50 and CAJ/69 (April 2014) agreed the FAQ.
- C(Extr.)/31 (April 2014) adopted FAQs

(see document C(Extr.)31/5 "Report on the Decisions", paragraph 15)

http://www.upov.int/about/en/faq/

Question: Does UPOV allow molecular techniques (DNA profiles) in the DUS examination?(Cont.)

The situation in UPOV is explained in documents TGP/15 'Guidance on the Use of Biochemical and Molecular Markers in the Examination of Distinctness, Uniformity and Stability (DUS)' and UPOV/INF/18 'Possible use of Molecular Markers in the Examination of Distinctness, Uniformity and Stability (DUS)'.

Question: Does UPOV allow molecular techniques (DNA profiles) in the DUS examination?(Cont.)

(a) Molecular markers can be used as a method of examining DUS characteristics that satisfy the criteria for characteristics set out in the General Introduction if there is a reliable link between the marker and the characteristic.

(b) A combination of phenotypic differences and molecular distances can be used to improve the selection of varieties to be compared in the growing trial if the molecular distances are sufficiently related to phenotypic differences and the method does not create an increased risk of not selecting a variety in the variety collection which should be compared to candidate varieties in the DUS growing trial.

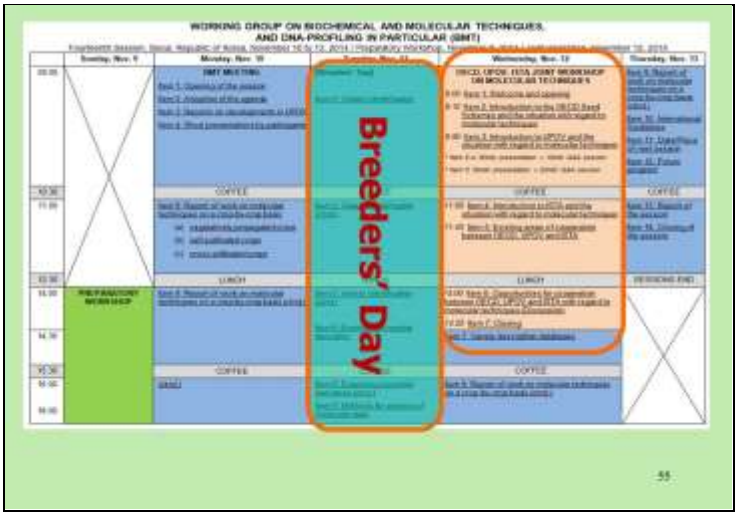
OECD-UPOV-ISTA

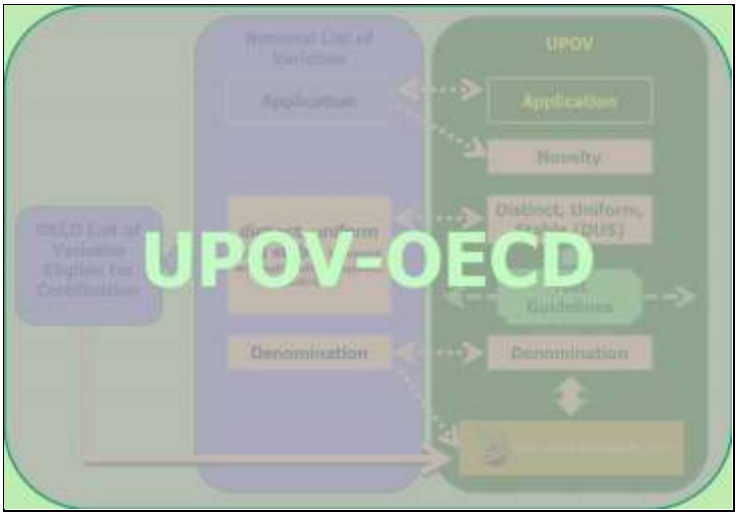
Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular (BMT)

To seek to organize a joint meeting of UPOV BMT in 2014 with ISO, ISTA and OECD and including breeders

Q & A for a wider audience

•The CC agreed that the draft FAQ concerning information on the situation in UPOV with regard to the use of molecular techniques for a wider audience, including the public in general, should be referred to the TC for consideration.





[End of Annex and of document]