REPORT 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

The Annex of this document contains a copy of a presentation “Report on Developments in UPOV concerning Biochemical and Molecular Techniques” to be made by the Office of the Union at the eighteenth session of the Working Group on Biochemical and Molecular Techniques, and DNA-Profiling in Particular.

[Annex follows]
BMT/18/2

ANNEX

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

Report on developments in UPOV
concerning
Biochemical and Molecular Techniques

Office of the Union

Hangzhou, China, October 16 to 18, 2019

Preview

Developments in UPOV:

• General
  – Membership & statistics
  – Calendar UPOV meetings 2019
  – Communicating the benefits of UPOV

• Biochemical and molecular techniques
  – Current guidance
  – Developments since BMT/17 in 2018
  – The Concept of Essentially Derived Varieties
  – The Role of UPOV in Variety Identification

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Preview

Developments in UPOV:

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UPOV Membership

The boundaries shown on this map do not imply the expression of any opinion whatsoever on the part of UPOV concerning the legal status of any country or territory.

1991 Act: 58 members
Other Acts: 17 members
[94 States covered by UPOV Convention]
First Examination of Laws by the Council by correspondence

Positive decision on the Draft Law of Nigeria

The Council took a positive decision on the conformity of the “Plant Variety Protection Bill of Nigeria” (“Draft Law”) with the 1991 Act of UPOV Convention, which allows Nigeria once the Draft Law is adopted with no changes and the Law is in force, to deposit its instrument of accession to the 1991 Act.

Positive decision on the Draft Law of Saint Vincent and the Grenadines

The Council took a positive decision on the conformity of the “Plant Breeders’ Protection Bill 2019 of Saint Vincent and the Grenadines” (“Draft Law”) with the 1991 Act of the UPOV Convention, which allows Saint Vincent and the Grenadines once the Draft Law is adopted with no changes and the Law is in force, to deposit its instrument of accession to the 1991 Act.
Examination of Laws by the Council (53rd session)

UPOV STATUS
on October 6, 2019

The boundaries shown on this map do not imply the expression of any opinion whatsoever on the part of UPOV concerning the legal status of any country or territory.

- Members of UPOV (75) (covering 94 States)
- Initiating States (20) and Organization (1)
- States (23) and Organization (1) in contact with the UPOV Office

Plant variety protection statistics (C/52/7 Rev.)

Applications filed and Titles granted (total = Resident and Non-Resident)

- Application filed (total)
- Titles granted (total)

Number

Year

Applications filed (total) = 18,306
Titles granted (total) = 12,685
Developments in UPOV:

- **General**
  - Membership & statistics
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- **Biochemical and molecular techniques**
  - Current guidance
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### Draft Schedule of the UPOV Technical Working Party on Automation and Computer Programs (TCP), Thirty-Seventh Session and The Working Group on Biochemical and Molecular Techniques, and DNA-profiling in particular (BMT), Eighteenth Session, Hangzhou, China

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Cooperation between the TWC and BMT

The TC received the following proposal from the Chairpersons of the TWC and BMT for matters to be considered on Wednesday, September 16, 2019, in order to facilitate discussion and cooperation between the TWC and BMT. The TC noted that the TWC would meet on the morning of September 16 and the BMT would meet later that day and the items below would be considered at the TWC or BMT session as appropriate.

Seminar on the impact of policy on essentially derived varieties (EDVs) on breeding strategy
To be held in Geneva, on the morning of October 30, 2019

Welcome address and opening

SESSION I: TO AN EDV CONCEPT FOR THE PRESENT AND THE FUTURE
- Plant breeding and the EDV concept: challenges of the past, opportunities for the future?
- UPOV guidance on EDV

SESSION II: IMPACT OF EDV CONCEPT ON PLANT BREEDING
- Outlook for agricultural crops
- Outlook for ornamental plants
- Outlook for vegetables
- Outlook for fruit
- Panel discussion and questions

Closing remarks
Developments in UPOV:

• General
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Celebration of the twentieth anniversary of the accession of China to UPOV Convention

Languages available: EN audio
Subtitles: EN

UPOV Videos

(Uruguay) New variety pest...
Canadian cherry grower David Machal has changed his mind about paying royalties. He argues it is very uncomfortable about paying because it pays for new cherry varieties “that I can be successful with in the future.”

@upov
@KPION!

David Machal
Head of Variety Development,
Prize Fruits, BC, Canada

The UPOn Union is pleased to announce the publication of the TWV report. Thanks to all participants for attending the meeting in Seoul. Here is where they came from (see upov/ann/18/12/12).

@upov
@KPION!

Peter Button
@upov

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@upov
@KPION!
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STATUS OF UPOV DOCUMENTS CONCERNING MOLECULAR TECHNIQUES

<table>
<thead>
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<th>Document reference</th>
<th>Title</th>
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<td>Guidance on the Use of Biochemical and Molecular Markers in the Examination of Distinctness, Uniformity and Stability (DUS) (2013)</td>
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<td>UPOV/INF/18/1</td>
<td>Possible Use of Molecular Markers in the Examination of Distinctness, Uniformity and Stability (2011)</td>
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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 […].

FAQ

FAQ: 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:
FAQ: 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.

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.
Model 1: Characteristic-specific molecular markers

*Example: gene specific marker for herbicide tolerance introduced by genetic modification*

On the basis that:

[...]

- there is verification of the reliability of the link between the marker and the characteristic;

- different markers for the same characteristic are different methods for examining the same characteristic;

[...]
Preview

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Review of BMT Guidelines

• UPOV/INF/17 “Guidelines for DNA-Profiling: Molecular Marker Selection and Database Construction (‘BMT Guidelines’)”

• Revisions were proposed on basis of joint comments provided by EU, France and the Netherlands
  - a number of deletions, additions and editorial changes
Proposed changes to BMT Guidelines

• In particular:
  - delete section 1 “Selection of Molecular Marker Methodology”
  - add new section 2 “Phase 2: Selection of the Detection Method”
  - do not add New Section 6: Phase 4: Database Management”
  - do not add New Section C: “Definitions”

• TC/54 agreed with the proposal BMT/17, for the EU, France and the Netherlands to prepare a new draft of UPOV/INF/17 for consideration at the BMT/18

⇒ To be considered under the agenda item 10: Review of document UPOV/INF/17

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**Inclusion of a new model “Genetic selection of similar varieties for the first growing cycle”**

The TC, at its fifty-fourth session, agreed with the inclusion of a new model “Genetic selection of similar varieties for the first growing cycle: example French Bean” in document TGP/15 on the basis of the proposal by the Netherlands [...] 

A draft of document TGP/15/2 incorporating the new model “Genetic selection of similar varieties for the first growing cycle: example French Bean” will be presented to the seventy-sixth session of the Administrative and Legal Committee (CAJ) [...] 

Subject to agreement by the CAJ at its seventy-sixth session, a draft of document TGP/15/2 will be presented for adoption by the Council, at its fifty third ordinary session
New Model 3: Genetic selection of similar varieties for the first growing cycle

Start

DNA profiling

DNA similarities

First selection

Check morphological database

discard on Qi grouping chars only

(shown) list of varieties to be put in field trial (1st cycle)

BMT/18/2
Annex, page 19
Fusarium race 0 ex 1

<table>
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<th>UPOV characteristics</th>
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⇒ To be considered at BMT/18 under the agenda item 14 “Revision of document TGP/15”

**Session to facilitate cooperation**

At the BMT/17, **Discussion groups** had been formed for: maize and soybeans; other agricultural crops; fruit crops and forest trees; ornamental plants; and vegetables, for BMT participants to exchange information on their work and explore areas for cooperation.

The TC/54 agreed that the results of the coordination session in the BMT be reported to the other Technical Working Parties (TWPs). The TC agreed to invite the **TWPs** to undertake a similar session to **build on the BMT outcomes** and **feed into the future work of the BMT**. The TC agreed that discussion groups should be formed for the main crops at **each TWP** to allow participants to exchange information on their work and explore areas for cooperation.

⇒ To be considered under the agenda item 15 “Session to facilitate cooperation”
**Cooperation between international organizations**

The TC/54 agreed that UPOV and OECD should make progress on the matters previously agreed by the TC, namely:

(a) to develop a joint document explaining the principal features of the systems of the OECD, UPOV and ISTA;

(b) to develop an inventory on the use of molecular marker techniques, by crop, with a view to developing a joint OECD/UPOV/ISTA document containing that information, in a similar format to UPOV/INF/16 “Exchangeable Software”, subject to the approval of the Council and in coordination with OECD and ISTA; and

(c) the BMT to develop lists of possible joint initiatives with OECD and ISTA in relation to molecular techniques for consideration by the TC.

⇒ To be considered under the agenda item 6 “Cooperation between international organizations”

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ESSENTIALLY DERIVED VARIETIES

• Purpose and concept
• Protection of EDVs
• Protection of Initial Variety
• Implementation
• UPOV guidance

PURPOSE:
to ensure sustainable progress in plant breeding development by:
  – providing effective protection for the breeder and
  – encouraging cooperation between breeders and developers of new technologies such as genetic modification
**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
ESSENTIALLY DERIVED VARIETIES

...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.

ESSENTIALLY DERIVED VARIETIES

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

• Purpose and concept
• Protection of EDVs
  • Protection of Initial Variety
  • Implementation
  • UPOV guidance

Can EDVs be protected?

YES

same conditions (novelty, DUS)

Can EDVs be commercialized?

authorization of the
PBR holder of the INITIAL VARIETY
and
PBR holder of EDV required

AUTHORIZATION NEEDED
ESSENTIALLY DERIVED VARIETIES

- Purpose and concept
- Protection of EDVs
- Protection of Initial Variety
- Implementation
- UPOV guidance

Initial Variety 'A' (Protected)

Authorization to commercialize variety B REQUIRED

Essentially Derived Variety 'B'

Commercialization

Breeder 1

Predominantly derived

- predominantly derived from ‘A’
- retains expression of essential chars. of ‘A’
- clearly distinguishable from ‘A’
- conforms to ‘A’ in essential chars. (except for differences from act of derivation)

Breeder 2

Commercialization

51

52
ESSENTIALLY DERIVED VARIETIES

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

INITIAL variety is not restricted to PROTECTED variety

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**ESSENTIALLY DERIVED VARIETIES**

- Predominantly derived from ‘A’
- Retains expression of essential chars. of ‘A’
- Clearly distinguishable from ‘A’
- Conforms to ‘A’ in essential chars. (except for differences from act of derivation)

Breeder 1

**Initial Variety ‘A’**
(Not protected)

Authorization to commercialize variety B
NOT required

Commercialization

Breeder 2

Essentially Derived Variety ‘B’
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
ESSENTIALLY DERIVED VARIETIES

Breeder 1
Initial Variety ‘A’ (Protected)

Authorization to commercialize variety C
REQUIRED

Breeder 2
Essentially Derived Variety ‘B’ (Protected)

Predominantly derived

Breeder 3
Essentially Derived Variety ‘C’

Authorization to commercialize variety C
NOT required

Commercialization

ESSENTIALLY DERIVED VARIETIES

Breeder 1
Initial Variety ‘A’ (NOT protected)

Authorization to commercialize variety C
NOT required

Breeder 2
Essentially Derived Variety ‘B’ (Protected)

Predominantly derived

Breeder 3
Essentially Derived Variety ‘C’

Authorization to commercialize variety C
NOT required

Commercialization
ESSENTIALLY DERIVED VARIETIES

Initial Variety ‘A’
(PROTECTED)
bred and protected by Breeder 1

Commercialization: authorization of

Essentially Derived Variety ‘B’
bred and protected by Breeder 2
- predominantly derived from ‘A’
- retains expression of essential characteristics of ‘A’
- clearly distinguishable from ‘A’
- conforms to ‘A’ in essential characteristics
  (except for differences from act of derivation)

Commercialization: authorization of
Breeder 1 and 2 required

Essentially Derived Variety ‘C’
bred and protected by Breeder 3
- predominantly derived from ‘A’ or ‘B’
- retains expression of essential characteristics of ‘A’
- clearly distinguishable from ‘A’
- conforms to ‘A’ in essential characteristics
  (except for differences from act of derivation)

Commercialization: authorization of
Breeder 1 and 3 required
(authorization of Breeder 2 not required)

Commercialization:
authorization of
Breeder 3 required
(authorization of Breeders 1 and 2 not required)

ESSENTIALLY DERIVED VARIETIES

Initial Variety ‘A’
(NOT PROTECTED)
bred and protected by Breeder 1

Commercialization: authorization of

Essentially Derived Variety ‘B’
bred and protected by Breeder 2
- predominantly derived from ‘A’
- retains expression of essential characteristics of ‘A’
- clearly distinguishable from ‘A’
- conforms to ‘A’ in essential characteristics
  (except for differences from act of derivation)

Commercialization:
Breeder 2 required
(authorization of Breeder 1 not required)

Essentially Derived Variety ‘C’
bred and protected by Breeder 3
- predominantly derived from ‘A’ or ‘B’
- retains expression of essential characteristics of ‘A’
- clearly distinguishable from ‘A’
- conforms to ‘A’ in essential characteristics
  (except for differences from act of derivation)

Commercialization:
Breeder 3 required
(authorization of Breeders 1 and 2 not required)
ESSENTIALLY DERIVED VARIETIES

• Purpose and concept
• Protection of EDVs
• Protection of Initial Variety
• **Implementation**
  
  – 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 guidance**
UPOV/EXN/EDV/2

ESSENTIALLY DERIVED VARIETY?

(Photos: stockphoto/valestrait)

Preview

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  – Communicating the benefits of UPOV

• Biochemical and molecular techniques
  – Current guidance
  – Developments since BMT/17 in 2018
  – The Concept of Essentially Derived Varieties
  – 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

• UPOV does not directly address variety identification - it is concerned with distinctness (related but not the same);

• The variety description can play a role in variety identification
Variety description developed at the time of the grant of the breeder’s right (original variety description)

Purposes:
(a) to describe the characteristics of the variety; and
(b) to identify and list similar varieties and differences from these varieties;

combined with the information on the basis for (a) and (b), namely:

- Date and document number of UPOV Test Guidelines;
- Date and/or document number of Reporting Authority’s test guidelines;
- Reporting Authority;
- Testing station(s) and place(s);
- Period of testing;
- Date and place of issue of document;
- Group: (Table: Characteristics; States of Expression; Note; Remarks);
- Additional Information:
  (a) Additional Data
  (b) Photograph (if appropriate)
  (c) RHS Colour Chart version used (if appropriate)
  (d) Remarks
Status in relation to the verification of the conformity of plant material to a protected variety for enforcement of the breeder’s right:

“While the UPOV Convention requires members of the Union to provide for appropriate legal remedies for the effective enforcement of breeders’ rights, it is a matter for breeders to enforce their rights.” (UPOV/EXN/ENF/1)

the description of the variety characteristics and the basis for distinctness from the most similar variety are linked to the circumstances of the DUS examination, namely:

- Date and document number of UPOV Test Guidelines;
- Date and/or document number of Reporting Authority’s test guidelines;
- Reporting Authority;
- Testing station(s) and place(s);
- Period of testing;
- Date and place of issue of document;
- Group: (Table: Characteristics; States of Expression; Note; Remarks);
- Additional information:
  - (a) Additional Data
  - (b) Photograph (if appropriate)
  - (c) RHS Colour Chart version used (if appropriate)
  - (d) Remarks

Variety description developed at the time of the grant of the breeder’s right (Continued)

(original variety description)

[End of Annex and of document]