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INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS GENEVA

<u>Associated Document</u> <u>to the</u> <u>General Introduction to the Examination</u> <u>of Distinctness, Uniformity and Stability and the</u> <u>Development of Harmonized Descriptions of New Varieties of Plants (document TG/1/3)</u>

DOCUMENT TGP/6

"ARRANGEMENTS FOR DUS TESTING"

Section 2: Examples of Arrangements for DUS Testing

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1. AUSTRALIA

Background

1.1 Australia has many climatic zones from alpine to tropical, from temperate to desert but does not have the infrastructure to provide testing facilities in all the necessary environments. In addition, movement of plant material to existing testing centers is made difficult, if not impossible, by internal quarantine barriers.

1.2 Australia protects a vast number of species (more than 500 species of 230 genera). With an average of one new variety each day; the first variety of the species every 10 days and the first variety of a genus every 2 weeks, collecting and maintaining national reference collections is very difficult, or more correctly, practically impossible if all international varieties, including farmers varieties are to be grown in comparative trials.

1.3 Equally it is impossible to expect examiner staff to be expert in all species and the therefore the Australian system had to find a way to access specialty knowledge held by others not directly employed in the PBR office, including experts in the private sector.

1.4 The Australian Government also decided that the system be 100% cost recovered by fees paid by applicants. Therefore there is a need to minimize costs and allow the applicant to choose the most economical way to have their variety examined.

1.5 Recognizing the overwhelming advantages of being part of UPOV, Australia needed to establish a system that could start small but grow with their requirements. And finally, a key of examination is to produce comparable and harmonized results

DUS Testing in Australia

1.6 Article 12 of the 1991 Act of the UPOV Convention provides options for an authority to gain information about a variety, namely, the authority may:

- (a) grow the variety or carry out other necessary tests,
- (b) cause the growing of the variety or the carrying out of other necessary tests, or
- (c) take into account the results of growing tests or other trials which have already been carried out.

1.7 In Australia a combination of options (b) and (c) is used to complete an effective, transparent and legally strong examination process.

1.8 In this context of breeder testing, the term breeder more accurately refers to the applicant for PBR, noting, however, that in most cases the applicant is also the breeder of the variety under test. In the Australian system, the onus of proof is on the applicant who has to show that the variety meets the DUS criteria. This is achieved by the applicants either conducting a comparative trial themselves, or by employing a third party adviser to do the trial on their behalf.

1.9 The comparative trial must conform to the usual scientific standards and use UPOV Test Guidelines where they are available. The applicant or their adviser designs the trial, including the selection of comparator varieties, collects and analyses the data, documents in

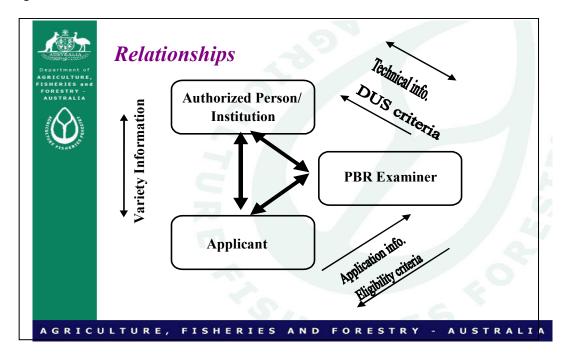
words and photographs the distinguishing features of the variety and rebuts any comments or objections. All the costs of conducting the trial are borne by the applicant and therefore the Australian PBR office does not have special facilities nor do they have to incur the time and expense of propagating or maintaining the trial.

1.10 This process is entirely consistent with other IP regimes where the applicant is solely responsible for defending their rights, including the validity of the grant, if an infringement action was heard in the courts. However, some people worry that public confidence in the scheme may be undermined if somebody other than the national authority does the testing implying that there is a possibility the results may be manipulated. Accordingly Australia has a series of special measures to ensure rigor and transparency.

Ensuring Rigor and Transparency

1.11 If the applicant is to complete the testing and description of their variety they have to be trained. In the same way that patent attorneys are trained in the requirements of patents so the Australian PBR office spends considerable amounts of time training applicants (and other interested parties) on the specific requirements of PBR. These requirements may be different (but not always) from normal agronomic work (see Figure 1). Without training it will be very difficult for an applicant to present information about their variety that meet the formal and DUS requirements.

Figure 1.



1.12 The PBR office accredits each successful trainee as a qualified person (QP) for one or more species.

1.13 Most important to breeder-testing is the access to expertise. If PBR has to cover all species of plants then it is unlikely that PBR staff will be expert in all of them. Accordingly, a (QP) accredited for the species in question undertakes the responsibility for all technical aspects of the work, including 'training and convincing' the PBR examiner that all aspects are correct. Therefore, Australia does not have to undertake extensive training of examiners prior to considering applications for varieties in new species. If accredited, the applicant can act as their own QP using their own facilities. Results are published in the Plant Varieties Journal (PVJ), which is now also available on the internet, for further scrutiny from the public.

1.14 The Australian PBR office undertakes a substantive examination of the data and then determines whether to visit the trial and verify the claims by repeating the measurements. This has two effects:

(i) firstly, the applicants take great care with the trial knowing that it is likely that an independent scientist will come to review their claims;

(ii) secondly, the building of public confidence because the public know that the work has been scrutinized by a referee. This type of testing is more comprehensive than publishing a scientific paper where the experimental work is not physically reviewed.

1.15 In addition the description of the variety is published and objections are invited from the public for a period of 6 months. This adds another level of examination, because for some species there is a considerable additional expertise held by other members of the community. This is a peer review step which also allows competitors to comment. About 1% of applications draw comment from the public, usually in the form of requests for more information.

1.16 The process of examining DUS under the implementation of Australian breeder-testing system is outlined in the following table:

(a) Examination of the Part 1 Application 1

Description	Objectives and Action
A brief description and a photograph of the variety are supplied.	To establish a preliminary (<i>prima facie</i>) case that the variety is distinct from all other varieties of common knowledge.
Claim of the main difference (s) of the new variety from the other most similar varieties of common knowledge.	PBR office reviews the Part 1 application. Claims are checked against existing data/information.
Full information on the origin and breeding of the variety is outlined.	Once the <i>prima facie</i> case is established the application is accepted in the PBR scheme and the variety is protected under provisional protection for 12 months.
Indication of the main difference (s) from the parental material if the parents are varieties of common knowledge.	The applicant nominates whether they wish to have the examination based on a comparative trial in Australia or on data provided by another member of the Union. In both cases the data have to be verified by a PBR accredited Qualified Person $(QP)^2$.
	<i>Prima facie</i> case not established \rightarrow Application refused.

(i) Applicant obtains UPOV Test Report

Description	Objectives and Action
For applications based on overseas UPOV test reports, the QP is advised on the need to verify the variety description under local conditions.	

<i>(ii) Comparative Growing Trial in Australia</i>
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Description	Objectives and Action
The trial may be on an applicant's premises or at a PBR accredited Centralised Testing Centre (CTC).	The QP reviews the Part 1 application and the UPOV Test Guidelines for the species (if available).
The QP plans and supervises the comparative growing trial.	By elimination process, the QP selects the most similar varieties of common knowledge for the comparative trial based on the following factors:
	 UPOV grouping characteristics. List of PBR varieties. List of other existing varieties. Suggestions from the PBR office. Parental/source material. Personal experience with the species. From other published information.
	The QP conducts the comparative growing trial using scientific methodologies. The data and assessment methods are recorded.
	The relevant characteristics of the candidate and the comparator varieties with their states of expression are confirmed.
	The QP is encouraged to use morphological characteristics; especially those least affected by environmental factors are preferred. Other characteristics, e.g. phenological, physiological or biochemical are also acceptable if these characteristics meet the requirements of the General Introduction. DNA data is not accepted for establishing distinctness.
	Quantitative differences are established based on statistical methods. Qualitative differences are established based on visual observation.
	Comparative photographs are taken to show the differences between the varieties in distinctness characteristics.
	On the basis of comparative trial, data and photograph, the QP submits the detailed description of the variety for publication in Part 2 application form.

(b) <u>Provisional Protection</u>

Description	Objectives and Action
Upon request and at discretion of the Registrar the 12 month provisional protection period is extendable to allow the establishment of the comparative trial and record observations or to obtain the test report.	

(c) Examination of the Part 2 Application³

(i) Examination of the Comparative trial

Description	Objectives and Action
The QP certifies the authenticity of	Where necessary, an independent examination of
the data and the scientific	the comparative trial by the PBR examiner at a time
methodologies used in conducting	when the distinctness characteristics are visible.
the trial. There are severe penalties	This ensures that the technical rigor is maintained in
under the PBR Act for falsifying	the trial and that the QP's data is consistent and
information or submitting misleading	repeatable.
data.	The PBR Examiner also checks the trial details and
The PBR office examines the Part 2	scientific methodologies and reserves the right to
application and determines the need	order another trial growing by an independent
to independently examine the trial. If	institution.
necessary, an independent	
examination is carried out by the	The PBR Examiner determines the distinctness
PBR examiner.	from their own observations in the form of a Field
	Examination Report. The Examiner's report and the
If the PBR office does not examine a	Part 2 data must be consistent for a positive decision on distinctness.
trial then the decision is made, from information provided, that the	decision on distinctness.
candidate variety is clearly distinct	If the examiner's report is positive on the decision
from other varieties of common	of distinctness but not consistent with QP's data,
knowledge such that no further	then further examination is necessary, or additional
examination is warranted.	data is supplied by the QP.
	Where the examiner's report is negative the QP is
	advised and, if appropriate, a further trial is conducted, otherwise the applicant is advised to
	withdraw the application
	million in upprouton
	The PBR examiner's decision, whether positive or
	negative, is reviewed by the Registrar.
	Distinctness, Uniformity, or Stability not confirmed
	\rightarrow Possible re-trial or withdrawal of the application

(ii) Publication of the detailed description of the variety for public review

Description	Objectives and Action
A public notice is published in the	
Plant Varieties Journal, which	
includes a detailed description of the	
variety including its distinctness	
features along with photograph	
showing the comparative differences.	

(iii) Public review process

Description	Objectives and Action
There is a six-month waiting period after the publication of the detailed description in the <i>Plant Varieties</i>	The 6-month public and peer review process is mandatory.
description in the <i>Plant varieties</i> Journal to allow reasonable time for the public or industry to comment or object against a published description.	If there are no objections or comments received within this public exposure period then the variety will proceed to a final examination for the grant of PBR. This public and peer review and transparency ensures the rigor of the breeder-testing system. If an objection or comment on Distinctness, Uniformity or Stability is received within this public exposure period, the PBR office will review the objection and will give an opportunity to the applicant to rebut the objection. If the issues are not resolved then a re-trial may be necessary including a requirement to re-publish (where necessary) the detailed description of the variety Where an objection is upheld and no further evidence in support of Distinctness, Uniformity or Stability is supplied \rightarrow Rejection of Application.
	J II JIII FF

(d) <u>Deposition of propagating material in a Genetic Resource Centre (GRC)</u>

Description	Objectives and Action
The applicant must deposit a	Lodging of the propagating material in a GRC
sufficient quantity of the propagating	ensures the easy availability of the variety for any
material of the variety to an approved	future comparative testing purposes and also
GRC.	reasonable public access of the variety for any other
	reasons.

(e) <u>Final Grant Examination</u>

Description	Objectives and Action
Final examination checks that all the	DUS is established \rightarrow Final Grant of PBR
formal and technical requirements	
have been met, including DUS has	DUS not established \rightarrow Rejection of PBR
been established and all objections	5
have been resolved.	

^{1.} Part 1 Application

Australian PBR application comes in two parts, Part 1 and Part 2. The Part 1 Application is similar to the UPOV Technical Questionnaire and has general information about the variety, along with its origin and breeding history and other technical information. The Part 1 application is used to establish a *prima facie* case for the distinctness of the candidate variety.

^{2.} Qualified Person

A qualified person, or 'QP', acts as a PBR applicant's technical consultant. They accept responsibility for overseeing the comparative trial and for providing evidence that a variety is distinct, uniform and stable. This role may involve the QP consulting on the choice of comparative varieties, experimental design, management regime, collection of data, statistical analysis, photography and preparation of the harmonized description of the variety.

^{3.} Part 2 Application

The Part 2 Application is submitted after the comparative trial has been completed. It contains the harmonized description of the variety including its distinctness, uniformity and stability. The QP certifies the authenticity of the description as well as the data and the scientific methodologies on which it is based.

2. FRANCE

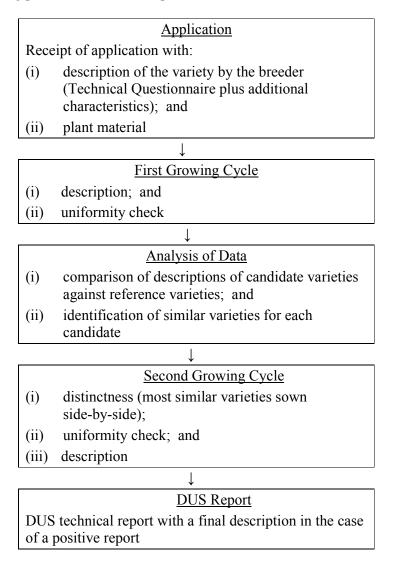
Introduction

2.1 For most crops in France, DUS testing can be characterized as a centralized official testing system. DUS testing is entrusted to an independent staff working for the Ministry of Agriculture (around 90 permanent civil servants). Most of these are employed at GEVES (Groupe d'études et de contrôle des variétés et des semences) which is the official agency appointed by the French authorities to conduct the tests for national listing and plant breeders rights.

2.2 Centralized testing is used in order to provide a common environmental basis for the examination of varieties and to facilitate the control of the interaction between varieties and environmental conditions. Under the centralized system, all new varieties and reference varieties are described and compared in the same environment.

General DUS procedure

2.3 The DUS testing procedure for annual species is summarized below:



2.4 The management of reference collections requires careful consideration. Reference collections are composed of varieties listed and/or protected in France and in countries with similar environmental conditions. The reference collection is updated each year: for each new variety, the breeder is asked to provide a seed sample and a brief variety description. Reference seed samples are, where possible, checked by comparison with the official sample received from the relevant authority and stored in a cold chamber (at 5°C and at 30% relative humidity).

2.5 Where possible, new entries in the reference collection are described under the French conditions over one or two growing cycles. At the end of this period, the varieties are included in the trials only if necessary, depending upon the characteristics of the candidate varieties. Example varieties are systematically included in the trials.

2.6 The level of involvement of the breeder in the conduct of the trials is quite low: the test is conducted entirely with GEVES facilities. Nevertheless, a close contact is kept with the breeder during each step of the process in order to inform him of any problem encountered and to invite him to submit complementary information if necessary. The DUS reports are established by GEVES.

DUS procedure on maize with the participation of the applicant

2.7 Although, in general, the level of involvement of the breeder in the conduct of the trials is quite low, the DUS procedure for maize can involve significant participation of the applicant. That procedure is explained below:

AIM

2.8 The aim of the procedure on maize is to have a greater degree of involvement of the breeder in the variety description work and to limit the workload for the official examination.

CONDITIONS

Official Agreement with the Applicant

2.9 The Technical Committee for National Listing, on behalf of the Ministry of Agriculture, is responsible for the official agreement with the breeder. That agreement requires:

- (a) the presence, for at least 5 years on French territory, of a nursery containing inbred lines, with observations on candidate and examples varieties;
- (b) the presence of technical staff able to make the description; and
- (c) regular training courses and an examination to check the ability of the technical staff.

Application procedure

2.10 The application procedure can be summarized as follows:

Year 1

- (i) Declaration of the application
- (ii) Plant material submission: small sample (200 kernels) of each parental line
- (iii) Breeder produces description on own premises

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	<u>Year 2</u>
(i)	Submission of all the information as requested for an application without the
partic	cipation of the breeder
(ii)	Additional information on the parental lines (if not already known):
	- genetic origin : compulsory, possibly submitted in a separate document
	- set of characteristics in addition to those already mentioned in the UPOV Technical Questionnaire (16 additional characteristics)
	- description of 11 electrophoretic characteristics
	Recommendations are made on how to establish descriptions:
	- visually observed : at least 10 individual observations
	- <i>measured characteristics</i> : average value of 10 measurements and indication of the value of the closest example varieties ;
	- <i>electrophoretic characteristics</i> : electrophoretic pattern established on at least 4 grains plus 16 grains if there is any heterogeneity. The recommended method is described in the Handbook published by GEVES.
(iii)	Plant material submission:
	 submission of the different categories (hybrid, - components as for any application without participation of the breeder) submission of 6 non threshed ears of each parental line (if not already known) with at least 100 kernels (70 for flint parental lines)

Visit to the Breeder's Premises

2.11 GEVES experts may, at any time, visit the trial on the breeder's premises to check the inclusion of the candidate varieties and example varieties and the layout of the trial.

DECISION RULES

Official Agreement

- 2.12 The agreement can be cancelled if:
 - (a) any of the conditions are no longer fulfilled
 - (b) the breeder does not respect the general rules or if too many discrepancies appear between the descriptions submitted by the applicant in year 1 and those produced by the official service in year 2

DUS Report

2.13 The general rules are applicable as soon the description submitted by the applicant is officially validated, according to the following procedure:

(a) <u>Validation of the description</u>

If there is any discrepancy between the description submitted by the applicant and the one established by GEVES, the description made by the applicant is rejected and a third year must be undertaken.

- (b) **Discrepancies**
 - (i) general

A discrepancy exists if, for any characteristic, the difference between the 2 notes for a given characteristic is higher than the minimum distance considered in the automatic comparison procedure (minimum distance = distance which is used in the software to take into account a difference)

(ii) electrophoretic characteristics

For electrophoretic characteristics, no discrepancy is accepted.

(c) <u>Distinctness</u>

If it is not a problem to clearly establish distinctness based on the automatic comparison procedure on the direct observations in the trial conducted by GEVES, the inbred line is declared distinct.

If not, a third year is requested.

(d) <u>Uniformity and Stability</u>

If the uniformity of the reference seed sample fulfils the UPOV requirement <u>and</u> if no more than 1 ear-row is different from the others and the reference seed sample, the inbred line is declared uniform and stable.

If there is a lack of uniformity on either the reference seed sample or the ear-rows, a third year is requested.

If both the reference seed sample and the ear-rows lack uniformity, the inbred line is declared not uniform and stable.

(e) <u>Description</u>

In the case of a positive DUS report, the description is established using the description submitted by the applicant <u>and</u> the two descriptions (two locations) made by GEVES.

2.14 As soon as an inbred line has a positive report using this procedure, the general rules for conducting the DUS test on a hybrid including that inbred line can be applied.

3. JAPAN

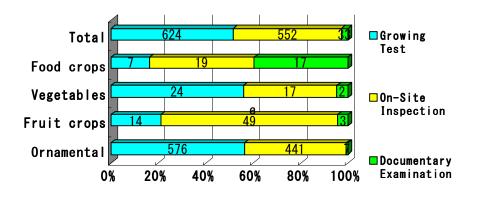
Background

3.1 From the introduction of plant variety protection in Japan, in 1979, to 2003, applications have been filed in Japan for 548 species and genera. A total of 17,083 applications have been filed in that time. Rose (1810), Chrysanthemum (1832), Carnation (1383), Cymbidium (941) and Rice (559) are the five top crop species, representing 38.2% of the total applications

Japanese Procedures

3.2 All applications are addressed to the Minister for Agriculture, Forestry and Fisheries. The administration of the plant variety protection is the responsibility of the Seeds and Seedlings Division of the Ministry of Agriculture, Forestry and Fisheries (MAFF). An application filed with the Seeds and Seedlings Division first undergoes a formal examination and then the examination of distinctness, uniformity and stability ("DUS") known as DUS testing. An examination of the proposed variety denomination is also conducted. At that stage the application is published for public comments.

- 3.3 The DUS testing is conducted in the following three forms:
 - Government Growing Test
 - On-site Inspection by Government Officials
 - Documentary Examination
- 3.4 The figure below shows how the DUS test is arranged for different categories of crops.



3.5 For each application the examiner should decide on how the DUS test should be conducted. The key features of the three forms are summarized below:

Government Growing Test

- 3.6 Government Growing Tests are conducted mainly by:
 - (a) the National Center for Seeds and Seedlings (NCSS)

NCSS has been separated from the MAFF and has the status of an "Independent Administrative Institution";

but may also be conducted by:

(b) a local government research institute (e.g. for rice)

Government Growing Tests may be conducted by public research stations, or other appropriate institutions with necessary expertise for the crop in question, under the instruction of the examiner and in accordance to national test guidelines.

- 3.7 Government Growing Tests are used for vegetables and ornamental plants
- 3.8 NCSS establishes the final DUS test report and variety description.

On-site Inspection by Government Officials (On-site Inspection)

3.9 The examiner judges the ability of the breeder to conduct DUS testing on his own premises. National test guidelines are used to provide guidance.

3.10 On-site Inspection is mainly used for ornamental plants (orchids, rose and fruit trees)

3.11 The examiner visits the DUS testing site to verify the conformity of the test design with the instructions given in the national test guidelines and to collect data for DUS test report.

3.12 The examiner establishes the final DUS test report and variety description

Documentary Examination

3.13 If a candidate variety has been tested by a public research institute for more than one year and the data provided can be considered to be reliable, the examiner may base his decision exclusively on the technical data prepared by that research institute.

3.14 The examiner can ask the research institute to submit additional data if considered necessary.

3.15 The examiner takes a decision on the grant of a protection title on the basis of the test report. The examiner establishes a final description of the candidate variety. Unless any reason to reject the application is found, or any objection or other relevant comment that might be influential on the fate of the application has been received from the public, the candidate variety is granted a protection title.

Variety Collections

3.16 The responsibility for developing and managing variety collections, and for selecting varieties for the growing trials, belongs to the party conducting the growing trials i.e. the NCSS / Local Government Research Institute (Government Growing Tests), the breeder (On-site Inspection) or the Public Research Institute (Documentary Examination), as appropriate. The activities are also under the control and guidance of the Examiner.

Procedure of DUS Testing in Rice in Japan

3.17 Most rice breeding activities in Japan are conducted by public breeding stations, either of the central Government or of local governments. In the formal rice breeding conducted by public breeding stations, official trials on the Value for Cultivation and Use (VCU) are conducted before the release of new rice varieties. Only those varieties which are officially recognized as being superior to the existing varieties will be commercialized. Normally, DUS data are also collected to ensure the reliability of the VCU trials. In the case of rice varieties bred by governmental breeding centers, where all technical information is collected systematically with a high level of technical reliability, the examiner can use the technical data provided by the breeders (researchers working at governmental research institutes). Technical data provided by prefectures can also be used if the examiner retains the possibility of performing an inspection of the DUS test from where the DUS data have been collected.

3.18 In the case of rice varieties bred by farmers or seed companies, which may not have the necessary expertise in DUS testing and preparing a DUS test report, a mechanism, in the form of additional trials conducted under the guidance of the examiner, is provided to complement the DUS test results prepared by the breeders. Because of the wide range of different environmental conditions under which rice varieties are bred in Japan (certain characteristics are only expressed under specific environmental conditions), additional DUS testing is conducted by different regional (prefectural or governmental) rice breeding stations, according to which are thought to be the best location for the expression of characteristics of candidate varieties.

4. SWITZERLAND

General Information

4.1 Switzerland has been a member of UPOV since 1979. By the end of 2004, the Swiss Plant Variety Protection Office had received 2,202 plant variety protection (PVP) applications, and had granted PVP for 1,760 varieties. None of the DUS tests for those varieties were conducted in Switzerland. All the DUS test results were purchased from other authorities.

4.2 This will not change after the revision of the PVP law and the ratification of the 1991 Act of the UPOV Convention. For a small country, such as Switzerland, it has proven to be appropriate and cost-effective to take over the DUS examination results from foreign testing stations.

4.3 The PVP laws are based on

- Swiss PVP laws and decree
- the UPOV Convention

Procedure for DUS Reports

4.4 The procedure starts with the application. Reference is made to the Technical Questionnaire of UPOV, and information is requested on ongoing or finalized DUS testing procedures.

4.5 Based on this information, the Plant Variety Protection Office will request the corresponding authority or testing station to either provide its DUS results or perform a DUS test on its behalf.

Administration of Examination Procedures

4.6 All information and indications from the testing station, as well as the status of the testing procedure, interim reports and the request to submit the plant material, are transmitted directly by the Plant Variety Protection Office to the owner of the variety or their representative.

4.7 All bills for interim reports or final examinations are settled directly by the Federal Office of Agriculture and are charged to the variety owner or their representative.

4.8 As soon as the Federal Office of Agriculture has received the final DUS test report of a variety, it is submitted to the appropriate research institute in Switzerland for verification and confirmation. The research institutes are part of the Plant Variety Protection Office and comprise various specialized sections (agricultural crops, fruits and berries, ornamental plants).

Granting of Plant Variety Protection

4.9 The testing partners of Switzerland are:

- UPOV member States
- the Community Plant Variety Office (CPVO) of the European Union in Angers.

The test guidelines of these authorities and testing stations are accepted by Switzerland.

4.10. Plant variety protection will only be granted after all fees and costs have been fully paid by the variety owner or their representative.

[End of Section 2]