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INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS
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ENLARGED EDITORIAL COMMITTEE

Geneva, January 7 and 8, 2015

REVISION OF DOCUMENT TGP/8: PART II: SELECTED TECHNIQUES USED IN DUS EXAMINATION,
 NEW SECTION: GUIDANCE FOR BLIND RANDOMIZED TRIALS

Document prepared by the Office of the Union

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1. The purpose of this document is to present draft guidance on data analysis for blind randomized trials for inclusion in a future revision of document TGP/8.

2. The following abbreviations are used in this document:

TC: Technical Committee
 TC-EDC: 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

3. The structure of this document is as follows:

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 ANNEX II: Extract from documents TGP/9/1: Examining distinctness: Section 6 “Supplementary procedures”: Subsection 6.4: “Use of randomized ‘blind’ testing” and TGP/8/1: Part I: DUS trial design and data analysis: Section 1.5.3.4 “Blind Randomized Trials”

BACKGROUND

4. The Technical Committee (TC), at its forty-eighth session, held in Geneva from March 26 to 28, 2012, agreed that the experts from France should develop guidance on data analysis for blind randomized trials from their experience, including their use of blind randomized trials for disease resistance and other examples (see document TC/48/22 “Report on conclusions”, paragraph 60).

COMMENTS BY THE TECHNICAL COMMITTEE IN 2013

5. The TC, at its forty-ninth session held in Geneva from March 18 to 20, 2013, agreed to the preparation of a new draft for a new Section on “Guidance for Data Analysis for Blind Randomized Trials” by an expert from France, on the basis of the Annex to document TC/49/30 and the comments by the TWPs at their sessions in 2012, and the TC-EDC at its meeting in 2013, for consideration by the TWPs at their sessions in 2013 (see document TC/49/41 “Report on the Conclusions”, paragraphs 67 and 68).

COMMENTS BY THE TECHNICAL WORKING PARTIES IN 2013

6. At their sessions in 2013, the TWO, TWF, TWV, TWC and TWA considered documents TWO/46/19, TWF/44/19, TWV/47/19, TWC/31/19 and TWA/42/19, respectively, which contained the draft guidance reproduced in Annex I to this document.

General	The TWO noted the comments made by the TWPs at their sessions in 2012 and the TC-EDC in 2013, and considered the draft new Section on “Guidance for Data Analysis for Blind Randomized Trials” (see document TWO/46/29 “Report”, paragraph 44).	TWO
	The TWF noted the comments made by the TWPs at their sessions in 2012 and the TC-EDC in 2013, and considered the draft new Section on “Guidance for Data Analysis for Blind Randomized Trials” (see document TWF/44/31 “Report”, paragraph 48). The TWF agreed that the drafter should further develop the guidance as set out in Annex II to document TWF/44/19 on draft guidance on data analysis for blind randomized trials for inclusion in a future revision of document TGP/8 (see document TWF/44/31 “Report”, paragraph 49).	TWF
	The TWV noted the comments made by the TWPs at their sessions in 2012 and the TC-EDC in 2013, and considered the draft new Section on “Guidance for Data Analysis for Blind Randomized Trials” (see document TWV/47/34 “Report”, paragraph 48).	TWV
	The TWC considered document TWC/31/19 and noted that the draft guidance should be described in general terms to become suitable for crops tested in plots or as individual plants and for the observation of the different types of characteristics (QN, PQ, QL) (see document TWC/31/32 “Report”, paragraph 46).	TWC
	The TWA noted the comments made by the TWPs at their sessions in 2012 and the TC-EDC in 2013, and considered the draft new Section on “Guidance for Data Analysis for Blind Randomized Trials.” The TWA agreed that the drafter should further develop the guidance as set out in Annex II to document TWA/42/19 on draft guidance on data analysis for blind randomized trials for inclusion in a future revision of document TGP/8. The TWA agreed that blind randomized trials were a useful method for specific circumstances and recalled the role of breeders in identifying their varieties and of DUS experts in the final decision of trials (see document TWA/42/31 “Report”, paragraphs 51 to 53).	TWA
Title	The TWO noted that the draft new section related to the DUS trial design and suggested to change the title to “Draft guidance for blind randomized trials conducted by the authority or a third party” (see document TWO/46/29 “Report”, paragraph 45).	TWO
Introduction	The TWO suggested that the introduction to be provided should be generic and requested the addition of an example for ornamental plants (see document TWO/46/29 “Report”, paragraph 46).	TWO

Origin of the material / Authorization for use of certain reference varieties	The TWV agreed that the drafter should further develop the guidance to include explanations that the origin of the material should not influence the final judgment and that the authorization of the breeder should be obtained for varieties that were the subject of an application, as well as certain parent lines (see document TWV/47/34 "Report", paragraph 49).	TWV
Preparation of the trial	The TWC agreed that the section describing the method of preparation of the trial should be further developed to clarify the procedure for coding the varieties to be used. The TWC requested an improvement to the example used in paragraph 4 with random allocation of codes and the duplication of all samples used, including "C" (Mixture) (see document TWC/31/32 "Report", paragraph 47). The TWC agreed that the guidance should include statistical consideration on the design of the trial, such as that the number of replications should be sufficiently large to ensure that there was only a small probability (e.g. <0.05 or 0.01) that the candidate variety was correctly labeled by chance (see document TWC/31/32 "Report", paragraph 48).	TWC
Analysis of results	The TWC agreed that the draft guidance should provide information about analysis of the results (see document TWC/31/32 "Report", paragraph 49).	TWC

COMMENTS BY THE TECHNICAL COMMITTEE IN 2014

7. The TC, at its fiftieth session, held in Geneva, from April 7 to 9, 2014, considered document TC/50/26 which contained the draft guidance reproduced in Annex I to this document. The TC agreed to request that experts from France continue the development of the proposed guidance on the basis of the comments by the TWPs, as set out in paragraph 7 of this document, and the following comments by the TC-EDC, at its meeting held in Geneva on January 8 and 9, 2014:

General remarks	- The TC-EDC noted that blind randomized trials were used only very rarely and suggested that the TC review whether it was appropriate to include guidance in TGP/8 on a method that is only used in exceptional circumstances on the basis that its inclusion in TGP/8 might imply that it was a routine method. If it is decided to retain the guidance, it was proposed that it should be clarified that blind randomized trials were a useful means by which authorities could demonstrate to breeders that varieties were not distinct, but which also offered the possibility for breeders to demonstrate differences in relevant characteristics that would have clearly distinguished varieties in the growing trial, with suitable knowledge. The TC-EDC further proposed that the structure of the document be reviewed in order to improve the clarity.
Cover page	to check whether to delete "Data analysis" from the title of the document.

8. The TC agreed that the circumstances under which blind randomized trials would be appropriate should be clarified.

9. The TC agreed that the structure of the document should be reviewed in order to improve clarity and that consideration should be given to including guidance on the use of blind randomized trials without data analysis, which would require deletion of "Data analysis" from the title of document. The TC agreed that the Office of the Union should seek information on the use of blind randomized trials for presentation to the TWPs and the TC (see document TC/50/36 "Report on the conclusions", paragraphs 59 to 61).

10. The expert from France informed the Office of the Union that, given the need for extensive redrafting of the text, it would not be possible to produce a text for consideration by the TWPs in 2014 and proposed that a new draft be prepared for consideration by the TC and TWPs in 2015. In order to facilitate the consideration by the TC, at its fifty-first session, it was further proposed that an initial draft be prepared for consideration by the TC-EDC at its meeting in January 7 and 8, 2015

COMMENTS BY THE TECHNICAL WORKING PARTIES IN 2014

11. At their sessions in 2014, the TWO, TWF, TWC, TWV and TWA considered documents TWO/47/19, TWF/45/19, TWV/48/19, TWC/32/19 and TWA/43/19, respectively, which contained the draft guidance reproduced in Annex I to this document.

General remarks	The TWO noted that the example in document TWO/47/19 referred to seed-propagated varieties and agreed that other aspects of the trial set up should be considered for vegetatively propagated plants, such as the type and source of plant material used, as considered under the item "Plant Material Submitted for Examination" (see document TWO/47/28 "Report", paragraph 53).	TWO
	The TWV agreed on the need to clarify the distinction to be made between trials at breeders' premises, blind trials and blind randomized trials in the guidance (see document TWV/48/43 "Report", paragraph 52).	TWV
	The TWA agreed that the guidance to be developed should explain the importance of sample size and how to minimize biases in the methodology (see document TWA/43/27 "Report", paragraph 46).	TWA
	The TWO considered document TWO/47/19 and agreed that blind randomized trials were rarely used. The TWO noted that blind randomized trials were used: in Brazil to confirm, in some cases, the assessment of distinctness under a breeder-based testing system for agricultural crops and vegetables; in New Zealand, for some fruit crops and in cases of dispute regarding distinctness; and in the United Kingdom and the Netherlands to confirm lack of distinctness between varieties (see document TWO/47/28 "Report", paragraph 52).	TWO
	<p>The TWF noted the information provided by the TWO at its forty-seventh session on the use of blind randomized trials in Brazil, New Zealand and in the United Kingdom, including the circumstances under which blind randomized trials are used (see document TWF/45/32 "Report", paragraph 43).</p> <p>The TWF noted that the expert of the International Community of Breeders of Asexually Reproduced Ornamental and Fruit Varieties (CIOPORA) was not in favor of the use of Blind Randomized Trials (see document TWF/45/32 "Report", paragraph 44).</p>	TWF
	The TWC considered document TWC/32/19 and agreed that blind randomized trials were rarely used. The TWC noted that blind randomized trials have been used in the Netherlands to confirm lack of distinctness between varieties. The TWC noted that some tests for disease resistance were organized by the Netherlands at the breeders' premises but the varieties were not coded. The TWC noted the suggestion by the expert from the Netherlands that guidance for such trials organized at the breeders' premises could be developed for inclusion in document TGP/6 "Arrangements for DUS testing" (see document TWC/32/28 "Report", paragraph 38).	TWC

	<p>The TWV noted the information provided by the experts from France and the Netherlands on their use of blind randomized trials, including the circumstances under which blind randomized trials are used (see document TWV/48/43 "Report", paragraph 50).</p> <p>The TWV agreed that in the case of the use of blind randomized trials, the authorities take the final decision according to the rules and criteria to fulfill a DUS examination, and that a blind randomized trial would only be carried out in exceptional cases.</p> <p>The TWV noted that the experts from Crop Life International and European Seed Association were in favor of the use of blind tests and of blind randomized trials in some cases (see document TWV/48/43 "Report", paragraphs 53 and 54).</p>	TWV
	<p>The TWA noted that blind randomized trials were used: in Brazil to confirm, in some cases, the assessment of distinctness under a breeder-based testing system for agricultural crops and vegetables; in the United Kingdom, for assessment of distinctness; and in France, for the assessment of disease resistance characteristics that are not tested by the authority. (see document TWA/43/27 "Report", paragraph 46).</p>	TWA

NEXT STEPS

12. On the basis of the experience in the Netherlands, reported at the TWPs at their sessions in 2014, the expert from France approached an expert from the Netherlands to discuss the development of the guidelines on blind randomized trials. As a result of their discussions it was proposed that further consideration be given to whether the existing guidance in document TGP/9 "Examining distinctness" and document TGP/8: Part I: "DUS trial design and data analysis" was sufficient to address the matter. Annex II to this document contains extracts from documents TGP/9 and TGP/8 concerning guidance on use of randomized blind testing.

13. *The TC-EDC is invited to note the information in this document to be presented to the TC and propose any improvements to the document in that regard.*

[Annexes follow]

ANNEX I

DRAFT GUIDANCE CONSIDERED BY THE TWPS AT THEIR SESSIONS IN 2013 AND 2014

Note for revisions on Annex I in 2014

~~Strikethrough~~ (highlighted) indicates proposed deletion of text.

Underlining (highlighted) indicates proposed insertion of text.

DRAFT GUIDANCE OF DATA ANALYSIS FOR BLIND RANDOMIZED TRIALS
CONDUCTED BY THE APPLICANT OR UNDER THEIR RESPONSIBILITY

Introduction:

[To be provided]

Background:

1. The blind randomized trials have been used in France for many years in order to:
 - confirm some characteristics announced by the applicant;
 - check some genetic disease resistances not officially tested by ~~le Groupe d'étude et de contrôle des variétés et des semences (GEVES)~~ the authority in charge of DUS examination.
2. In cases of difficulties with distinctness after one or two growing cycles, the blind randomized trials have been used to take account of specific adaptations in DUS test (regional, climatic, etc.).

Preparation of the trial:

- The applicant has the choice to accept ~~or not~~ this possibility or not;
 - Seeds are sent to the applicant under code A, B, C, D, E ... (variety in DUS test + closed reference variety + mixture);
 - The trial is conducted in the applicant's facilities on the basis of at least two replications;
 - The number of plants observed must be at least the number recommended in the guideline;
 - The applicant must inform ~~GEVES~~ the authority of on the progress of the trial for an eventual visit.
3. In the case of a problem of distinctness, a blind test may be planted in ~~GEVES~~ the authority's facilities to avoid identification by other methods (e.g. DNA profiling). The applicant is invited to visit this trial. The protocol of the test is not compulsory but ~~GEVES~~ the authority could ask him and some recommendations are made to the applicant; (number of ~~replications~~ plants to be observed).

Transmission of results:

4. The results are transmitted to ~~GEVES~~ the authority by the applicant as below:

A = Candidate variety
B = Reference variety
C = Mixture
D = Candidate variety
E = Reference variety

5. The fact that the applicant gives good results is a very important point, but not enough. The final decision is always taken by ~~GEVES~~ after analysis of all results. In the case of a distinctness problem, the characteristics used by the applicant to distinguish the varieties must be more or less the same as those observed by ~~GEVES~~ during official cycles.
6. This approach amounts to formalize the results obtained through a non-official test.

[Annex III follows]

ANNEX II

EXTRACT FROM DOCUMENT TGP/9/1: EXAMINING DISTINCTNESS; SECTION 6: SUPPLEMENTARY PROCEDURES

“6.4 Use of randomized “blind” testing

“6.4.1 After, or during, the examination, some doubts may exist over the distinctness of a variety on the basis of the growing trial. In such cases, the following situations are possible:

- (a) with no differences observed, the application is rejected;
- (b) with no clear difference observed and a claim of distinctness from the breeder/applicant, the examining authority may decide to arrange additional tests.

“6.4.2 In the case of visually observed characteristics, one possible arrangement for an additional test is “blind” testing.

“6.4.3 The aim of “blind” testing is to assess distinctness between a pair of varieties avoiding any pre-judgement in the observation by making the samples in the trial anonymous (the expert is “blind” in respect to the identity of the variety in each plot). This kind of test plays a clarifying role when the differences between the candidate and (a) similar variety(ies) are not clearly definable. In such a case, another test during or after the examination of distinctness may provide evidence for a definitive decision by the authority.

“6.4.4 The following are some examples of “blind” testing:

Randomized variety plots: duplicates samples of the same variety receive individual codes and are randomly distributed in the trial.

Plots containing a mixture of varieties: plots with a mixture of material from the varieties under examination are included in the trial. This can be useful for seed-propagated varieties.

Parts of plants of varieties: randomized parts of plants from the varieties under examination (e.g. leaves or fruit).

“6.4.5 Breeders/applicants may be part of the “blind” testing process. They may also be invited to visit the “blind” test and be requested to try to identify the plots of their variety.

“6.4.6 At the end of the “blind” testing a variety may be declared as distinct:

- (a) if the expert and, where appropriate, the breeder/applicant always identify the variety; and
- (b) the difference can be considered as a clear difference for that characteristic.

“6.4.7 In all cases, it is the authority which decides on distinctness.”

EXTRACT FROM DOCUMENT TGP/8/1: PART I: DUS TRIAL DESIGN AND DATA ANALYSIS: SECTION 1.5.3.4 “BLIND RANDOMIZED TRIALS”

“1.5.3.4 Blind Randomized Trials

“1.5.3.4.1 Part of a trial may consist of plots sown specifically for randomized “blind” testing, such as plots containing plants of both the varieties to be distinguished between, with the plants sown in a random but known order, or alternatively a mixture of pots with the two varieties in a greenhouse. The two varieties comprise the candidate plus the variety with which the distinctness of the candidate is in dispute. The principle of randomized “blind” testing is that a judge, sometimes the breeder, is presented with the plants and is asked to tell plant by plant which is the candidate, and which is the other variety.

“1.5.3.4.2 To allow this, the plants must be presented or sown in a random order but such that the tester knows which is which variety, the judge judges each plant, and the tester counts the number of times the different varieties are correctly identified. In order to reinforce the blindness of the test, a different number of

plants from each of the two varieties are presented, for instance 51 of the candidate and 69 of the other, rather than 60 of each. As differences may occur at different stages of growth, the judge can assess the plants on more than one occasion.”

[End of Annex II and of document]