BMT/15/2
ORIGINAL: English
DATE: April 26, 2016

INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS

Geneva

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

Fifteenth Session

Moscow, Russian Federation, May 24 to 27, 2016

REPORTS ON DEVELOPMENTS IN UPOV CONCERNING BIOCHEMICAL AND MOLECULAR TECHNIQUES

Document prepared by the Office of the Union

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EXECUTIVE SUMMARY

1. The purpose of this document is to report on developments in UPOV concerning biochemical and molecular techniques.

2. The BMT is invited to note The BMT is invited to note the developments on molecular techniques in the TC and the TWPs, as set out in this document.

3. 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
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
TWPs:	Technical Working Parties
TWV:	Technical Working Party for Vegetables

4. The structure of this document is as follows:

DEVELOPMENTS IN 2015

Technical Committee

5. The TC, at its fifty-first session, held in Geneva, from March 23 to 25, 2015, received the following presentations on molecular techniques (in order of presentation) (see document TC/51/39 "Report", paragraph 172):

Reports on developments in UPOV Concerning Biochemical and Molecular Techniques	UPOV Office
Marker-Assisted Selection of "Similar Variety" in DUS Testing	Republic of Korea (Mr. Seung-In Yi)
The Use of Reference Varieties in Varietal Distinctness: An Approach under Investigation in the United States of America for Potential Application in Plant Variety Protection	United States of America (Mr. Paul Nelson)
A European Potato Database as Centralized Collection of Varieties of Common Knowledge	United Kingdom (Mr. Alex Reid)
Development of EST-SSR Markers of Lettuce and Application for Variety Identification	Republic of Korea (Mr. Seung-In Yi)
Ownership and Use of DUS Samples and of DNA and DNA Data During and After the DUS Tests	Netherlands (Mr. Kees van Ettekoven)
Existing Areas of Cooperation Between OECD, UPOV and ISTA	UPOV Office

6. The TC, at its fifty-first session, noted that a copy of the presentations would be made available on the UPOV website (see document TC/51/39 "Report", paragraph 173).

7. The TC, at its fifty-first session, considered document TC/51/11 Rev. "Molecular techniques" (see document TC/51/39 "Report", paragraph 174). The TC noted the report on developments in the TC, TWPs and BMT, as set out in paragraphs 4 to 22 of document TC/51/11 Rev. (see document TC/51/39 "Report", paragraph 175). The TC approved the program for the fifteenth session of the BMT, to be held in 2016, including the dedication of a particular date ("Breeders' Day"), for the items on the use of molecular techniques in the consideration of essential derivation and in variety identification (see document TC/51/39 "Report", paragraph 176).

Technical Working Parties

8. The TWC, at its thirty-third session, held in Natal, Brazil from June 30 to July 2, 2015, noted an oral report by Mr. Kees van Ettekoven, Chairman of the BMT, highlighting the developments on molecular techniques presented at the fourteenth session of the BMT, held in Seoul, Republic of Korea from November 10 to 13, 2014, in particular: a presentation by the Republic of Korea (see document BMT/14/16 Rev.2 "Use of Molecular Marker Techniques for Selection of 'Similar Variety' about 'Candidate Variety"); the United States of America (see documents BMT/14/5 and BMT/14/5 Add. "The Use of Reference Varieties in Varietal Distinctness: An Approach under Investigation in the United States of America for Potential Application in Plant Variety Protection"); the Netherlands (see Document BMT/14/11 "Ownership and Use of DUS Samples and of DNA and DNA Data During and After the DUS Tests") and on cooperation between UPOV, OECD and ISTA on molecular techniques (see document TC/52/11 "Molecular Techniques", paragraph 6).

9. The TWF, at its forty-sixth session, held in Mpumalanga, South Africa, from August 24 to 28, 2015, noted that molecular marker techniques were being used by many UPOV members for variety identification and were an important tool in cases of enforcement of plant breeder's rights (PBR). The TWF agreed that it would be useful to provide information to a wider audience that molecular marker techniques were widely used in the context of PBR for variety identification and enforcement of the breeder's rights (see document TC/52/11 "Molecular Techniques", paragraph 7).

10. The TWF noted that France had been using molecular distances in combination with phenotypical distance for optimizing the size of trials in fruit crops since 2000. The TWF agreed that molecular markers also provided useful information on species for which the authorities did not hold standard samples of living material (see document TC/52/11 “Molecular Techniques”, paragraph 8).

11. The TWF noted that in many UPOV members, breeders were requesting authorities to accept molecular marker information with applications for plant breeders’ rights. The TWF noted that authorities did not require molecular marker information with the application for plant breeder’s rights although some authorities accepted it as complementary information. The TWF noted the concern expressed by some members on matters relating to the confidentiality of molecular marker information and whether such information could be made available to the public. (see document TC/52/11 “Molecular Techniques”, paragraph 9).

12. The TWO, at its forty-eighth session, held in Cambridge, United Kingdom, from September 14 to 18, 2015, noted that some breeders were providing molecular marker information with applications for plant breeders’ rights and agreed that unless the information was validated by the authorities it would not have a proven link to the material used in the examination of DUS (see document TC/52/11 “Molecular Techniques”, paragraph 10).

DEVELOPMENTS IN 2016

13. The TC, at its fifty-second session, held in Geneva, from March 14 to 16, 2016, noted that the BMT agenda item 5 “Report of work on molecular techniques in relation to DUS examination” would provide an opportunity for UPOV members to report on latest developments concerning the use of molecular techniques in DUS examination, and that this could form the basis to propose new application models for inclusion in document TGP/15 “Guidance on the Use of Biochemical and Molecular Markers in the Examination of Distinctness, Uniformity and Stability (DUS)” (see document TC/52/29 “Report”, paragraph 132).

14. The TC, at its fifty-second session, noted that the European Union was conducting a project on the use of molecular marker techniques in DUS examination in different crops (see document TC/52/29 “Report”, paragraph 133).

FREQUENTLY ASKED QUESTIONS

15. The Consultative Committee, at its eighty-eighth session, held in Geneva, on October 15, 2014, 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 (see document C/48/19 “Report by the President on the work of the eighty-sixth session of the Consultative Committee; adoption of recommendations, if any, prepared by that Committee”, paragraph 48).

16. The TC, at its fifty-second session, agreed a draft question and answer concerning the information on the situation in UPOV with regard to the use of molecular techniques for a wider audience, including the public in general, to read as follows (see document TC/52/29 “Report”, paragraph 131):

> “Is it possible to obtain protection of a variety on the basis of its DNA-profile?
>
> “For a variety to be protected, it needs to be clearly distinguishable from all existing varieties on the basis of characteristics that are physically expressed, e.g. plant height, time of flowering, fruit color, disease resistance etc. The DNA-profile is not the basis for obtaining the protection of a variety, although this information may be used as supporting information.
>
> “A more detailed explanation is provided in the FAQ ‘Does UPOV allow molecular techniques (DNA profiles) in the examination of Distinctness, Uniformity and Stability (“DUS”)?’
>
> “See also:
> “What are the requirements for protecting a new plant variety?”

17. Subject to agreement by the CAJ, at its seventy-third session, to be held in Geneva, on October 25, 2016, and the Consultative Committee, at its ninety-second session, to be held in Geneva, on October 27, 2016, the draft question and answer concerning the information on the situation in UPOV with regard to the use of molecular techniques for a wider audience, including the public in general will be presented for adoption by the Council, at its fiftieth ordinary session, to be held in Geneva on October 28, 2016.

18. The BMT is invited to note the developments on molecular techniques in the TC and the TWPs, as set out in this document.

[Annex follows]

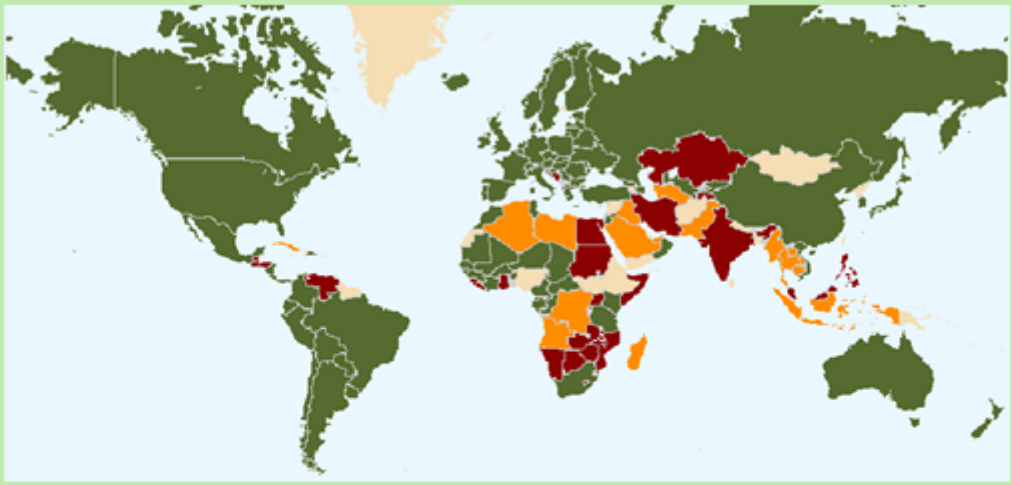
Working Group on
Biochemical and Molecular Techniques
and DNA-Profiling in Particular (BMT)
Fifteenth Session

Report on developments in UPOV concerning biochemical and molecular techniques

Moscow, Russian Federation
May 24-27, 2016

Preview

- Developments in UPOV
- Developments concerning biochemical and molecular techniques



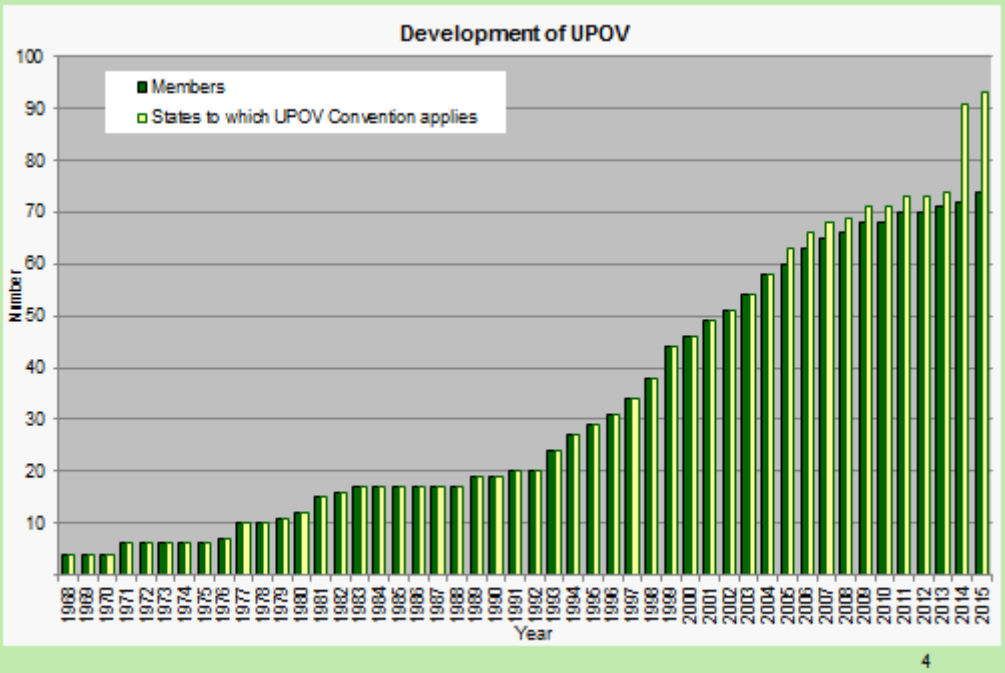
The boundaries shown on this map do not imply the expression of any opinion whatsoever on the part of UPOV concerning the legal status of any country or territory

Members of UPOV (74)

Initiating States (15) and Organization (1)

States (23) and Organization (1) in contact with the UPOV Office

3



4

Development of UPOV since BMT/14

New members:

- Montenegro (September 24, 2015)
- The United Republic of Tanzania (November 22, 2015)

Ratification of the 1991 Act:

- Canada (July 19, 2015)

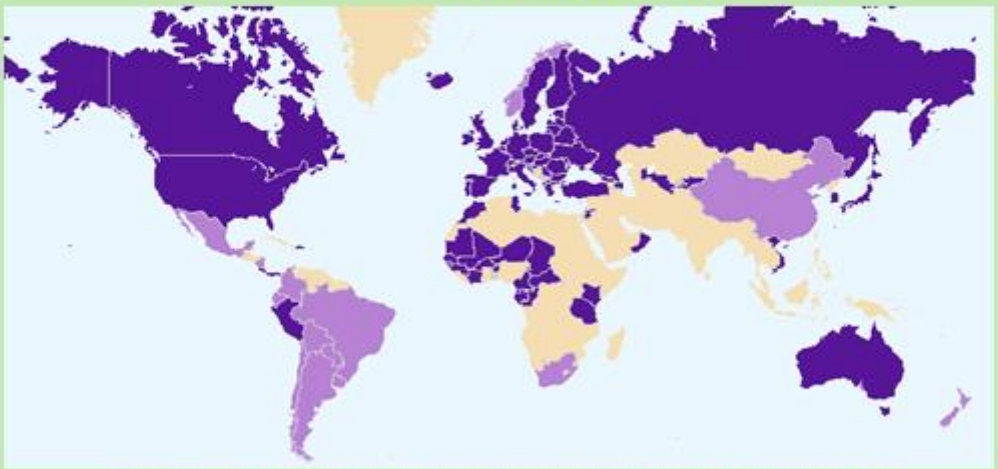
Accession to the 1991 Act:

- Kenya (April 11, 2016)

5

UPOV membership 2016
Territories covered

1991 Act: 56 members – Other Acts: 18 members



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

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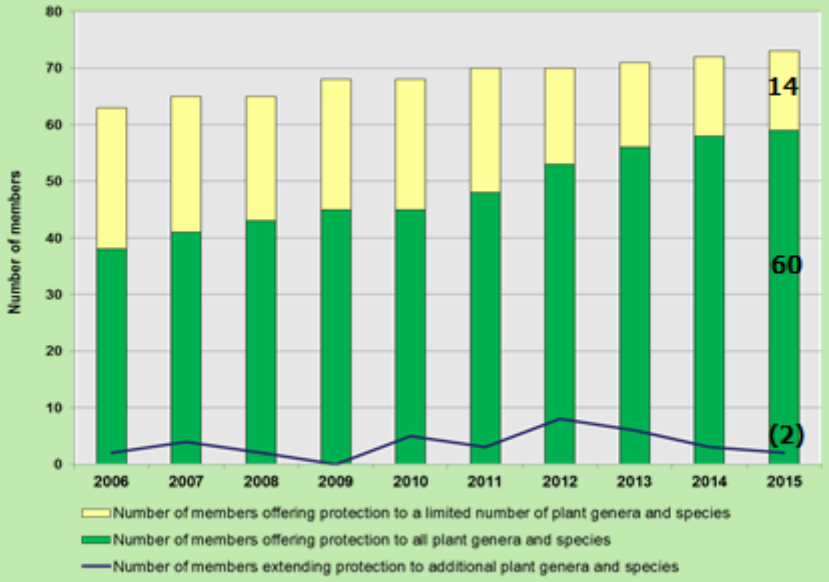
Taxa protected by the members of the Union (C/49/6)



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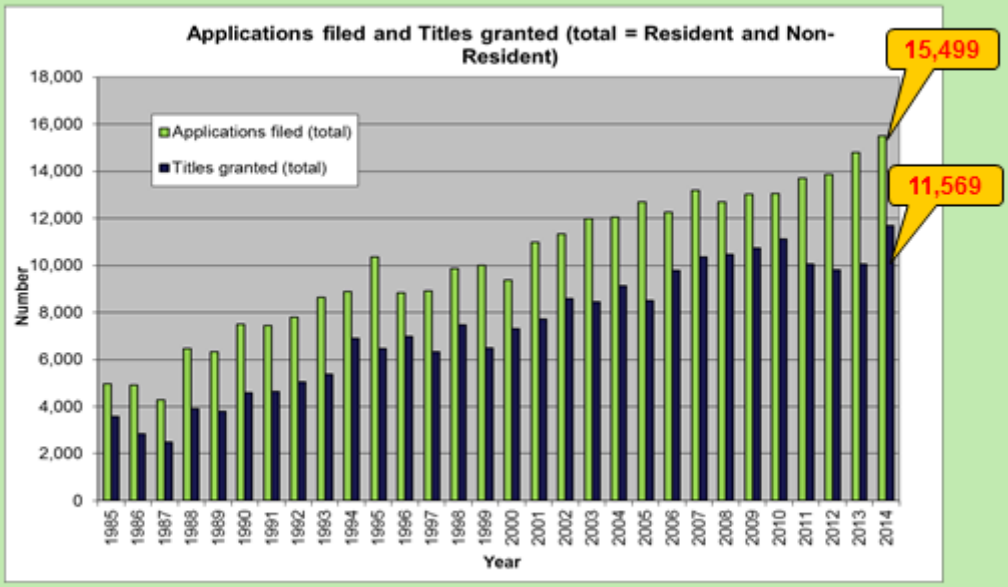
Applications filed / Titles granted (document C/49/7)



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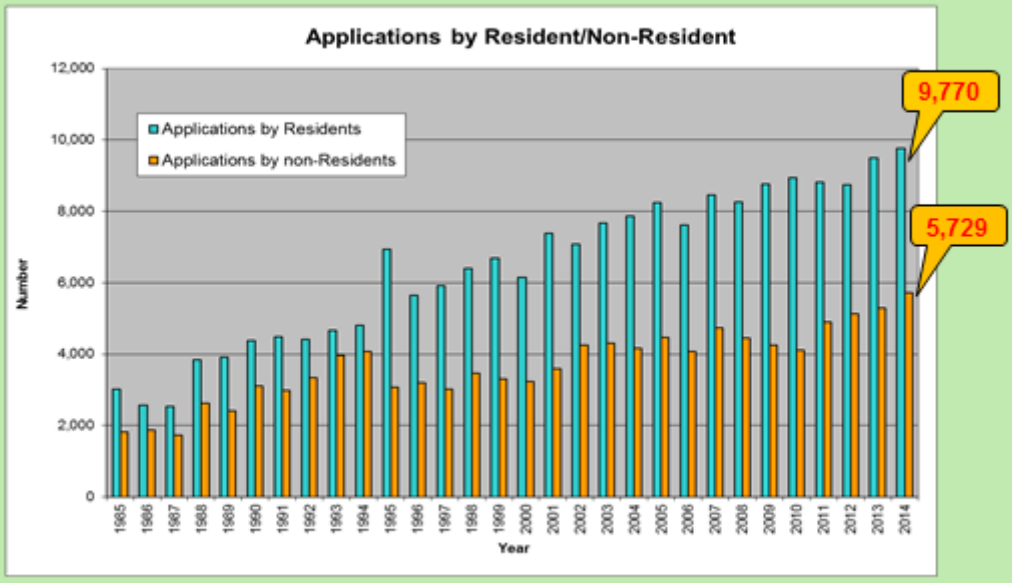
Applications by resident / non-resident (document C/49/7)



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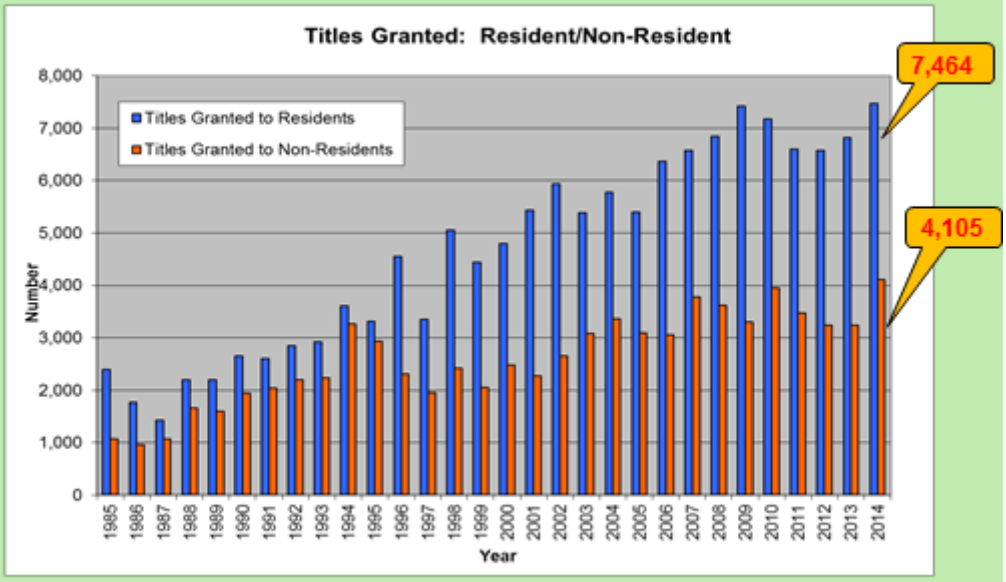
Titles granted by Resident / Non-Resident (document C/49/7)



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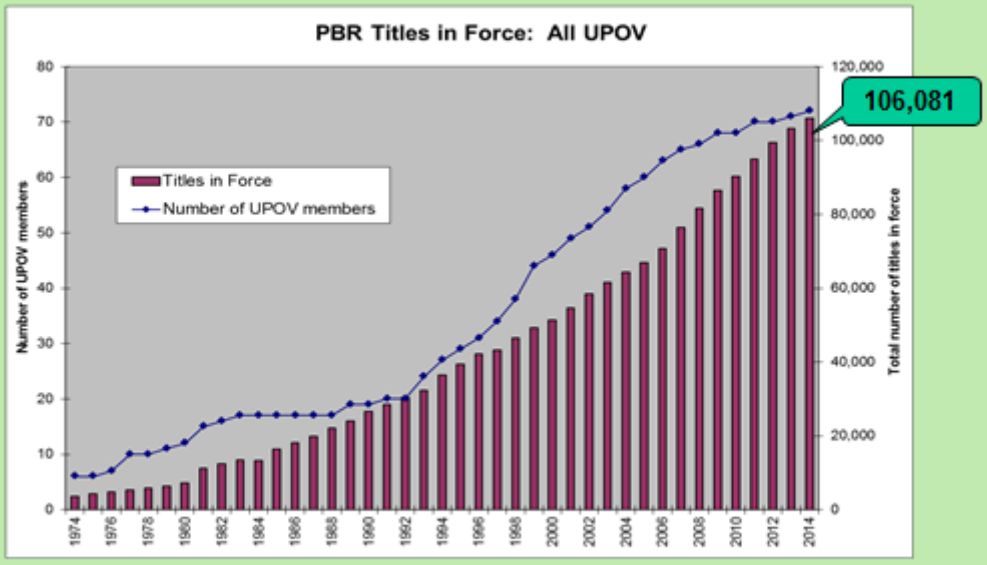
Titles in Force (document C/49/7)



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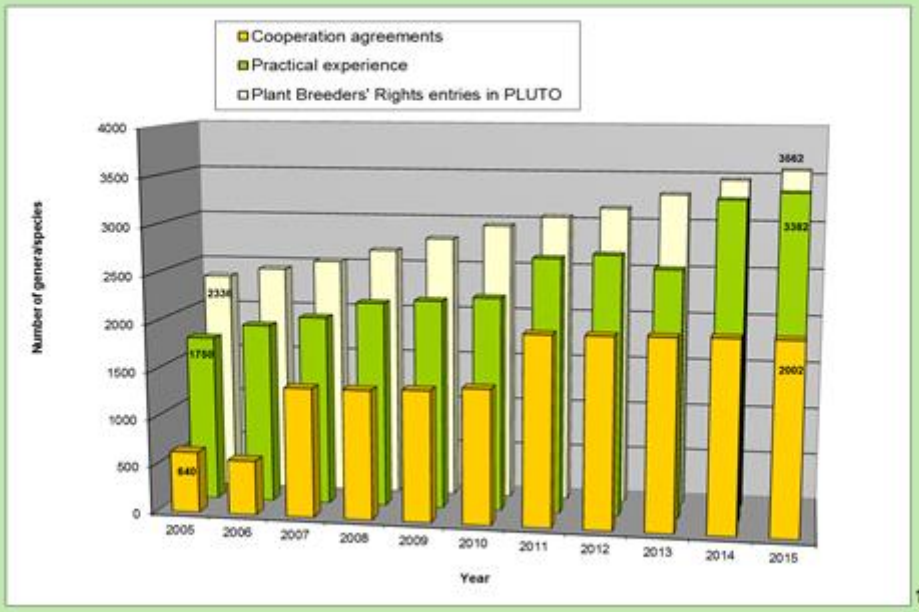
Cooperation in examination (C/49/5)



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SITUATION in UPOV

Examination of Laws

	Council session	Advice
Egypt (Draft Law)	March 27, 2015	Positive
Islamic Republic of Iran (Law)	October 29, 2015	Amendments recommended

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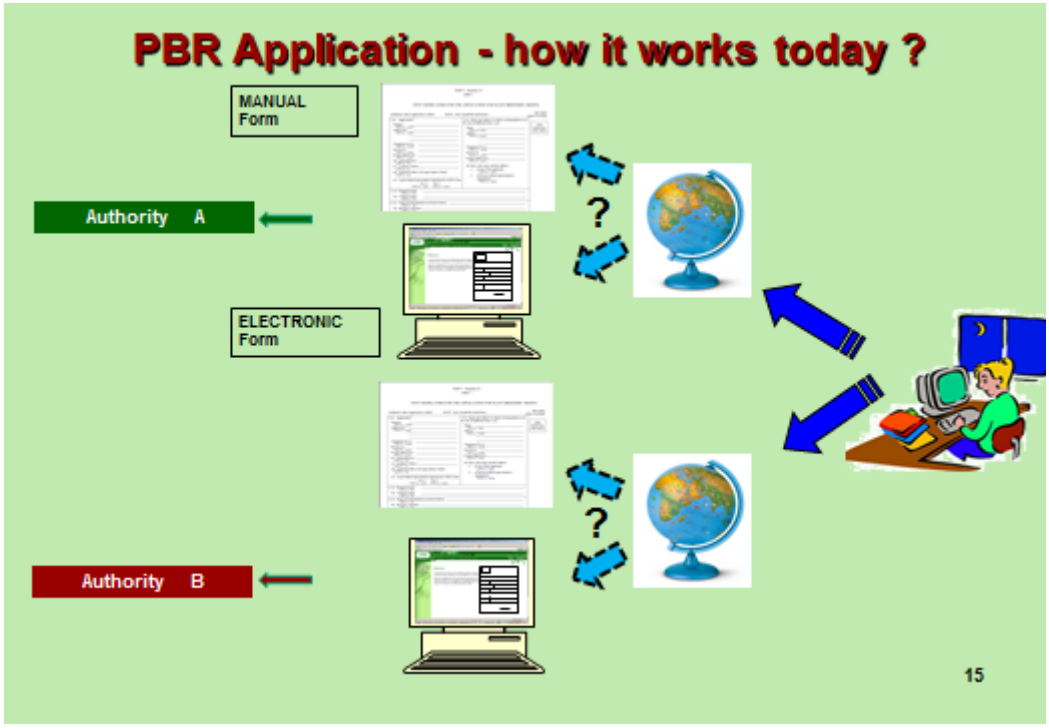
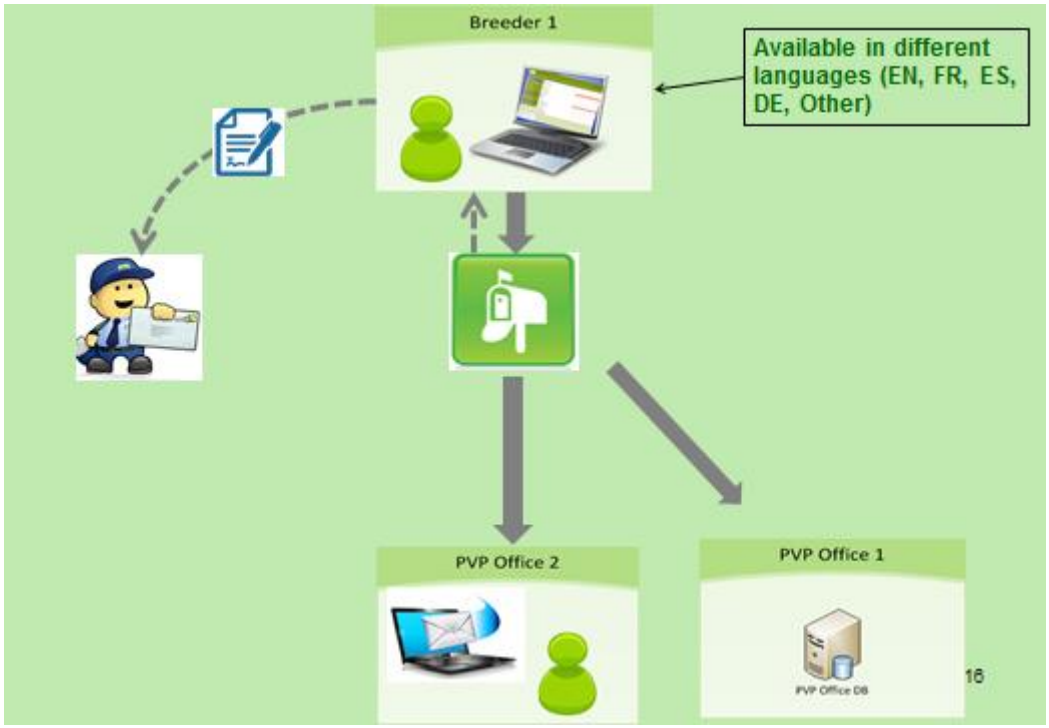
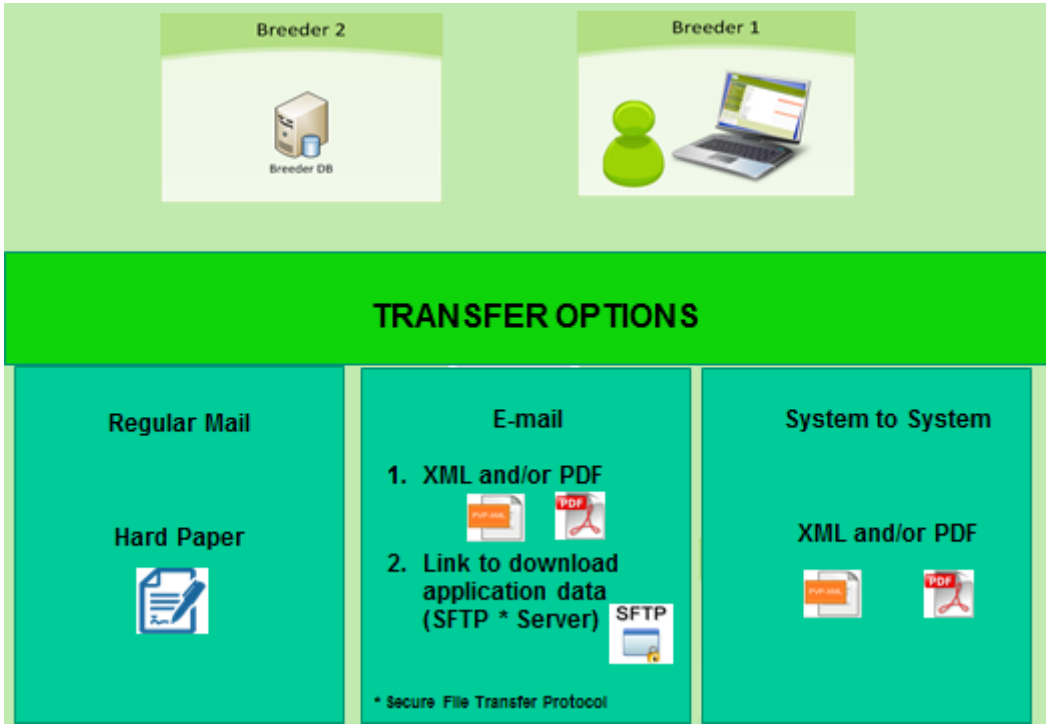
Harmonization and Cooperation

	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	


PBR Application - how it works today ?
MANUAL Form
Authority A
ELECTRONIC Form
Authority B
?
?
15


Breeder 1
Available in different languages (EN, FR, ES, DE, Other)
PVP Office 2
PVP Office 1
PVP Office DB
16



Target for Prototype Electronic Application Form Version 1 (PV1)

Functioning Prototype

by October 2015 (EAF/6 meeting)

=

Data can be transferred (and reused) from participating breeders to participating PVP Offices according to the specific information that they require for an application in the requested format

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Validation of PV1

Done

- Validation by participating members and UPOV members
  - EAF/6 (October 26, 2015)
  - CAJ (October 27, 2015)
  - Consultative Committee (October 28, 2015)

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Target for Prototype Electronic Application Form Version 2 (PV2)

Functioning system

by October 2016 (EAF/8 meeting)

including:

Scaling-up of the system, i.e. addition of further crops, languages and PVP Offices, and

Enable implementation by PVP Offices for the application process (filing, authorization, payment, submission…) for the selected crops

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Agreement by EAF/6 meeting on PV2

To be included in PV2 (see EAF/6/4 "Report")
Different languages: EN, FR, DE, ES
New crops: Apple Fruit Varieties, Rose, Soya Bean and Potato
Payment modes and user authentication/authorization
Possibility to introduce and/or modify questions (update of the form) and routine maintenance
Confidentiality of data and Security policies in terms of data transfer.
View application in XML/ PDF format
High availability of the system
Interaction with existing external systems (Genie DB, WIPO Accounts, PVP Office)

Opportunity to participate in PV2

UPOV members and breeders
were invited to join the project
and provide their information for PV2

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Participating Authorities in PV2*				
Argentina	Canada	Kenya	Org. Africaine de la Propriété Intellectuelle (OAPI)	South Africa
Australia	Czech Republic	Republic of Korea	Sweden	Switzerland
Bolivia	European Union	Mexico	Tunisia	
Brazil	France	Netherlands	United States of America	
Chile	Georgia	New Zealand	Uruguay	
Colombia	Japan	Norway	Viet Nam	

26 UPOV members (cover 69 countries)

* Participating UPOV members in the EAF who provided their forms / information to be used in the prototype electronic form PV2

Supported crops in EAF-PV2

Crops	Priority*
Rose (17)	1
Soya Bean (20)	1
Lettuce (19)	2
Apple Fruit Varieties (18)	2
Potato (18)	3





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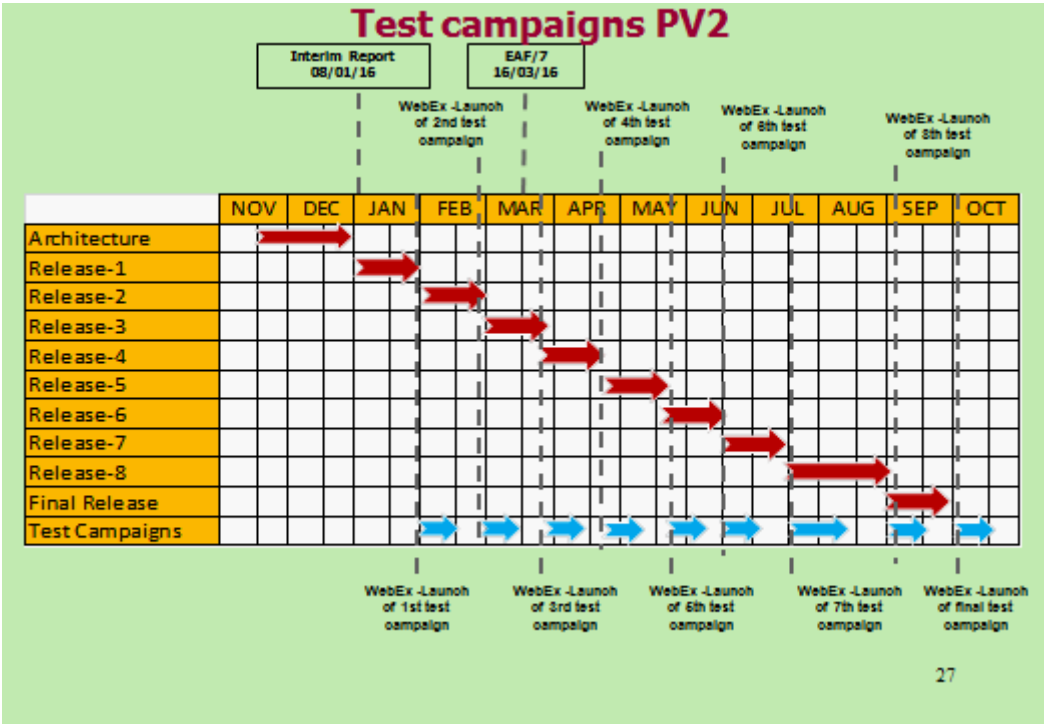
* According to time available

Agreement on the Technical Architecture of PV2

See EAF/6/4 "Report"
Payment modalities
User authentication
Security requirements in terms of Data confidentiality and Access rights management
High availability (HA) of the system
Communication with existing and external systems such as the GENIE Database, WIPO Users Account and existing systems in PVP Offices
International Reference Number (IRN) and unique Breeder's reference
Legal aspects
Level of compliance with Web Content Accessibility Guidelines (WCAG)

Test campaigns PV2

Test Campaign	Milestone Release (MR) Contents/ Functionalities to be tested
Release 1	Updated PVP-XML Application Form (AF) for new participants and new crops
Release 2	Updated PVP-XML Technical Questionnaire (TQ) for new participants and new crops, User feedback from MR1
Release 3	Authentication/Authorization, Multi-language feature, Add new participants (except BO, CO), user feedback from MR2
Release 4	Manage forms interface, Add BO and CO, Add crops (Rose+Lettuce), user feedback from MR3
Release 5	Reuse TQ, user feedback from MR4
Release 6	Add Soya Bean*, Payment, user feedback from MR5
Release 7	Add Apple Fruit Varieties*, Office/Breeder Preference Interface, integration with Genie DB and CPVO validation service, user feedback from MR6
Release 8	Add potato*,Encryption, Secure RESTful services, user feedback from MR7
Final Release	User feedback from MR8 and Full prototype



Preview

- Developments in UPOV
- Developments concerning biochemical and molecular techniques

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Overview

- Use of biochemical and molecular markers in the examination of Distinctness, Uniformity and Stability (DUS)
- Frequently Asked Questions in molecular techniques (FAQ)
- OECD-UPOV-ISTA joint workshop
- Databases

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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)

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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 […]

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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 the UPOV website.*

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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

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APPLICATION MODELS in TGP/15

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

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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.

Overview

- Use of biochemical and molecular markers in the examination of Distinctness, Uniformity and Stability (DUS)
- Frequently Asked Questions in molecular techniques (FAQ)
- OECD-UPOV-ISTA joint workshop
- Databases

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Background

- 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/

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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:

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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.

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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)'.

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FAQ for wider audience

- With regard to a wider audience, the TC/50 (April 2014) agreed that the question was not framed in an appropriate way, and agreed that the question should be rephrased after clarification of the issues of interest to a wider audience.

- TC/52 (March 2016) agreed a draft question and answer. The draft will be considered for adoption by the Council in October 2016.

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DRAFT

Question: Is it possible to obtain protection of a variety on the basis of its DNA-profile?

For a variety to be protected, it needs to be clearly distinguishable from all existing varieties on the basis of characteristics that are physically expressed, e.g. plant height, time of flowering, fruit color, disease resistance etc. The DNA-profile is not the basis for obtaining the protection of a variety, although this information may be used as supporting information.

A more detailed explanation is provided in the FAQ 'Does UPOV allow molecular techniques (DNA profiles) in the examination of Distinctness, Uniformity and Stability ("DUS")?

See also:
"What are the requirements for protecting a new plant variety?"

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Overview

- Use of biochemical and molecular markers in the examination of Distinctness, Uniformity and Stability (DUS)
- Frequently Asked Questions in molecular techniques (FAQ)
- OECD-UPOV-ISTA joint workshop
- Databases

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OECD-UPOV-ISTA joint workshop
held in conjunction with BMT/14

- Held in Seoul, Republic of Korea, on November 12, 2014
- Agenda items:

a) Introduction to OECD, UPOV, ISTA and ISO, and the situation with regard to molecular techniques;

b) Existing areas of cooperation between OECD, UPOV and ISTA; and

c) Opportunities for cooperation between OECD, UPOV, ISO and ISTA with regard to molecular techniques.

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TC/51:

a) to develop a joint document explaining the principal features of the systems of the OECD, UPOV and ISTA , subject to the approval of the Council and in coordination with OECD and ISTA;

b) to develop an inventory on the use of molecular marker techniques, by crop, subject to the approval of the Council and in coordination with OECD and ISTA; and

c) the proposal for the BMT/15, to develop lists of possible joint initiatives with OECD and ISTA in relation to molecular techniques for consideration by the TC/53.

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Future OECD-UPOV-ISTA joint workshop

- TC/51: noted that it would be useful to repeat the joint workshop at relevant meetings of the OECD and ISTA.
- TC/52: noted the plans for the OECD Seed Schemes to organize a Joint OECD/UPOV/ISTA/AOSA Workshop, in Paris, France, on June 8, 2016.

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Overview

- Use of biochemical and molecular markers in the examination of Distinctness, Uniformity and Stability (DUS)
- Frequently Asked Questions in molecular techniques (FAQ)
- OECD-UPOV-ISTA joint workshop
- Databases

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TC/52:

- noted that the TWF/46 had agreed that databases for fruit crops containing morphological and/or molecular data could be useful for grouping varieties and organizing the growing trials and for the analysis of distinctness.

- considered discussions on facilitating the development of databases and agreed to invite members of the Union to make presentations at the BMT/15 on how databases containing molecular data might be developed in UPOV. It noted that the outcome of those discussions would be reported to the TC/53 under the agenda item "Variety description databases".

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[End of document]